Appendices

Appendix A: Search Strategy

Database: MEDLINE® and Cochrane Central Trials Registry (CCTR) (1995-December 2008)

Number	Search History
1	atrial fibrillation.mp. or exp Atrial Fibrillation/
2	pulmonary vein$.mp. or exp Pulmonary Veins/
3	1 or 2
4	exp Catheter Ablation/ or radiofrequency ablation.mp.
5	radiofrequency catheter ablation.mp. or exp Catheter Ablation/
6	ablation.mp.
7	radiofrequency.mp.
8	(catheter adj ablation).mp. [mp=ti, ot, ab, nm, hw, sh, kw]
9	or/4-8
10	3 and 9
11	limit 10 to (humans and yr="1995 - 2008") [Limit not valid in CCTR; records were retained]
12	limit 11 to (addresses or bibliography or biography or case reports or comment or editorial or lectures or legal cases or letter or news or newspaper article or "review") [Limit not valid in CCTR; records were retained]
13	11 not 12

Appendix B: List of Excluded Studies

Reason for Rejection: Cohort Studies for Adverse Events with Less than 100 Patients

Arentz T, von Rosenthal J, Blum T, et al. Feasibility and safety of pulmonary vein isolation using a new mapping and navigation system in patients with refractory atrial fibrillation. Circulation 2003;108:2484–90.

Arentz T, Ott P, von Rosenthal J, et al. Effect of atrial overdrive pacing on pulmonary vein focal discharge in patients with atrial fibrillation. Europace 2003;5:25–31.

Berkowitsch A, Neumann T, Kurzidim K, et al. Comparison of generic health survey SF-36 and arrhythmia related symptom severity check list in relation to post-therapy AF recurrence. Europace 2003;5:351–5.

Berkowitsch A, Greiss H, Vukajlovic D, et al. Usefulness of atrial fibrillation burden as a predictor for success of pulmonary vein isolation. Pacing & Clinical Electrophysiology 2005;28:1292–301.

Bertaglia E, Stabile G, Senatore G, et al. Long-term outcome of right and left atrial radiofrequency ablation in patients with persistent atrial fibrillation. Pacing & Clinical Electrophysiology 2006;29:153–8.

Callans DJ, Gerstenfeld EP, Dixit S, et al. Efficacy of repeat pulmonary vein isolation procedures in patients with recurrent atrial fibrillation. Journal of Cardiovascular Electrophysiology 2004;15:1050–5.

Cauchemez B, Extramiana F, Cauchemez S, et al. High-flow perfusion of sheaths for prevention of thromboembolic complications during complex catheter ablation in the left atrium. Journal of Cardiovascular Electrophysiology 2004;15:276–83.

Cheema A, Dong J, Dalal D, et al. Long-term safety and efficacy of circumferential ablation with pulmonary vein isolation. Journal of Cardiovascular Electrophysiology 2006;17:1080–5.

Chen J, Hoff PI, Erga KS, et al. A clinical study of patients with and without recurrence of paroxysmal atrial fibrillation after pulmonary vein isolation. Pacing & Clinical Electrophysiology 2005;28:Suppl-9.

De Piccoli B, Rossillo A, Zanella C et al. Role of transoesophageal echocardiography in evaluating the effect of catheter ablation of atrial fibrillation on anatomy and function of the pulmonary veins. Europace 2008;10:1079–84.

Essebag V, Wylie Jr. JV, Reynolds MR et al. Bi-directional electrical pulmonary vein isolation as an endpoint for ablation of paroxysmal atrial fibrillation. Journal of Interventional Cardiac Electrophysiology 2006;17:111–7.

Gerstenfeld EP, Guerra P, Sparks PB, et al. Clinical outcome after radiofrequency catheter ablation of focal atrial fibrillation triggers. Journal of Cardiovascular Electrophysiology 2001;12:900–8.

Giazitzoglou E, Korovesis S, Karvouni E, et al. Proarrhythmic effects of atrial fibrillation ablation techniques. Hjc Hellenic Journal of Cardiology 2006;47:211-7.

Gillinov AM, Sirak J, Blackstone EH, et al. The Cox maze procedure in mitral valve disease: predictors of recurrent atrial fibrillation. Journal of Thoracic & Cardiovascular Surgery 2005;130:1653–60.

Haissaguerre M, Jais P, Shah DC, et al. Electrophysiological end point for catheter ablation of atrial fibrillation initiated from multiple pulmonary venous foci. Circulation 2000;101:1409–17.

Haissaguerre M, Sanders P, Hocini M, et al. Catheter ablation of long-lasting persistent atrial fibrillation: critical structures for termination. Journal of Cardiovascular Electrophysiology 2005;16:1125–37.

Horlitz M, Schley P, Shin DI, et al. Circumferential pulmonary vein ablation for treatment of atrial fibrillation using an irrigated-tip catheter. American Journal of Cardiology 2004;94:945–7.

Hsieh MH, Tai CT, Lee SH, et al. Catheter ablation of atrial fibrillation versus atrioventricular junction ablation plus pacing therapy for elderly patients with medically refractory paroxysmal atrial fibrillation. Journal of Cardiovascular Electrophysiology 2005;16:457–61.

Husser D, Bollmann A, Kang S, et al. Effectiveness of catheter ablation for coexisting atrial fibrillation and atrial flutter. American Journal of Cardiology 2004;94:666–8.

Jais P, Hocini M, Sanders P, et al. Long-term evaluation of atrial fibrillation ablation guided by noninducibility. Heart Rhythm 2006;3:140–5.

Jayam VK, Dong J, Vasamreddy CR, et al. Atrial volume reduction following catheter ablation of atrial fibrillation and relation to reduction in pulmonary vein size: an evaluation using magnetic resonance angiography. Journal of Interventional Cardiac Electrophysiology 2005;13:107–14.

Jiang CY, Wang JA, He H, et al. Segmental radiofrequency ablation of pulmonary vein ostia for patients with refractory paroxysmal atrial fibrillation using multi-slice spiral computed tomography guidance. Journal of Zhejiang University 2005;Science:1153–6.

Kanagaratnam L, Tomassoni G, Schweikert R, et al. Empirical pulmonary vein isolation in patients with chronic atrial fibrillation using a three-dimensional nonfluoroscopic mapping system: long-term follow-up. Pacing & Clinical Electrophysiology 2001;24:1774–9.

Klemm HU, Ventura R, Rostock T, et al. Correlation of symptoms to ECG diagnosis following atrial fibrillation ablation. Journal of Cardiovascular Electrophysiology 2006;17:146–50.

Kumagai K, Muraoka S, Mitsutake C, et al. A new approach for complete isolation of the posterior left atrium including pulmonary veins for atrial fibrillation. Journal of Cardiovascular Electrophysiology 2007;18:1047–52.

Lang CC, Santinelli V, Augello G, et al. Transcatheter radiofrequency ablation of atrial fibrillation in patients with mitral valve prostheses and enlarged atria: safety, feasibility, and efficacy. Journal of the American College of Cardiology 2005;45:868–72.

Lemola K, Hall B, Cheung P, et al. Mechanisms of recurrent atrial fibrillation after pulmonary vein isolation by segmental ostial ablation. Heart Rhythm 2004;1:197–202.

Lemola K, Oral H, Chugh A, et al. Pulmonary vein isolation as an end point for left atrial circumferential ablation of atrial fibrillation. Journal of the American College of Cardiology 2005;46:1060–6.

Lim TW, Jassal IS, Ross DL, et al. Medium-term efficacy of segmental ostial pulmonary vein isolation for the treatment of permanent and persistent atrial fibrillation. Pacing & Clinical Electrophysiology 2006;29:374–9.

Nakashima H, Kumagai K, Noguchi H, et al. Evaluation of the recurrence of atrial fibrillation after pulmonary venous ablation. Journal of Cardiology 2002;40:87–94.

Neumann T, Erdogan A, Dill T, et al. Asymptomatic recurrences of atrial fibrillation after pulmonary vein isolation. Europace 2006;8:495–8.

Nilsson B, Chen X, Pehrson S, et al. Increased resting heart rate following radiofrequency catheter ablation for atrial fibrillation. Europace 2005;7:415–20.

O'Donnell D, Furniss SS, Dunuwille A, et al. Delayed cure despite early recurrence after pulmonary vein isolation for atrial fibrillation. American Journal of Cardiology 2003;91:83–5.

Pratola C, Baldo E, Notarstefano P, et al. Radiofrequency atrial fibrillation ablation based on pathophysiology: a diversified protocol with long-term follow-up. Journal of Cardiovascular Medicine 2008;9:68–75.

Purerfellner H, Martinek M, Aichinger J, et al. Quality of life restored to normal in patients with atrial fibrillation after pulmonary vein ostial isolation. American Heart Journal 2004;148:318–25.

Ren JF, Marchlinski FE, Callans DJ, et al. Intracardiac Doppler echocardiographic quantification of pulmonary vein flow velocity: an effective technique for monitoring pulmonary vein ostia narrowing during focal atrial fibrillation ablation. Journal of Cardiovascular Electrophysiology 2002;13:1076–81.

Saad EB, Rossillo A, Saad CP, et al. Pulmonary vein stenosis after radiofrequency ablation of atrial fibrillation: functional characterization, evolution, and influence of the ablation strategy. Circulation 2003;108:3102–7.

Sartini RJ, Scanavacca MI, Sosa E, et al. Radiofrequency ablation of paroxysmal atrial fibrillation: factors determining long-term clinical efficacy. Arquivos Brasileiros de Cardiologia 90 (2):112–8, 2008.

Schmitt C, Estner H, Hecher B, et al. Radiofrequency ablation of complex fractionated atrial electrograms (CFAE): preferential sites of acute termination and regularization in paroxysmal and persistent atrial fibrillation. Journal of Cardiovascular Electrophysiology 2007;18:1039–46.

Schneider C, Ernst S, Bahlmann E, et al. Transesophageal echocardiography: a screening method for pulmonary vein stenosis after catheter ablation of atrial fibrillation. European Journal of Echocardiography 2006;7:447–56.

Seow SC, Lim TW, Koay CH, et al. Efficacy and late recurrences with wide electrical pulmonary vein isolation for persistent and permanent atrial fibrillation. Europace 2007;9:1129–33.

Shin SH, Park MY, Oh WJ, et al. Left atrial volume is a predictor of atrial fibrillation recurrence after catheter ablation. Journal of the American Society of Echocardiography 2008;21:697–702.

Stabile G, Turco P, La Rocca V, et al. Is pulmonary vein isolation necessary for curing atrial fibrillation? Circulation 2003;108:657–60.

Stabile G, Bertaglia E, Senatore G, et al. Feasibility of pulmonary vein ostia radiofrequency ablation in patients with atrial fibrillation: a multicenter study (CACAF pilot study). Pacing & Clinical Electrophysiology 2003;26:t–7.

Thomas SP, Boyd AC, Aggarwal G, et al. Percutaneous pulmonary vein isolation for treatment of atrial fibrillation. Internal Medicine Journal 2004;34:453–7.

Tops LF, Bax JJ, Zeppenfeld K, et al. Effect of radiofrequency catheter ablation for atrial fibrillation on left atrial cavity size. American Journal of Cardiology 2006;97:1220–2.

Udyavar AR, Chang SL, Tai CT, et al. The important role of pulmonary vein carina ablation as an adjunct to circumferential pulmonary vein isolation. Journal of Cardiovascular Electrophysiology 2008;19:593–8.

Vasamreddy CR, Lickfett L, Jayam VK, et al. Predictors of recurrence following catheter ablation of atrial fibrillation using an irrigated-tip ablation catheter. Journal of Cardiovascular Electrophysiology 2004;15:692–7.

Vasamreddy CR, Dalal D, Eldadah Z, et al. Safety and efficacy of circumferential pulmonary vein catheter ablation of atrial fibrillation. Heart Rhythm 2005;2:42–8.

Verma A, Kilicaslan F, Adams JR, et al. Extensive ablation during pulmonary vein antrum isolation has no adverse impact on left atrial function: an echocardiography and cine computed tomography analysis. Journal of Cardiovascular Electrophysiology 2006;17:741–6.

Weerasooriya R, Jais P, Hocini M, et al. Effect of catheter ablation on quality of life of patients with paroxysmal atrial fibrillation. Heart Rhythm 2005;2:619–23.

Wnuk-Wojnar AM, Trusz-Gluza M, Czerwinski C, et al. Circumferential pulmonary vein RF ablation in the treatment of atrial fibrillation: 3-year experience of one centre. Kardiologia Polska 371;63:362–70.

Yamada T, Murakami Y, Okada T, et al. Electrophysiological pulmonary vein antrum isolation with a multielectrode basket catheter is feasible and effective for curing paroxysmal atrial fibrillation: efficacy of minimally extensive pulmonary vein isolation. Heart Rhythm 2006;3:377–84.

Yamada T, Murakami Y, Okada T, et al. Pulmonary vein antrum not always coaxial to the pulmonary vein: a dimensional pitfall to the circumferential isolation technique. Circulation Journal 2007;71:1430–6.

Yasuda T, Kumagai K, Ogawa M, et al. Predictors of successful catheter ablation for atrial fibrillation using the pulmonary vein isolation technique. Journal of Cardiology 2004;44:53–8.

Reason for Rejection: Studies Used Conventional 4 mm Tip Catheter Only

Anselme F, Gahide G, Savoure A, et al. MR evaluation of pulmonary vein diameter reduction after radiofrequency catheter ablation of atrial fibrillation. European Radiology 2006;16:2505–11.

Bourke JP, Dunuwille A, O'Donnell D, et al. Pulmonary vein ablation for idiopathic atrial fibrillation: six month outcome of first procedure in 100 consecutive patients. Heart 2005;91:51–7.

Chang SL, Tai CT, Lin YJ, et al. The efficacy of inducibility and circumferential ablation with pulmonary vein isolation in patients with paroxysmal atrial fibrillation. Journal of Cardiovascular Electrophysiology 2007;18:607–11.

Chen SA, Hsieh MH, Tai CT, et al. Initiation of atrial fibrillation by ectopic beats originating from the pulmonary veins: electrophysiological characteristics, pharmacological responses, and effects of radiofrequency ablation. Circulation 1999;100(18):1879–86.

Deisenhofer I, Schneider MA, Bohlen-Knauf M, et al. Circumferential mapping and electric isolation of pulmonary veins in patients with atrial fibrillation. American Journal of Cardiology 2003;91:159–63.

Dixit S, Ren JF, Callans DJ, et al. Favorable effect of pulmonic vein isolation by partial circumferential ablation on ostial flow velocity. Heart Rhythm 2004;1:262–7.

Fiala M, Chovancik J, Nevralova R, et al. Pulmonary vein isolation using segmental versus electroanatomical circumferential ablation for paroxysmal atrial fibrillation: over 3-year results

of a prospective randomized study. Journal of Interventional Cardiac Electrophysiology 2008;22:13–21.

Gerstenfeld EP, Callans DJ, Dixit S, et al. Incidence and location of focal atrial fibrillation triggers in patients undergoing repeat pulmonary vein isolation: implications for ablation strategies. Journal of Cardiovascular Electrophysiology 2003;14:685–90.

Gerstenfeld EP, Callans DJ, Dixit S, et al. Mechanisms of organized left atrial tachycardias occurring after pulmonary vein isolation. Circulation 2004;110:1351–7.

Herweg B, Sichrovsky T, Polosajian L, et al. Anatomic substrate, procedural results, and clinical outcome of ultrasound-guided left atrial-pulmonary vein disconnection for treatment of atrial fibrillation. American Journal of Cardiology 2005;95:871–5.

Hsieh MH, Tai CT, Tsai CF, et al. Clinical outcome of very late recurrence of atrial fibrillation after catheter ablation of paroxysmal atrial fibrillation. Journal of Cardiovascular Electrophysiology 2003;14:598–601.

Jiang H, Lu Z, Lei H, et al. Predictors of early recurrence and delayed cure after segmental pulmonary vein isolation for paroxysmal atrial fibrillation without structural heart disease. Journal of Interventional Cardiac Electrophysiology 2006;15:157–63.

Katritsis DG, Ellenbogen KA, Panagiotakos DB, et al. Ablation of superior pulmonary veins compared to ablation of all four pulmonary veins. Journal of Cardiovascular Electrophysiology 2004;15:641–5.

Kumagai K, Ogawa M, Noguchi H, et al. Comparison of 2 mapping strategies for pulmonary vein isolation. Circulation Journal 2005;69:1496–502.

Kumagai K, Noguchi H, Ogawa M, et al. New approach to pulmonary vein isolation for atrial fibrillation using a multielectrode basket catheter. Circulation Journal 2006;70:88–93.

Lee SH, Tai CT, Hsieh MH, et al. Predictors of early and late recurrence of atrial fibrillation after catheter ablation of paroxysmal atrial fibrillation. Journal of Interventional Cardiac Electrophysiology 2004;10:221–6.

Lin WS, Tai CT, Hsieh MH, et al. Catheter ablation of paroxysmal atrial fibrillation initiated by non-pulmonary vein ectopy. Circulation 2003;107:3176–83.

Maciel W, Andrea E, Araujo N, et al. Prognostic criteria of success and recurrence in circumferential ablation for the treatment of atrial fibrillation. Arquivos Brasileiros de Cardiologia 2007;88:134–43.

Mangrum JM, Mounsey JP, Kok LC, et al. Intracardiac echocardiography-guided, anatomically based radiofrequency ablation of focal atrial fibrillation originating from pulmonary veins. Journal of the American College of Cardiology 2002;39:1964–72.

Marchlinski FE, Callans D, Dixit S, et al. Efficacy and safety of targeted focal ablation versus PV isolation assisted by magnetic electroanatomic mapping. Journal of Cardiovascular Electrophysiology 2003;14:358–65.

Mortada ME, Chandrasekaran K, Nangia V, et al. Periprocedural anticoagulation for atrial fibrillation ablation. Journal of Cardiovascular Electrophysiology 2008;19:362–6.

Nademanee K, McKenzie J, Kosar E, et al. A new approach for catheter ablation of atrial fibrillation: mapping of the electrophysiologic substrate. Journal of the American College of Cardiology 2004;43:2044–53.

Oral H, Ozaydin M, Tada H, et al. Mechanistic significance of intermittent pulmonary vein tachycardia in patients with atrial fibrillation. Journal of Cardiovascular Electrophysiology 2002;13:645–50.

Oral H, Knight BP, Ozaydin M, et al. Clinical significance of early recurrences of atrial fibrillation after pulmonary vein isolation. Journal of the American College of Cardiology 2002;40:100–4.

Oral H, Knight BP, Tada H, et al. Pulmonary vein isolation for paroxysmal and persistent atrial fibrillation. Circulation 2002;105:1077–81.

Oral H, Veerareddy S, Good E, et al. Prevalence of asymptomatic recurrences of atrial fibrillation after successful radiofrequency catheter ablation. Journal of Cardiovascular Electrophysiology 2004;15:920–4.

Oral H, Chugh A, Scharf C, et al. Incremental value of isolating the right inferior pulmonary vein during pulmonary vein isolation procedures in patients with paroxysmal atrial fibrillation. Pacing & Clinical Electrophysiology 2004;27:480–4.

Sanders P, Morton JB, Deen VR, et al. Immediate and long-term results of radiofrequency ablation of pulmonary vein ectopy for cure of paroxysmal atrial fibrillation using a focal approach. Internal Medicine Journal 2002;32:202-7.

Scharf C, Sneider M, Case I, et al. Anatomy of the pulmonary veins in patients with atrial fibrillation and effects of segmental ostial ablation analyzed by computed tomography. Journal of Cardiovascular Electrophysiology 2003;14:150–5.

Scharf C, Veerareddy S, Ozaydin M, et al. Clinical significance of inducible atrial flutter during pulmonary vein isolation in patients with atrial fibrillation. Journal of the American College of Cardiology 2004;43:2057–62.

Schwartzman D, Nosbisch J, Housel D. Echocardiographically guided left atrial ablation: characterization of a new technique. Heart Rhythm 2006;3:930–8.

Shah DC, Haissaguerre M, Jais P, et al. Curative catheter ablation of paroxysmal atrial fibrillation in 200 patients: strategy for presentations ranging from sustained atrial fibrillation to no arrhythmias. Pacing & Clinical Electrophysiology 2001;24:1541–58.

Strohmer B, Hwang C, Peter CT, et al. Selective atrionodal input ablation for induction of proximal complete heart block with stable junctional escape rhythm in patients with uncontrolled atrial fibrillation. Journal of Interventional Cardiac Electrophysiology 2003;8:49–57.

Tada H, Oral H, Knight BP, et al. Randomized comparison of bipolar versus unipolar plus bipolar recordings during segmental ostial ablation of pulmonary veins. Journal of Cardiovascular Electrophysiology 2002;13:851–6.

Tada H, Naito S, Kurosaki K, et al. Segmental pulmonary vein isolation for paroxysmal atrial fibrillation improves quality of life and clinical outcomes. Circulation Journal 2003;67:861–5.

Tojo H, Kumagai K, Noguchi H, et al. Hybrid therapy with pilsicainide and pulmonary vein isolation for atrial fibrillation. Circulation Journal 2005;69:1503–7.

Tsai CF, Tai CT, Hsieh MH, et al. Initiation of atrial fibrillation by ectopic beats originating from the superior vena cava: electrophysiological characteristics and results of radiofrequency ablation. Circulation 2000;102:67–74.

Weerasooriya R, Jais P, Scavee C, et al. Dissociated pulmonary vein arrhythmia: incidence and characteristics. Journal of Cardiovascular Electrophysiology 2003;14:1173–9.

Yamada T, Murakami Y, Muto M, et al. Computerized three-dimensional potential mapping with a multielectrode basket catheter can be useful for pulmonary vein electrical disconnection. Journal of Interventional Cardiac Electrophysiology 2005;12:23–33.

Yu WC, Hsu TL, Tai CT, et al. Acquired pulmonary vein stenosis after radiofrequency catheter ablation of paroxysmal atrial fibrillation. Journal of Cardiovascular Electrophysiology 2001;12:887–92.

Reason for Rejection: Cohort Studies (No Comparison) with Less than 50 Patients

Alaeddini J, Wood MA, Lee BP, et al. Incidence, time course, and characteristics of microbubble formation during radiofrequency ablation of pulmonary veins with an 8-mm ablation catheter. Pacing & Clinical Electrophysiology 2006;29:979–84.

Alaeddini J, Wood MA, Parvez B, et al. Site localization and characterization of pain during radiofrequency ablation of the pulmonary veins. Pacing & Clinical Electrophysiology 2007;30:1210–4.

Arentz T, Jander N, von Rosenthal J, et al. Incidence of pulmonary vein stenosis 2 years after radiofrequency catheter ablation of refractory atrial fibrillation. European Heart Journal 2003;24:963–9.

Arentz T, Weber R, Jander N, et al. Pulmonary haemodynamics at rest and during exercise in patients with significant pulmonary vein stenosis after radiofrequency catheter ablation for drug resistant atrial fibrillation. European Heart Journal 2005;26:1410–4.

Arentz T, von Rosenthal J, Weber R, et al. Effects of circumferential ostial radiofrequency lesions on pulmonary vein activation recorded with a multipolar basket catheter. Journal of Cardiovascular Electrophysiology 2005;16:302–8.

Artuso E, Stomaci B, Verlato R, et al. Transesophageal echocardiographic follow-up of pulmonary veins in patients undergoing ostial radiofrequency catheter ablation for atrial fibrillation. Italian Heart Journal: Official Journal of the Italian Federation of Cardiology 2005;6:595–600.

Aryana A, Heist EK, D'Avila A, et al. Pain and anatomical locations of radiofrequency ablation as predictors of esophageal temperature rise during pulmonary vein isolation. Journal of Cardiovascular Electrophysiology 2008;19:32–8.

Bai R, Patel D, Di Biase L, et al. Phrenic nerve injury after catheter ablation: should we worry about this complication? Journal of Cardiovascular Electrophysiology 2006;17:944–8.

Bedogni F, Brambilla N, Laudisa ML, et al. Acquired pulmonary vein stenosis after radiofrequency ablation treated by angioplasty and stent implantation. Journal of Cardiovascular Medicine 2007;8:618–24.

Bulava A, Slavik L, Fiala M, et al. Endothelial damage and activation of the hemostatic system during radiofrequency catheter isolation of pulmonary veins. Journal of Interventional Cardiac Electrophysiology 2004;10:271–9.

Cappato R, Negroni S, Pecora D, et al. Prospective assessment of late conduction recurrence across radiofrequency lesions producing electrical disconnection at the pulmonary vein ostium in patients with atrial fibrillation. Circulation 2003;108:1599–604.

Chang SH, Tsao HM, Wu MH, et al. Morphological changes of the left atrial appendage after catheter ablation of atrial fibrillation. Journal of Cardiovascular Electrophysiology 2007;18:47–52.

Chang SL, Tai CT, Lin YJ, et al. The role of left atrial muscular bundles in catheter ablation of atrial fibrillation. Journal of the American College of Cardiology 2007;50:964–73.

Cheung P, Hall B, Chugh A, et al. Detection of inadvertent catheter movement into a pulmonary vein during radiofrequency catheter ablation by real-time impedance monitoring. Journal of Cardiovascular Electrophysiology 2004;15:674–8.

Cummings JE, Schweikert R, Saliba W, et al. Left atrial flutter following pulmonary vein antrum isolation with radiofrequency energy: linear lesions or repeat isolation. Journal of Cardiovascular Electrophysiology 2005;16:293–7.

Cummings JE, Schweikert RA, Saliba WI, et al. Brief communication: atrial-esophageal fistulas after radiofrequency ablation. Annals of Internal Medicine 2006;144:572–4.

Di BL, Fahmy TS, Patel D, et al. Remote magnetic navigation: human experience in pulmonary vein ablation. Journal of the American College of Cardiology 2007;50:868–74.

Dill T, Neumann T, Ekinci O, et al. Pulmonary vein diameter reduction after radiofrequency catheter ablation for paroxysmal atrial fibrillation evaluated by contrast-enhanced three-dimensional magnetic resonance imaging. Circulation 2003;107:845–50.

Donal E, Grimm RA, Yamada H, et al. Usefulness of Doppler assessment of pulmonary vein and left atrial appendage flow following pulmonary vein isolation of chronic atrial fibrillation in predicting recovery of left atrial function. American Journal of Cardiology 2005;95:941–7.

Dong J, Vasamreddy CR, Jayam V, et al. Incidence and predictors of pulmonary vein stenosis following catheter ablation of atrial fibrillation using the anatomic pulmonary vein ablation approach: results from paired magnetic resonance imaging. Journal of Cardiovascular Electrophysiology 2005;16:845–52.

Earley MJ, Abrams DJ, Staniforth AD, et al. Catheter ablation of permanent atrial fibrillation: medium term results. Heart 2006;92:233–8.

Erdogan A, Carlsson J, Neumann T, et al. Quality-of-life in patients with paroxysmal atrial fibrillation after catheter ablation: results of long-term follow-up. Pacing & Clinical Electrophysiology 2003;26:678–84.

Estner HL, Hessling G, Ndrepepa G, et al. Acute effects and long-term outcome of pulmonary vein isolation in combination with electrogram-guided substrate ablation for persistent atrial fibrillation. American Journal of Cardiology 2008;101:332–7.

Gerstenfeld EP, Dixit S, Callans D, et al. Utility of exit block for identifying electrical isolation of the pulmonary veins. Journal of Cardiovascular Electrophysiology 2002;13:971–9.

Goldberg A, Menen M, Mickelsen S, et al. Atrial fibrillation ablation leads to long-term improvement of quality of life and reduced utilization of healthcare resources. Journal of Interventional Cardiac Electrophysiology 2003;8:59–64.

Gonzalez-Zuelgaray J, Perez A. Regular supraventricular tachycardias associated with idiopathic atrial fibrillation. American Journal of Cardiology 2006;98:1242–4.

Jin Y, Ross DL, Thomas SP. Pulmonary vein stenosis and remodeling after electrical isolation for treatment of atrial fibrillation: short- and medium-term follow-up. Pacing & Clinical Electrophysiology 2004;27:1362–70.

Jongbloed MR, Bax JJ, Zeppenfeld K, et al. Anatomical observations of the pulmonary veins with intracardiac echocardiography and hemodynamic consequences of narrowing of pulmonary vein ostial diameters after radiofrequency catheter ablation of atrial fibrillation. American Journal of Cardiology 2004;93:1298–302.

Khan MN, Jais P, Cummings J et al. Pulmonary-vein isolation for atrial fibrillation in patients with heart failure. New England Journal of Medicine 2008;359:1778–85.

Kumagai K, Gondo N, Matsumoto N, et al. New technique for simultaneous catheter mapping of pulmonary veins for catheter ablation in focal atrial fibrillation. Cardiology 2000;94:233–8.

Lemola K, Sneider M, Desjardins B, et al. Effects of left atrial ablation of atrial fibrillation on size of the left atrium and pulmonary veins. Heart Rhythm 2004;1:576–81.

Lemola K, Desjardins B, Sneider M, et al. Effect of left atrial circumferential ablation for atrial fibrillation on left atrial transport function. Heart Rhythm 2005;2:923–8.

Lickfett L, Mahesh M, Vasamreddy C, et al. Radiation exposure during catheter ablation of atrial fibrillation. Circulation 2004;110:3003–10.

Lickfett L, Hackenbroch M, Lewalter T, et al. Cerebral diffusion-weighted magnetic resonance imaging: a tool to monitor the thrombogenicity of left atrial catheter ablation. Journal of Cardiovascular Electrophysiology 2006;17:1–7.

Liu X, Ouyang F, Mavrakis H, et al. Complete pulmonary vein isolation guided by three-dimensional electroanatomical mapping for the treatment of paroxysmal atrial fibrillation in patients with hypertrophic obstructive cardiomyopathy. Europace 2005;7:421–7.

lling-Boer D, Van der MN, Adams J, et al. Ablation of focally induced atrial fibrillation: selective or extensive? Journal of Cardiovascular Electrophysiology 2004;15:200–5.

Lo LW, Tai CT, Lin YJ, et al. Mechanisms of recurrent atrial fibrillation: comparisons between segmental ostial versus circumferential pulmonary vein isolation. Journal of Cardiovascular Electrophysiology 2007;18:803–7.

MacLe L, Jais P, Scavee C, et al. Electrophysiologically guided pulmonary vein isolation during sustained atrial fibrillation. Journal of Cardiovascular Electrophysiology 2003;14:255-60.

Martinek M, Aichinger J, Nesser HJ, et al. New insights into long-term follow-up of atrial fibrillation ablation: full disclosure by an implantable pacemaker device. Journal of Cardiovascular Electrophysiology 2007;18:818–23.

Miyairi T, Nakao M, Kigawa I, et al. A closed biatrial procedure using bipolar radiofrequency ablation. Journal of Thoracic & Cardiovascular Surgery 2006;132:168–9.

Nakashima H, Kumagai K, Tojo H, et al. Simultaneous catheter mapping of the pulmonary veins in focal atrial fibrillation: significance of rapid focal activation, effectiveness for catheter ablation. Japanese Heart Journal 2002;43:357–65.

Natale A, Pisano E, Beheiry S, et al. Ablation of right and left atrial premature beats following cardioversion in patients with chronic atrial fibrillation refractory to antiarrhythmic drugs. American Journal of Cardiology 2000;85:1372–5.

Oral H, Morady F. Conducting randomized trials in the electrophysiology laboratory: lessons from a randomized comparison of recording methods during pulmonary vein isolation by segmental ostial ablation. Cardiac Electrophysiology Review 2003;7:247–51.

Ouyang F, Bansch D, Ernst S, et al. Complete isolation of left atrium surrounding the pulmonary veins: new insights from the double-Lasso technique in paroxysmal atrial fibrillation. Circulation 2004;110:2090–6.

Ouyang F, Ernst S, Chun J, et al. Electrophysiological findings during ablation of persistent atrial fibrillation with electroanatomic mapping and double Lasso catheter technique. Circulation 2005;112:3038–48.

Ouyang F, Antz M, Ernst S, et al. Recovered pulmonary vein conduction as a dominant factor for recurrent atrial tachyarrhythmias after complete circular isolation of the pulmonary veins: lessons from double Lasso technique. Circulation 2005;111:127–35.

Pachon MJ, Pachon ME, Pachon MJ, et al. A new treatment for atrial fibrillation based on spectral analysis to guide the catheter RF-ablation.[erratum appears in Europace. 2005 Jan;7(1):92–3]. Europace 2004;6:590–601.

Packer DL, Keelan P, Munger TM, et al. Clinical presentation, investigation, and management of pulmonary vein stenosis complicating ablation for atrial fibrillation. Circulation 2005;111:546–54.

Piorkowski C, Kottkamp H, Tanner H, et al. Value of different follow-up strategies to assess the efficacy of circumferential pulmonary vein ablation for the curative treatment of atrial fibrillation. Journal of Cardiovascular Electrophysiology 2005;16:1286–92.

Prakash A, Saksena S, Krol RB, et al. Catheter ablation of inducible atrial flutter, in combination with atrial pacing and antiarrhythmic drugs ("hybrid therapy") improves rhythm control in patients with refractory atrial fibrillation. Journal of Interventional Cardiac Electrophysiology 2002;6:165–72.

Pratola C, Baldo E, Notarstefano P, et al. Radiofrequency ablation of atrial fibrillation: is the persistence of all intraprocedural targets necessary for long-term maintenance of sinus rhythm? Circulation 2008;117:136–43.

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Reason for Rejection: Other Reasons (See Specific Reason After Each Citation)

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Daoud EG, Weiss R, Augostini R, et al. Proarrhythmia of circumferential left atrial lesions for management of atrial fibrillation. Journal of Cardiovascular Electrophysiology 2006;17:157–65. **Mean f/up <6 mo**

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Khaykin Y, Marrouche NF, Martin DO, et al. Pulmonary vein isolation for atrial fibrillation in patients with symptomatic sinus bradycardia or pauses. Journal of Cardiovascular Electrophysiology 2004;15:784–9. **Mixed with sick sinus syndrome**

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Lip GY. Paroxysmal atrial fibrillation, stroke risk and thromboprophylaxis. Thrombosis & Haemostasis 2008;100:11–3. **Review article**

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Mason PK, Wood MA, Lake D, et al. Influence of the randomized trials, AFFIRM and RACE, on the management of atrial fibrillation in two University Medical Centers. American Journal of Cardiology 2005;95:1248–50. **Not PVI**

Mickelsen S, Dudley B, Treat E, et al. Survey of physician experience, trends and outcomes with atrial fibrillation ablation. Journal of Interventional Cardiac Electrophysiology 2005;12:213–20. **Secondary surgery**

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Occhetta E, Bortnik M, Dell'era G, et al. Evaluation of pacemaker dependence in patients on ablate and pace therapy for atrial fibrillation. Europace 2007;9:1119–23. **AVN ablation**

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Puggioni E, Brignole M, Gammage M, et al. Acute comparative effect of right and left ventricular pacing in patients with permanent atrial fibrillation. Journal of the American College of Cardiology 2004;43:234–8. **Select patients only post-RFA**

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Richter B, Derntl M, Marx M, et al. Therapy with angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, and statins: no effect on ablation outcome after ablation of atrial fibrillation. American Heart Journal 2007;153:113–9. **Duplicate publication**

Ruchat P, Dang L, Schlaepfer J, et al. Use of a biophysical model of atrial fibrillation in the interpretation of the outcome of surgical ablation procedures. European Journal of Cardio-Thoracic Surgery 2007;32:90–5. **Model, surgery only**

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Shah DC, Haissaguerre M, Jais P, et al. Electrophysiologically guided ablation of the pulmonary veins for the curative treatment of atrial fibrillation. Annals of Medicine 2000;32:408–16. **Inadequate reporting. Eg, no data on f/up duration**

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Steel KE, Roman-Gonzalez J, O'Bryan CL. Images in cardiovascular medicine. Severe left atrial edema and heart failure after atrial fibrillation ablation. Circulation 2006;113:e659. **Case report**

Thiagalingam A, Manzke R, D'Avila A, et al. Intraprocedural volume imaging of the left atrium and pulmonary veins with rotational X-ray angiography: implications for catheter ablation of atrial fibrillation. Journal of Cardiovascular Electrophysiology 2008;19:293–300. **Studies on pre-procedural variables only**

Verma A, Marrouche NF, Yamada H, et al. Usefulness of intracardiac Doppler assessment of left atrial function immediately post-pulmonary vein antrum isolation to predict short-term recurrence of atrial fibrillation. American Journal of Cardiology 2004;94:951–4. **Mean f/up <6 mo**

Wong T, Markides V, Peters NS, et al. Anatomic left atrial circumferential ablation to electrically isolate pulmonary veins using a novel focused ultrasound balloon catheter. Heart Rhythm 2006;3:370–1. **Case report**

Yamada T, Murakami Y, Okada T, et al. Plasma brain natriuretic peptide level after radiofrequency catheter ablation of paroxysmal, persistent, and permanent atrial fibrillation. Europace 2007;9:770-–4. **Mean f/up <6 mo**

Yao Y, Zheng L, Zhang S, et al. Stepwise linear approach to catheter ablation of atrial fibrillation. Heart Rhythm 2007;4:1497–504. **Linear ablations only**

Appendix C: Evidence Tables

Al Chekakie Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Al Chekakie, 2007 US 17593228				x		MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Al Chekakie, 2007 US 17593228	Paroxysmal or persistent AF refractory to anti-arrhythmic drug therapy who met the criteria: (1) no previous ablation procedure for AF and (2) antral PVI alone	Patients who underwent segmental ostial isolation or additional left atrial linear lesions	January 2003 to December 2004	nd	Structural heart disease 23%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Al Chekakie, 2007 US 17593228	nd	First PVI	177	75	23% >65 years old	71	6.06	nd	53% >4.2	8% <50%	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Al Chekakie, 2007 US 17593228	yes	100% [entrance block into all PVs, with elimination of all recordable high-frequency potentials confirmed by a circular mapping catheter placed at the venous ostium]	Cavotricuspid isthmus in patients with previously documented spontaneous or inducible cavotricuspid isthmus dependent atrial flutter	nd	4-mm or 8-mm tip (SOLID TIP)	40-50	60	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Al Chekakie, 2007 US 17593228	Recurrence of AF	An electrocardiographically documented episode lasting >30 seconds, irrespectively of symptoms	First PVI	13.8	45	177						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (24-hr Holter monitoring at 6 and 12 months and 30-day transtelephonic monitoring at 3 and 9 months after the procedure)		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	2 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Men	Al Chekakie, 2007 US 17593228	Recurrence of AF	An electrocardiographically documented episode lasting >30 seconds, irrespectively of symptoms	First PVI	13.8			HR: 1.28	0.67-2.44	.462	1.25	0.63-2.51	.53
Age >65								1.33	1.73-2.44	.355	1.42	0.72-2.79	.31
Persistent AF								1.66	0.92-2.98	.091	1.10	0.55-2.20	.79
Structural heart disease								1.45	0.78-2.69	.244	0.91	0.45-1.86	.80
La diameter >42 mm								1.01	0.58-1.76	.976	0.87	0.47-1.60	.65
Hypertension								1.81	1.04-3.17	.037	1.82	0.87-3.79	.11
EF<50%								3.66	1.76-7.61	<.001	2.70	1.13-6.46	.03
AF duration (years)								0.96	0.91-1.02	.195	0.95	0.89-1.02	0.13
ACE-I								2.10	1.12-3.93	.02	1.29	0.57-2.93	.54
ARB								0.17	0.02-1.23	.079	0.17	0.02-1.34	.09
Stain								1.40	0.78-2.52	.265	1.10	0.55-2.27	.80
RAS blockers								1.19	0.65-2.19	.573	0.94	0.46-1.93	.87
RAS blockers and statins								1.23	0.70-2.16	.478	1.02	0.54-1.93	.96

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/–); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Al Chekakie, 2007 US 17593228	no	NA	NA	NA (retrospective study)	nd	Yes (0% dropout)	yes	yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	no	yes	no				
Explanation for Overall Quality Grade:				Retrospective study						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Al Chekakie, 2007 US 17593228			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Arentz Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Arentz 2007 Germany 17562956	x				individual PVI vs. large area PVI; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Arentz 2007 Germany 17562956	symptomatic drug resistant AF	LAD >55 mm; intracardiac thrombi; MI or heart surgery previous 3 mo; previous AF ablation	2004-2006	1 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Arentz 2007 Germany 17562956	nd	Individual vein PVI	55	61	56	75	5.5	nd	4.0	nd	B	moderate
		ipsilateral veins PVI	55									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Arentz 2007 Germany 17562956	y	100%(implied) [disappearance or dissociation of PV potentials on basket catheter or Lasso catheter]	(1)Circumferential ablation of ipsilateral veins (2) When PV conduction was still present after WACA, both PVs were mapped sequentially for site of earliest activation (lesion placed on ablation line)	n	irrigated tip	25-35	50	49 58

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Arentz 2007 Germany 17562956	primary end point	freedom from AF with no AAD; no AF or AT symptoms; no AT >30 s; after 1 ablation	individual vein PVI	15 mo	27	55	49%					
			ipsilateral veins PVI		37	55	67%		≤0.05			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal AF	Arentz 2007 Germany 17562956	primary end point	freedom from AF with no AAD; no AF or AT symptoms; no AT >30 s; after 1 ablation	individual vein PVI	15	19	35						
				ipsilateral veins PVI		23	32			0.1			
persistent AF				individual vein PVI	15	8	20						
						14	23			0.16			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Arentz 2007 Germany 17562956	individual vein PVI		40%, 1/55 (1.8%)	1/55 (1.8%)						
	ipsilateral veins PVI		40%, 1/55 (1.8%)	1/55 (1.8%)					pulmonary edema (transient)	1/55 (1.8%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Arentz 2007 Germany 17562956	y	nd	n	y (?)	n	n	y	NA	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	n				
Explanation for Overall Quality Grade:				randomization technique not reported; unclear if there were any dropouts at followup						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Arentz 2007 Germany 17562956		X	
Explanation for Applicability Grade:		N=55 in each arm; relatively young patients	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Arruda Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Arruda, 2007 US 17850288					X (prospectively comparing 2 non-concurrent groups)	MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Arruda, 2007 US 17850288	Consecutive patients with symptomatic AF, refractory to 3±1 AAD trials	None reported	nd	"41 patients were controlled with a previously ineffective AAD" (time was not reported)	Persistent AF = 10% Permanent AF = 39%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Arruda, 2007 US 17850288	nd	PVI (n=190) PVI + SVCI (superior vena cava electrical isolation) (n=217)	407*	51	55	79	6	nd	nd	nd	C	Wide

*No breakdown patients' characteristics per intervention

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Arruda, 2007 US 17850288	yes	PVI: nd [Endpoint – RF was delivered until EGMs on circular catheter were eliminated. Presumably 100%]	none	yes	4-mm, 8-mm (Biosense Webster, Baldwin Park, CA), or irrigated tip (EP technologies, Sunnyvale, CA)	nd	55 (4- or 8-mm tip); 35 (irrigated tip	Nd
	yes	PVI+SVCI: nd for PVI; 59% for SVCI [abolishing all high frequency SVC potentials]	superior vena cava electrical isolation					nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Arruda, 2007 US 17850288	Recurrence of AF	nd	PVI or PVI+SVCI	14.8	66	407						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24-hour or greater ECG screening performed?	No		
Was a blanking period (time when AFib episodes were not recorded) used?	No	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Arruda, 2007 US 17850288	no	NA	NA	Yes (assumed no dropout)	nd	Yes (0% dropout)	no	no	no	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		no	no	yes	no	no				
Explanation for Overall Quality Grade:				Poor reporting of interventions and patients' characteristics; the only comparison between the two techniques were among 25 patients who had a repeat procedure (see reviewer's comment)						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Arruda, 2007 US 17850288			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Arruda, 2007 US 17850288	A repeat ablation procedure was performed in 25 of the 66 patients who had recurrence AF. Five of these 25 patients (20%) were found to have AF recurrence initiated by SVC triggers, of whom four were among group I patient (4/190, 2%) and one was from group III (1/217; 0.4%), p<0.05. All patients remained arrhythmia-free after repeat PVI and SVCI.

Berkowitsch Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Berkowitsch, 2005 Germany 15683534				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Berkowitsch, 2005 Germany 15683534	• Highly symptomatic paroxysmal AF • Refractory to > 3 AAD	nd	nd	nd	Only severe PV stenosis was assessed. No efficacy/effectiveness outcomes reported.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Berkowitsch, 2005 Germany 15683534	nd	PVI (ostial)	104	100	55	33	nd	nd	nd	nd	AE data only	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Berkowitsch, 2005 Germany 15683534	Yes	nd	nd	Nd	4 mm, cooled tip (Chilli)	15-50	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Berkowitsch, 2005 Germany 15683534	PVI (ostial)	12	Severe*: 16/104** (15%)	nd	nd	nd	nd	nd	Nd	

Only PV stenosis was assessed by MRI
*Severe stenosis was defines as a ≥ 70% narrowing of the initial ostial diameter.
**Patient is the unit of analysis. 18/357 per PV-based analysis (Severe stenoses was observed in 18 out of 357 total PVs, meaning that two patients developed severe stenosis in two left PVs).
Multivariate analyses by the Cox regression identified RRPVD1 ≥ 25% (HR=1.5 (95% CI, 2.5-8.3 (p<0.001))), RA >180˚ (HR=10.3 (95% CI, 2.4-47.8 (p<0.02))), and CE > 22000(J) (HR=2.9 (95% CI, 1.2-7.8 (p<0.03))) as statistically significant factors that predicted severe stenosis development. RRPVD1, relative reduction of PV after the procedure (day 1); RA, summary radial angle of energy delivery at the ostial circumference; CE, cumulative energy delivery per PV. Only factors associated with energy delivery were taken into account and no clinical/patient characteristics or operator characteristics were explored in the analyses.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Berkowitsch, 2005 Germany 15683534	No	NA	NA	nd	NA	NA	Yes	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	NA	No	No	NA				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Berkowitsch, 2005 Germany 15683534			
Explanation for Applicability Grade:		Only paroxysmal. The details on patient characteristics and ablation procedure were not well described.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Berkowitsch, 2005 Germany 15683534	Definition of severe stenosis was based on imaging results (MRI). Clinical symptoms were not taken into account. Only factors associated with energy delivery were taken into account and no clinical/patient characteristics or operator characteristics were explored in the multivariate analyses.

Berruezo Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Berruezo, 2007 Spain 17395676			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Berruezo, 2007 Spain 17395676	Patients referred for AF ablation	Age<18 or .75 years, anteroposterior LAD at transthoracic echocardiography >55 mm, presence of LA thrombus on transesophageal echocardiography, and the presence of a mechanical prosthetic heart valve.	January 2003 to November 2005	nd	Persistent AF=23.6% Permanent AF=15.5% Structural heart disease=19.6%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Berruezo, 2007 Spain 17395676	Instituto de Salud Carlos III, Madrid, Spain and Spanish Society of Cardiology	Circumferential pulmonary vein ablation	148	60.8	52	82.4	6.2	nd	4.1	60	B	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Berruezo, 2007 Spain 17395676	yes	Yes (100% implied) - in order to achieve a local electrogram 0.15 mV within this area.- electrical disappearance/reduction was checked by mapping the encircled area (low voltage inside the encircled area)	WACA, linear lesions LA posterior wall, roof, and mitral isthmus	no	8 mm or irrigated tip (Navistar, Biosense Webster)	8-mm: 60 Irrigated: 40	8-mm: 55 Irrigated: 45	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Berruezo, 2007 Spain 17395676	AF recurrence	Symptomatic or asymptomatic AF episodes presenting after the first month	Circumferential pulmonary vein ablation	13.1	39	148						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (24 hr Holter monitoring at follow-up visits)		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	1 month

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Age (year)	Berruezo, 2007 Spain 17395676	AF recurrence	Symptomatic or asymptomatic AF episodes presenting after the first month	Circumferential pulmonary vein ablation	13.1			HR: 1.03	1.00-1.06	.031			ns
Male gender								HR: 1.02	0.45-2.32	.942			ns
Hypertension								HR: 2.70	1.43-5.07	.002	HR: 2.8	1.5-5.4	.002
Permanent AF								HR: 2.23	1.08-4.59	.042			ns
Structural heart disease								HR: 1.28	0.61-2.69	.331			ns
AF duration (months)								HR: 1.00	1.00-1.00	.989			ns
LAD (mm)								HR: 1.11	1.05-1.18	.001	HR: 1.1	1.06-1.2	0.01
IVEDD (mm)								HR: 1.05	0.98-1.12	.175			ns
IVESD (mm)								HR: 1.07	1.00-1.15	.029			ns
LVEF (%)								HR: 0.98	0.95-1.01	.128			ns
LVS (mm)								HR: 0.99	0.78-1.27	.843			ns
LVPW (mm)								HR: 1.05	0.74-1.48	.927			ns

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Berruezo, 2007 Spain 17395676	Circumferential pulmonary vein ablation		0 (at 4 month follow-up)						Transient cerebrovascular ischemia	2/148 (1.3%)
									pericarditis	6/148 (4%)
									Dressler syndrome	2/148 (1.3%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Berruezo, 2007 Spain 17395676	no	NA	NA	0 (assumed)	nd	Yes (0% dropout)	yes	yes	yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	no				
Explanation for Overall Quality Grade:				Observational study						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Berruezo, 2007 Spain 17395676			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Berruezo, 2007 Spain 17395676	A 2nd procedure was performed in 22 (14.8%) patients, and a third procedure was necessary in 4 of these patients (2.7%)

Bertaglia 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Bertaglia, 2005 Italy 15869666				x		MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Bertaglia, 2005 Italy 15869666	Patients who underwent circumferential anatomical PV ablation using the CARTO nonfluoroscopic navigation system (Biosense Webster) for paroxysmal or persistent AF refractory to ≥2 antiarrhythmic drugs in 3 different Italian hospitals (Cirie, Maddaloni, Mirano). 143/158 (91%) consecutive patients who had not yet undergone a PV ablation procedure were selected	nd	March 2001 to March 2003	64 patients were still on a previous ineffective AAD: 40 on amiodarone, and 24 on 1C class drug (during a mean follow-up of 18.7 months, ranged 9-36 months)	Structural heart disease 62% 6% patients with LVEF <40%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Bertaglia, 2005 Italy 15869666	nd	circumferential anatomical PV ablation	143	45	61.4	66	5.0	nd	4.7	57.7	C	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Bertaglia, 2005 Italy 15869666	yes	PVI: 87% [conduction block around each PV or around ipsilateral PVs according to the anatomy]	WACA Starting from the beginning of 2002, adjunctive RF ablation lines were created in the right or left atrium: along the cavotricuspid isthmus with electrophysiological assessment of transisthmic block, and along the isthmus between the mitral annulus and the left inferior PV without electrophysiological assessment of transisthmic block 83% received ablation of right isthmus 68% received ablation of left isthmus	no	3.5 mm cooled-tip (Navistar, Biosense Webster Inc.)	50	45	55.5

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Bertaglia, 2005 Italy 15869666	Responders	Patients who did not present symptomatic or asymptomatic atrial tachyarrhythmias lasting >30 seconds after the first 3 months of follow-up	circumferential anatomical PV ablation	18.7	102	143						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (24-hr ECG Holter monitoring at followup)		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	3 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Early relapse (within 3 months post RFA)	**Bertaglia, 2005 Italy 15869666**	**Responders**	Patients who did not present symptomatic or asymptomatic atrial tachyarrhythmia lasting >30 seconds after the first 3 months of follow-up	**circumferential anatomical PV ablation**	18.7	28	65			<.0001, chi-square test			
No early relapse						74	78						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Bertaglia, 2005 Italy 15869666	circumferential anatomical PV ablation			2/143 (1.4%)					Transient paralysis of the right phrenic nerve	1/143 (0.7%)
									Transient ischemic attack	1/143 (0.7%)
									AV block	1/143 (0.7%)
									Pseudoaneurysm of the right femoral artery	1/143 (0.7%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Bertaglia, 2005 Italy 15869666	no	NA	NA	retrospective	no	no	no	no	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	no	yes	no				
Explanation for Overall Quality Grade:		Retrospective study (143/158 consecutive patients who had not yet undergone a PV ablation procedure were selected); post-hoc analyses.								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Bertaglia, 2005 Italy 15869666			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Bertaglia 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Bertaglia, 2007 Italy 17905330			x			MC/AG

Zoppo 2008 (18695424) is a post-hoc analysis of the same data

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Bertaglia, 2007 Italy 17905330	Of the 32 Italian electrophysiology laboratories listed in the Italian Association of Arrhythmology and Cardiostimulation ablation procedures national Registry, 10 agreed to participate in this prospective registry, which was set up in April 2005. All consecutive patients who were undergoing catheter ablation in their laboratories for every type of AF. Not all centers entered the Registry within the same time period.	None	18 months from April 2005.	nd	Persistent AF: 34.5% Permanent AF: 5.5% Structural heart disease: 32.6%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Bertaglia, 2007 Italy 17905330	nd	All ablation strategies aimed at isolating or encircling the PVs were included. Additional linear lesions in the right or left atrium also were allowed.	1,011	60	57.9	74.4	4.7	nd	4.4	56.7	AE data only	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Bertaglia, 2007 Italy 17905330	yes	nd [a circumferential PV mapping catheter was used in 35% patients and a multipolar basket catheter in 4.3% patients to completely isolate the PV]	Linear lesions in 688 (66%) patients at the cavotricuspid isthmus, in 474 (46.8%) at the mitral-to-left inferior PV isthmus, and in 266 (26.3%) at the left atrium roof.	nd	4-mm or 8-mm tip, or 3.5-mm open irrigated tip (ThermoCool, Biosense Webster Inc.) 89.5% used irrigated tip, 8.5% used 8-mm tip and 2% used 4-mm tip.	4-mm: 40* 8-mm: 100* Irrigated: 50*	4-mm: 50 8-mm: 60 Irrigated: 45	42.9

*When ablation was performed in the posterior wall of the left atrium, RF power was reduced to 30, 50, and 25 W for the 3 modalities, respectively.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Bertaglia, 2007 Italy 17905330	All ablation strategies aimed at isolating or encircling the PVs		4/1011 (0.4% [PV Stenosis >50%. All but 1 without any clinical consequence]	6/1011 (0.6%)	4/1011 (0.4%)*		12/1011 (1.2%)	0	Pericardial effusion (all conservatively treated)	8/1011 (0.8%)
									Cerebral embolism (including stroke and transient ischemic attack)	5/1011 (0.5%)
									Aortic root puncture during the transseptal approach, without any clinical consequence	1/1011 (0.1%)
									Complete atrioventricular block during ablation in the septal left atrium region, with subsequent dual-chamber pacemaker implantation	1/1011 (0.1%)
									Transient phrenic nerve paralysis during right PV isolation	1/1011 (0.1%)
									Pneumothorax conservatively treated	1/1011 (0.1%)
									Pleural hematic effusion that required drainage	1/1011 (0.1%)

*3 strokes occurred on the day after the procedure while switching from intravenous unfractionated heparin to oral anticoagulation, whereas only 1 stroke occurred during the procedure.

Difference in catheter-tip (8-mm standard vs. irrigated cooled) was not a significant predictor of 5 major complications (pericardial tamponade/effusion, PV stenosis, stroke, all complications, vascular complications) Zoppo 2008 (18695424) ← this info is not relevant to our key questions…

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
		Was RFA Procedure Adequately Described?	Were the Recurrence Outcomes Fully Defined?	Was Success Rate After a Single Procedure (not including redo) Reported?	Was Asymptomatic AFib Screened For?	Was Compliance with Screening Reported?				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Bertaglia, 2007 Italy 17905330			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Bertaglia, 2007 Italy 17905330	152 procedures (15% of cases) were performed in the initial phase of the centers' learning curve (defined as <50 procedure). Predictors of complications: On multivariate analysis, only a history of coronary artery disease (OR 5.603, 95% CI 1.559 to 20.139, P<.008) continued to characterize patient who presented hemorrhagic complications (including cardiac tamponade and pericardial effusion, n=14). Multivariate analyses did not find any variable significantly predict vascular complications or cerebral embolic complications.

Beukema Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Beukema, 2005 Netherlands 16203925				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Beukema, 2005 Netherlands 16203925	Symptomatic paroxysmal or persistent AF	nd	nd	3 mo (96% of patients) followed by gradual tapering	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Beukema, 2005 Netherlands 16203925	nd	PV circumferential ablation	105	50	52	70	6.8	nd	4.2	54	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Beukema, 2005 Netherlands 16203925	Yes	Nd (100% inferred) [Bipolar electrogram amplitude ≤ 0.5 mV in the encircled area]	WACA LA: a line between left PVs and LA appendage (all), mitral isthmus line (n=42), and posterior LA line (some) RA: cavo-tricuspid isthmus line (in case of typical atrial flutter)	No	8 mm (Navistar)	80	60	nd
					3.5 mm irrigated (Navistar)*	50	50	nd

*N=32 pts

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Beukema, 2005 Netherlands 16203925	Sinus rhythm at last follow-up	Unclear	PV circumferential ablation	14.6	76	105	72%					
Beukema, 2005 Netherlands 16203925	Re-procedure	Patients who required a second procedure due to recurrent AF between 3 and 6 months after the first procedure	PV circumferential ablation	14.6?	23	105						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	NA

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Beukema, 2005 Netherlands 16203925	Change in LAD	Decrease in LAD between before and after procedure	cm	PV circumferential ablation	6	105?	4.2	nd	Nd*	<0.01 (t-test)

Duplicate one row per outcome and per RFA intervention.
*Difference between before and after therapy in each subgroup in each therapy, not net difference between independent subgroups.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal AF	Beukema, 2005 Netherlands 16203925	AF free survival	unclear	PV circumferential ablation	14.6	45	52	87%					
Persistent AF	Beukema, 2005 Netherlands 16203925	AF free survival	unclear	PV circumferential ablation	14.6	41	53	77%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
Kaplan-Meier estimates

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Persistent	Beukema, 2005 Netherlands 16203925	Change in LAD	Decrease in LAD between before and after procedure	cm	PV circumferential ablation	6	53?	4.4	nd	Nd*	0.001 (t-test)
Persistent (only remain SR during follow-up)	Beukema, 2005 Netherlands 16203925	Change in LAD	Decrease in LAD between before and after procedure	cm	PV circumferential ablation	6	41?	4.4	4.0	0.4*	<0.01 (t-test)
Persistent (only recurrent AF during follow-up)	Beukema, 2005 Netherlands 16203925	Change in LAD	Decrease in LAD between before and after procedure	cm	PV circumferential ablation	6	12?	4.5	4.9	-0.4*	0.001 (t-test)
Paroxysmal	Beukema, 2005 Netherlands 16203925	Change in LAD	Decrease in LAD between before and after procedure	cm	PV circumferential ablation	6	52?	4.1	3.8	0.3*	<0.01 (t-test)
Paroxysmal (only recurrent AF during follow-up)	Beukema, 2005 Netherlands 16203925	Change in LAD	Decrease in LAD between before and after procedure	cm	PV circumferential ablation	6	7?	4.0	4.1	-0.1*	NS (t-test)

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Difference between before and after therapy in each subgroup in each therapy, not net difference between independent subgroups.

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Beukema, 2005 Netherlands 16203925	PV circumferential ablation	14.6	0/105							

Data on only PV stenosis were reported.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Beukema, 2005 Netherlands 16203925	No	NA	NA	nd	nd	Nd/NA	Yes?	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Yes?/nd	Yes	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Beukema, 2005 Netherlands 16203925			Wide
Explanation for Applicability Grade:		No explicit exclusion criteria ➔ inferring clinical practice comparable patient spectrum	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Bhargava Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Bhargava, 2004 USA 15028066				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Bhargava, 2004 USA 15028066	Symptomatic drug-refractory AF	nd	nd	nd	• Comparison among different age groups (<50 vs. 51-60 vs. >60) • May overlap Chen 2004 (Cleveland) • Age <50 group had a statistically significantly lower % of concomitant/underlying structural heart disease or hypertension than Age 51- group (33% vs. 60%, P<0.05) • Age <50 group had a statistically significantly lower number of failed prior AAD (but probably clinically insignificant) than Age 51- group (2.85 vs. 3.22, P<0.05)

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Bhargava, 2004 USA 15028066	nd	PVI (PV ostial)	323	54	54	80	6.2	NA	4.3	53	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Bhargava, 2004 USA 15028066	Yes	Nd (100% implied) [nd]	SVC if mapping demonstrated high-frequency potentials	No	4 mm cooled-tip (EP technologies)	35	35-40	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	8 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
<50 years	Bhargava, 2004 USA 15028066	Freedom from recurrent AF	AF persisted beyond 8-week blanking period	PVI (PV ostial)	14.9	90	106	85%		NS (Chi-squared)			
51-60 years					14.8	95	114	83%					
>60 years					14.7	84	103	82%					
<50 years, only paroxismal	Bhargava, 2004 USA 15028066	Freedom from recurrent AF	AF persisted beyond 8-week blanking period	PVI (PV ostial)	14.9	58	64	91%		NS (Chi-squared)			
51-60 years, only paroxysmal					14.8	52	56	86%					
>60 years, only paroxismal					14.7	46	54	85%					
<50 years, only persistent	Bhargava, 2004 USA 15028066	Freedom from recurrent AF	AF persisted beyond 8-week blanking period	PVI (PV ostial)	14.9	9	11	82%		NS (Chi-squared)			
51-60 years, only persistent					14.8	13	16	81%					
>60 years, only persistent					14.7	6	8	75%					
<50 years, only permanent	Bhargava, 2004 USA 15028066	Freedom from recurrent AF	AF persisted beyond 8-week blanking period	PVI (PV ostial)	14.9	23	31	74%		NS (Chi-squared)			
51-60 years, only permanent					14.8	34	42	81%					
>60 years, only permanent					14.7	32	41	78%					
Paroxysmal	Bhargava, 2004 USA 15028066	Freedom from recurrent AF	AF persisted beyond 8-week blanking period	PVI (PV ostial)	14.8	152	174	87%					
Persistent						28	35	80%					
Permanent						89	114	78%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Crude estimates. The number of relapse cases in each subgroup was reported in the paper.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Bhargava, 2004 USA 15028066	PVI (PV ostial)	14.8	6/323* (2%)	3/323 (1%)	3/323** (1%)	nd	nd	nd	Nd	

*Defined as >70 narrowing by CT.
**All the three patients belonged to Age>60 group (P<0.05). No statistically significant difference detected among groups in the other complications.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Bhargava, 2004 USA 15028066	No	NA	NA	nd	nd	nd	no	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Yes	Yes	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Bhargava, 2004 USA 15028066			Wide
Explanation for Applicability Grade:		Seems similar to clinical practice	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Calò Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Calò, 2006 Italy 16781381	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Calò, 2006 Italy 16781381	RFA for symptomatic persistent or permanent AFib AFib resistant >3 attempts of Rx or electric cardioversion or recurrent, persistent AFib despite prophylaxis with ≥3 different AAD (I±III)	None reported	Amiodarone (or sotalol, flecainide, propafenone if contraindication) x 6 mo	Persistent AFib: lasting >7 d Permanent AFib: resistant to cardioversion or relapsing within 24 hr Idiopathic dilated cardiomyopathy 11% Valvular disease 9%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Calò, 2006 Italy 16781381	nd	Circumferential RFA plus mitral and cavotricuspid isthmus ablation (LA ablation)	41	0% (Persistent 54% Permanent 46%)	59	65%	7 yr	nd	5.1 cm	50.7%	A	Moderate
		Biatrial ablation	39									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Calò, 2006 Italy 16781381	Yes	Not checked The endpoint was completion of lesions. Neither definite isolation of PV nor complete block was a required prerequisite of the procedure.	L Atrium: WACA, Mitral isthmus line (Within circles where local electrogram amplitude ≥0.1 mV) RA: Cavotricuspid isthmus ablation	No	8 mm Navistar	L atrium ≤80 W	50-60° x 20-60 sec	44 min (LA arm)
			Biatrial: L Atrium: Same as above R Atrium: Posterior intercaval line Septal line from septal SVC to fossa ovalis, then to CS ostium with a circumferential line around ostium, then to IVC electrical disconnection of SVC from R atrium			R atrium (specifically SVC isolation) ≤40 W	50° (target)	63 min (bilat arm)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Calò, 2006 Italy 16781381	Recurrence	Documented AFib post blanking	LA RFA	13 mo	16	41	OR 0.28	0.10, 0.81	.03			
			Bilat RFA	15 mo	6	39						
	On AAD at 6 mo		LA RFA	6 mo	21	41						
			Bilat RFA	6 mo	18	39						
	Free of AAD without recurrence		LA RFA	13 mo	7	41						
			Bilat RFA	15 mo	16	39						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
Kaplan Meier actuarial estimates at 3, 6, 18 months also reported (page 4 just above figure)

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	6 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Calò, 2006 Italy 16781381	Time to first recurrence	Not including blanking period (6 wk)	months	LA RFA	13 mo	41		3.0±1.5		
				Bilat RFA	15 mo	39		3.9±2.3		

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

Multivariable Cox regression:
adjusting for age, gender, LAD, structural heart disease, persistent vs permanent AF, continuation of AAD p-6 mo:
Bilateral RFA a negative predictor of AF recurrence: HR = 5.2 (2.0-13.3), P=.001

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)
Calò, 2006 Italy 16781381	LA RFA		Echo performed at 3 mo, but data not reported						Retroperitoneal hematoma (n=1) Hemothorax (n=1)
	Bilat RFA								None reported

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Calò, 2006 Italy 16781381	Yes	Yes	nd	Yes (0%)	No	Yes	Yes	Yes	Yes	A
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:				No flaws						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Calò, 2006 Italy 16781381		Moderate	
Explanation for Applicability Grade:		Persistent or Permanent AFib only	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Calò, 2006 Italy 16781381	Power calculation: 20% AFib recurrence (bilat) vs 50% (LA), alpha = 0.05, beta = 0.80: 40 per arm.

Cha Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Cha 2008 US 18474813				x	KQ2, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Cha 2008 US 18474813	symptomatic AF; followup ≥3 mo		2000-2005	AAD ≥ 2-3 mo in pts with early recurrence	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Cha 2008 US 18474813	industry	PVI (57%) or WACA (42%)	523	58	54	84	6.4	nd	nd	58	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Cha 2008 US 18474813	y in WACA	100% (implied?)	WACA + cavotricuspid isthmus ablation (± mitral line, or SVC, or vein of Marshall, or CS ablation)	y in WACA	5 mm in PVI	30	50	*
					8 mm in WACA	35	50	*

Total ablation time for all pts (523) 53 +/- 26 min

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Cha 2008 US 18474813	AF elimination	freedom from AF (no AAD)	PVI or WACA	12 mo	311	432	72%					
Cha 2008 US 18474813	AF elimination	freedom from AF (no AAD)	PVI or WACA	24 mo	212	296	72%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
lean (BMI<25)	Cha 2008 US 18474813	AF elimination	freedom from AF	PVI or WACA	12 mo	60	80	75%					
overweight (25-29.9)		AF elimination				139	192	72%					
obese (≥30.0)		AF elimination				112	160	70%	-6.9% to 16.9%	0.42 (obese vs. lean)			
lean (BMI<25)	Cha 2008 US 18474813	AF elimination	freedom from AF	PVI or WACA	24 mo	45	61	74%					
overweight (25-29.9)		AF elimination				95	130	73%					
obese (≥30.0)		AF elimination				72	105	69%	-9.1% to 19.1%	0.49 (obese vs. lean)			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Cha 2008 US 18474813	PVI or WACA		≥50%, 7/523 (1.3%)	12/523 (2.3%)	4/523 (0.8%)				hemi-diaphragm paralysis	4/523 (0.8%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Cha 2008 US 18474813	n	NA	n	y	n	n	y	y	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		n	n	n	n	n				
Explanation for Overall Quality Grade:		retrospective; unclear if outcome included redos								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Cheema Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Cheema 2006 USA 17019636				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Cheema, 2006 USA 17019636	• PV-based ablation (segmental or circumferential) • Minimum follow-up 12 mo	nd	nd	At least 2 mo. Only patients free from recurrent AF discontinued AADs thereafter.	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Cheema, 2006 USA 17019636	nd	PV-based ablation (segmental or circumferential)	200	46	56	66	6.4	nd	4.4	59	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Cheema, 2006 USA 17019636	Yes (segmental, n=87)	Nd [verified by circular mapping catheter]	Cavo-tricuspid isthmus line	No	Irrigated 4 mm (Chilli RPM)	35	39	nd
	No (circumferential, n=113)	NA	WACA Cavo-tricuspid isthmus line Mitral isthmus line Posterior LA line Linear lesion in the LA ('figure-of-eight')*	No	8 mm (Biosense Webster)	70	55	nd

*Only the first 42 patients. This addition was terminated because two patients developed PV stenosis.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	56	200	28%					
Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	14	200	7%					
Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (segmental or circumferential)	26	70	200	35%					
Cheema, 2006 USA 17019636	Re-procedure	Patients who failed single procedure, and underwent at least one repeat procedure**	PV-based ablation (segmental or circumferential)	26	64	200	32%					
Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	83	200	42%					
Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	23	200	12%					
Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	106	200	53%					

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

Only crude estimates presented.

**Most asymptomatic patients did not undergo a repeat procedure. Some patients underwent the procedure more than twice (n=35 but the total number of reprocedures was 64). Multivariate analyses by logistic regression model showed that only non-paroxysmal AF and type of ablation (segmental vs. circumferential) were the statistically significant independent factors to predict long-term treatment results (OR=2.83 (95% CI, 1.23-6.05; P<0.01) and 0.44 (95% CI, 0.21-1.07; P=0.03), respectively). Other covariates taken into account were age, gender, AF duration, LAD, LVEF, and structural heart disease.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	3 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Cheema, 2006 USA 17019636	QOL	Symptomatic burden (Darber scale*)	Scale	PV-based ablation (segmental or circumferential)	26	200?	24	9	15**	<0.01

Duplicate one row per outcome and per RFA intervention.
*Modification of the University of Toronto AF Severity Scale.
**Difference between before and after therapy in each subgroup in each therapy, not net difference between independent subgroups.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95 % CI	P btw	Result*	95% CI	P btw
Segmental, any AF	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental)	26	19	87	22%					
Segmental, any AF	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental)	26	9	87	10%					
Segmental, any AF	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of “long-term success” and “long-term improvement” (only single procedure)	PV-based ablation (segmental)	26	28	87	32%					
Segmental, paroxysmal only	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental)	26	17	50	34%					

Segmental, paroxysmal only	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental)	26	3	50	6%					
Segmental, paroxysmal only	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (segmental)	26	20	50	40%					
Segmental, non-paroxysmal	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental)	26	2	37	5%					
Segmental, non-paroxysmal	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental)	26	5	37	13%					
Segmental, non-paroxysmal	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (segmental)	26	7	37	19%					

Circumferential, any AF	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (circumferential)	26	37	113	32%					
Circumferential, any AF	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (circumferential)	26	5	113	4%					
Circumferential, any AF	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of “long-term success” and “long-term improvement” (only single procedure)	PV-based ablation (circumferential)	26	42	113	37%					
Circumferential, paroxysmal only	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (circumferential)	26	17	42	40%					
Circumferential, paroxysmal only	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (circumferential)	26	3	42	7%					

Circumferential, paroxysmal only	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (circumferential)	26	20	42	47%					
Circumferential, non-paroxymal	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (circumferential)	26	20	71	28%					
Circumferential, non-paroxymal	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (circumferential)	26	3	71	4%					
Circumferential, non-paroxymal	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (circumferential)	26	23	71	32%					
Paroxysmal only (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	34	92	37%					

Paroxysmal only (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	6	92	6%					
Paroxysmal only (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (segmental or circumferential)	26	40	92	43%					
Non-paroxysmal (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	22	108	20%					
Non-paroxysmal (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	8	108	7%					
Non-paroxysmal (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (only single procedure)	PV-based ablation (segmental or circumferential)	26	30	108	28%					

Paroxysmal only (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	46	92	50%					
Paroxysmal only (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	11	92	12%					
Paroxysmal only (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of “long-term success” and “long-term improvement” (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	57	92	62%					
Non-paroxysmal (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	37	108	34%					

Non-paroxysmal (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	12	108	11%					
Non-paroxysmal (segmental or circumferential)	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	49	108	45%					
Patients with early (<3 mo) recurrence	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	38	128	30%					
Patients with early (<3 mo) recurrence	Cheema, 2006 USA 17019636	Long-term improvement	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	8	128	6%					
Patients with early (<3 mo) recurrence	Cheema, 2006 USA 17019636	Long-term satisfactory clinical outcome	Combination of "long-term success" and "long-term improvement" (repeat procedures included)	PV-based ablation (segmental or circumferential)	26	46	128	36%					

Patients with early (<3 mo) recurrence	Cheema, 2006 USA 17019636	Long-term success	The absence of symptomatic AF during the 6 mo off AAD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	20	128	9%		<0.01 (Chi-squared)			
Patients without early (<3 mo) recurrence	Cheema, 2006 USA 17019636	Long-term success	>90% reduction of symptomatic AF during the 6 mo off ADD prior to last follow-up excluding 3-mo blanking period (only single procedure)	PV-based ablation (segmental or circumferential)	26	36	72	50%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
Crude estimates only.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Patients with long-term success	Cheema, 2006 USA 17019636	QOL	Symptomatic burden (Darber scale*)	Scale	PV-based ablation (segmental or circumferential)	26	83	24	0	24**	<0.01
Patients with long-term improvement	Cheema, 2006 USA 17019636	QOL	Symptomatic burden (Darber scale*)	Scale	PV-based ablation (segmental or circumferential)	26	23	24	2	24**	<0.01
Patients with failure	Cheema, 2006 USA 17019636	QOL	Symptomatic burden (Darber scale*)	Scale	PV-based ablation (segmental or circumferential)	26	94	24	18	6**	<0.01

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Modification of the University of Toronto AF Severity Scale.
** Difference between before and after therapy in each subgroup in each therapy, not net difference between independent subgroups.

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Cheema, 2006 USA 17019636	PV-based ablation (segmental or circumferential)	26	3/264 (1%)*	6/264 (2%)	3/264 (1%)	nd	21/264**	nd	• Transient heart block • Valve injury	1/264 (0.3%) 1/264 (0.3%)

Total 264 procedures in 200 patients were analyzed (35 patients reportedly underwent at least one repeat procedure). There was no statistically significant difference between different types of procedure (segmental vs. circumferential).
*Severe stenosis was defined as >70% narrowing of PV by MRI.
**Pseudoaneurysm in the groin or retroperitoneal bleeding requiring transfusion.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Cheema, 2006 USA 17019636	No	NA	NA	Yes	nd	nd	Yes?	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	No	NA				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Cheema, 2006 USA 17019636		Moderate	
Explanation for Applicability Grade:		Patients with short follow-up were excluded, possibly affecting patient spectrum.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Chen Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Chen, 2004 USA 15028358				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Chen, 2004 USA 15028358	Symptomatic AF; refractoriness to AAD; and no indication for open heart surgery.	nd	12/2000-01/2003		• Patients in the EF<40% group had more heart disease (ischemic, hypertensive, or idiopathic) and more advanced CHF (NYHA III+IV) than those in the EF≥40% group. • Twenty-three patients had undergone a prior cavotricuspid isthmus ablation for atrial flutter.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Chen, 2004 USA 15028358	nd	PVI (PV ostial)	377	51	55	78	5.2	100*	4.5	50	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Chen, 2004 USA 15028358	Yes	100% implied [To abolish all PV potentials measured by mapping catheter]	• Cavotricuspid isthmus line* • Ablation of non-PV foci** (No mitral lines)	No	4mm cooled-tip (Chilli, EP Technology)	nd	35	nd

*Thirty-five patients.
**Four patients in a second procedure (details unclear)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	No	**If yes, how long was it?**	NA

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
EF≥40%	Chen, 2004 USA 15028358	Freedom From AF	Any episode of AF identified through the Holter, loop recorder, or standard ECG regardless of duration or symptoms. Blanking period unclear.	PVI (PV ostial)	14	247	283	87%	nd	0.03 (log-rank)			
EF<40%						69	94	73%	nd				
EF≥40%	Chen, 2004 USA 15028358	Total cure off AAD	Unclear (second procedure was included)	PVI (PV ostial)	14	266	283	94%	Nd	0.2 (?)			
EF<40%						90	94	96%	nd				
EF≥40%	Chen, 2004 USA 15028358	Freedom from atrial flutter	Unclear	PVI (PV ostial)	14	279	283	99%	nd	Nd			
EF≥40%	Chen, 2004 USA 15028358	Second procedure	Unclear	PVI (PV ostial)	14	19	283	7%		0.05 (?)			
EF<40%						21	94	21%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
EF<40%	Chen, 2004 USA 15028358	Change in cardiac function	Improvement of LVEF before and 6 mo after procedure	%	PVI (PV ostial)	6	94	36	41	5	0.1
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of physical functioning before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	28.7	90.8	62.1	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of role limitation due to physical health before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	8.3	65.8	57.5	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of role limitation due to physical problem before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	22.2	62.2	40.0	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of energy and fatigue before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	25.2	61.2	36.0	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of emotional well-being before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	39.7	72.0	32.3	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of social functioning before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	44.2	93.2	49.0	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of pain before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	68.9	95.2	26.3	<0.05
EF<40%	Chen, 2004 USA 15028358	QOL	Improvement of general health before and 6 mo after procedure	Score	PVI (PV ostial)	6	43	48.5	76.9	28.4	<0.05
EF≥40%	Chen, 2004	QOL	Improvement of physical functioning before and 6	Score	PVI (PV ostial)	6	150	28.7	96.8	68.1	<0.05

	USA 15028358		mo after procedure								
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of role limitation due to physical health before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	8.3	70.8	62.5	<0.05
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of role limitation due to physical problem before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	22.2	65.2	43.0	<0.05
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of energy and fatigue before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	25.2	65.2	40.0	<0.05
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of emotional well-being before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	39.7	76.0	36.3	<0.05
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of social functioning before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	44.2	93.2	49.0	<0.05
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of pain before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	68.9	97.2	28.3	<0.05
EF≥40%	Chen, 2004 USA 15028358	QOL	Improvement of general health before and 6 mo after procedure	Score	PVI (PV ostial)	6	150	48.5	78.9	30.4	<0.05

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Chen, 2004 USA 15028358	PVI (PV ostial)	14	6/377 (2%)*	2/377 (1%)	5/377 (1%)	nd	nd	nd	Pulmonary edema	1/377 (0.3%)

*defined as >70 of narrowing by spiral CT

All reported complications rates were not statistically different in the two groups (with or without impaired LV function); thus combined results were presented here.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Chen, 2004 USA 15028358	No	NA	NA	nd	nd	nd	Yes?	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Chen, 2004 USA 15028358			Wide
Explanation for Applicability Grade:		Inclusion criteria and no exclusion sound like day-to-day clinical practice	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Chugh Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Chugh, 2005 USA 15840468				X	May overlap other cohort studies conducted in U. Michigan (e.g. Oral 2006)	TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Chugh, 2005 USA 15840468	nd	nd	nd	AAD and any rate-control medications were discontinued at 3 mo after procedure if patients were free from symptomatic AF*	

*58 out of 349 (17%) did not take any AAD after the procedure.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Chugh, 2005 USA 15840468	nd	LACA + additional lines	349	65	54	79	6	nd	4.2	55 or 50*	C	Wide

*Selected after recognition of the risk of esophageal perforation

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Chugh, 2005 USA 15840468	No*	NA	• WACA/LACA • Posterior line or roof line (LA)** • Mitral isthmus line (LA) • Cavo-tricuspid isthmus line*** • Ablation of foci of AT in the LA	Yes	8 mm (Navistar)	70	55	nd

* Voltage abatement (by >80% or <0.1mV by local electrogram) was the ablation endpoint; however, it is not clear whether PVI was confirmed or not. The presence of complete block across ablation lines was not assessed in systematic fashion.
**Selected after recognition of the risk of esophageal perforation
***Only patients with prior history of or inducible atrial flutter

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Chugh, 2005 USA 15840468	Freedom from AT	AT: a regular supraventricular rhythm with a cycle length ≥ 200 ms and a consistent atrial activation sequences	LACA + additional lines	12.7	264	349	76% (Kaplan-Meier)					
Chugh, 2005 USA 15840468	Re-procedure	Re-ablation procedure due to AT	LACA + additional lines	12.7	28	349	8% (?)					
Chugh, 2005 USA 15840468	Freedom from AF	No explicit definition of relapse. No explicit definition of blanking period.	LACA + additional lines	12.7	197	349	87% (Kaplan-Meier)					
Chugh, 2005 USA 15840468	Re-procedure	Re-ablation procedure due to symptomatic AF	LACA + additional lines	12.7	35	349	10% (?)					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No*		
Was a blanking period (time when AFib episodes were not recorded) used?	No	**If yes, how long was it?**	NA

*A device to monitor the recurrence was provided only to symptomatic patients.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Patients who developed AT during the first procedure	Chugh, 2005 USA 15840468	Freedom from AT	AT: a regular supraventricular rhythm with a cycle length ≥ 200 ms and a consistent atrial activation sequences	LACA + additional lines	12.7	32	71	45%					
Persistent or chronic AF	Chugh, 2005 USA 15840468	Freedom from AF	No explicit definition of relapse. No explicit definition of blanking period.	LACA + additional lines	12.7	91	122	75% (Kaplan-Meier)					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
In multivariate analyses (by the logistic regression) taking account of age, sex, LVEF, LA, AF category, AAD, RFA duration, and AT during the first procedure, only the presence of AT during the procedure was a statistically significant independent factor to predict recurrent AT (OR=10.7, 95% CI, 5.3-21.9, P<0.001). However, this was not a statistically significant factor to predict recurrent AF (P=0.1).

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

No adverse events reported except for a patient who died of unrelated cause at 2 mo after the procedure.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Chugh, 2005 USA 15840468	No	NA	NA	Yes ("No drop out")	nd	nd	Yes	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	nd	No (only symptomatic)	NA				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Chugh, 2005 USA 15840468			Wide
Explanation for Applicability Grade:		Included patients sound like from everyday clinical practice, inferring wide applicability	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Corrado Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Corrado 2008 US & Italy 18363688				X		EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Corrado 2008 US & Italy 18363688	>75 yo, symptomatic AF, drug refractory, ≥9 months followup	nd	2001-2006	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Corrado 2008 US & Italy 18363688	nd 1 author with industry grants		174	55%	77	63	7	nd	4.6	53	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Corrado 2008 US & Italy 18363688	Yes	Around PV antrum (lasso poles)	PVAI and SVC isolation	No	8 mm	30 W up to microbubbles	55	nd

See Verma 2004 (Corrado 2008 methods).pdf

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Corrado 2008 US & Italy 18363688	2nd ablation			20	20	174	11%					
	SR off AAD	after 1st ablation		20	127	174	73%					
		after 1st or 2nd ablation		20	143	174	82%					
	SR on/off AAD	after 1st or 2nd ablation		20	165	174	95%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	8 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Corrado 2008 US & Italy 18363688				0/194	1/194* (0.5%)	0/194	0/194		Hemothorax	1/194* (0.5%)

* in 174 patients

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Corrado 2008 US & Italy 18363688	No	NA	NA	Yes	NA	~Yes	Yes	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:				retrospective study						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Della Bella Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Della Bella 2005 Italy 15763523				x	learning curve; KQ 1, 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Della Bella 2005 Italy 15763523	symptomatic AF, failed ≥2 AADs		2001-2003	69%	evidence for learning curve

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Della Bella 2005 Italy 15763523	nd	PVI	234	78	56	78	6.2	nd	nd	nd	C	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Della Bella 2005 Italy 15763523	y	90% [elimination of PV muscle conduction distal to ablation site]	cavotricuspid isthmus ablation in 20/234 pts with atrial flutter	n	thermocouple-equipped (prior to 9/02)	25-30	50	nd
					irrigated tip (after 9/02)	25-30	43	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Della Bella 2005 Italy 15763523	success	sinus rhythm maintenance	PVI	6 mo			72%					
		sinus rhythm maintenance	PVI	12 mo			65%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal AF	Della Bella 2005 Italy 15763523	success	sinus rhythm maintenance	PVI	12 mo			68%					
persistent AF								54%		0.008			
isolated all 4 PVIs	Della Bella 2005 Italy 15763523		arrhythmia event free survival	PVI	12 mo			71%					
isolated <4 PVIs								37%		<0.001			
Last 100 ablations	Della Bella 2005 Italy 15763523	learning curve	mean procedure time; mean fluoroscopy time	PVI				210 ± 86 min; 46 ± 35 min					
First 100 ablations								300 ± 108 min; 64 ± 41 min					
	Della Bella 2005 Italy 15763523	Age, sex, structural heart disease, HTN, mitral valve disease were not predictive of long-term outcome on multivariate analysis.											
		No significant difference was observed in the arrhythmia recurrence rate between pts who had conventional tip versus those with irrigated tip ablation.											

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Della Bella 2005 Italy 15763523	PVI		2 symptomatic (required stent) and 1 asymptomatic high grade (70-90%), 3/234 (1.3%)	3/234 (1.3%)	1/234 (0.4%)				AV-fistula required surgery	4/234 (1.7%)
									venous thrombosis required prolonged anticoagulation	2/234 (0.9%)
									pericardial effusion	12/234 (5.1%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Della Bella 2005 Italy 15763523	n	NA	n	NA	n	n	y	y	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	n				
Explanation for Overall Quality Grade:				retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Della Bella 2005 Italy 15763523			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Della Bella 2005 Italy 15763523	evidence for a learning curve

Dixit 2006 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Dixit, 2006 US 16879626	X 2x2 factorial					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Dixit, 2006 US 16879626	Drug refractory AFib undergoing 1st ablation	Contraindication to RFA	Yes. Usually class IC or sotalol (6 wk minimum)	Arrhythmogenic PVs = veins documented to initiate AFib and or atrial premature complexes, by intracardiac catheters 11/2003-2/2005

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Dixit, 2006 US 16879626	Boston Scientific (unrestricted). Authors: Proctor Gamble, Biosense Warner, Boston Scientific	2x2 Factorial:		72%	57	73%	5.2 yr	nd	nd	nd	A (except C for multivariable analysis)	Moderate
		>PVI all										
		>PVI arrhythmogenic PV										
		* 8 mm (Navistar)	42									
		* Cooled tip (Chilli)	40									

Arrhythmogenic PVs only: n=37 (18 cool tip; 19 8-mm); All PVs: n=45 (22 cool tip; 23 9-mm)

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Dixit, 2006 US 16879626	Yes	Cool tip: 1144/118 PVs (97%) 8 mm: 134/135 PVs (99.3%) [Loss of PV potentials (entry block) and failure to capture LA during pacing (exit block)]	No	Yes (stimulation protocol)	8 mm	≤70	≤50°	nd
					Cooled	≤50	≤40°	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Dixit, 2006 US 16879626	Long-term control of AFib	Complete freedom and/or >90% reduction in AFib burden on or off previously ineffective AA drugs at 6 months	8 mm	6 mo	32	41*	1.52	0.56, 4.15	NS			
			Cooled		28	40						
	Complete freedom from AFib off AAD		8 mm	6 mo	25	41	1.56	0.65, 3.70	NS			
			Cooled		20	40						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
* Excluding patient who died from LA-esophageal fistula.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 month

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Dixit, 2006 US 16879626	Cooled tip		Significant (≥70%) 0/40*	0/40	TIA (complete recovery w/in 24°) 45 min p-RFA 1/40 (2.5%)	0/40	nd	0/40		
	8 mm		0/42*	0/42	0/42	LA-esophageal fistula at 2 wk -> death 1/42 (2%)	nd	1/42 (2%)		

*75/81 had spiral CT at 3 mo to evaluate.

OTHER:

Unadjusted OR for 6 mo Long term control (defined above):			**Unadjusted OR for Freedom from AF at 6 mo w/o AA drug**		
Male vs Female	1.20 (0.39, 3.65)	NS	2.00	NS	
Parox AF Y v N	**4.40 (1.52, 12.8)**	**P=.006**	**4.34 (1.53, 12.3)**		**.006**
HTN YvN	0.61 (0.23, 1.67)	NS	0.59	NS	
Sleep Apnea YvN	1.06 (.26, 2.13)	NS	1.73	NS	
Any Comorbidity YvN	0.75 (0.26, 2.13)	NS	0.68	NS	
Non PV triggers YvN	0.57 (0.21, 1.54)	NS	0.83	NS	

Adjusted OR for 6 mo Long term control (defined above): **Adjusted OR for Freedom from AF at 6 mo w/o AA drug**

Adjusted for all above factors (including catheter tip) and apparently also recurrence at 6 wk check. Not explicitly listed though.

Parox AF Y v N **"5 x more likely"** **P<.05** **nd (>1)** **P<.05**

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Dixit, 2006 US 16879626	Yes	nd	nd	Yes (0%)	Patient blinded	Yes (no dropout)	Yes	Yes	Yes (except for multivariable analysis)	A (except C for multivariable analysis)
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	Yes				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Dixit, 2006 US 16879626		Moderate	
Explanation for Applicability Grade:		N<100	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Dixit, 2006 US 16879626	Oddly, no explicit analysis of PVI of all PV vs only arrhythmogenic PVs.

Dixit 2008 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Dixit 2008 US 18242535	x					MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Dixit 2008 US 18242535	Drug-refractory AF undergoing their first ablation procedure	Any contraindication to undergoing AF ablation and/or inability to provide informed consent	July 2003 to February 2005	Upon completion of the procedure, patients were started on antiarrhythmic drugs (usually class IC agent or sotalol) and warfarin (Coumadin)	58% had comorbidities: hypertension, chronic pulmonary disease, diabetes, and sleep apnea

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Dixit 2008 US 18242535	private	2x2 factorial design: - isolate all versus arrhythmogenic PVs - cool tip vs. 4- (July, 2003 to Nov 2003) or 8-mm (Nov, 2003 to Feb 2005) tip catheter	105	73	57	72	5.2	nd	nd	nd	A	moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Dixit 2008 US 18242535	yes	100% [loss of PV potentials and failure to capture LA during pacing from all bipoles of the Lasso catheter]	Simulation protocol to elicit non-PV triggers, which also were targeted Non PV triggers consisted of APCs (23pts) and Typical atrial flutter (3pts)	yes	4 mm (used in 11% patients)	<=50	<=52	Isolated all veins: 50 +- 30 min Isolated arrhythmogenic veins: 40 +-23 min
					8 mm (used in 41% patients)	<=70	<=50	
					Chili (used in 48% patients)	<=50	<=40	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Dixit 2008 US 18242535	Long-term control of AF	Complete freedom and/or >=90% reduction in AF burden either off or on previously ineffective antiarrhythmic drug at 1 year after a single ablation procedure	Isolated all PVs	1 yr	38	51	OR=1.18	0.50, 2.83	0.7			
			Isolated arrhythmogenic PVs	1 yr	37	52						
Dixit 2008 US 18242535	Freedom from AF at 1 year off AAD	Secondary endpoint	Isolated all PVs	1 yr	30	51	OR=1.03	0.47, 2.27	0.9			
			Isolated arrhythmogenic PVs	1 yr	31	52						
Dixit 2008 US 18242535	Long-term control of AF	Complete freedom and/or >=90% reduction in AF burden either off or on previously ineffective antiarrhythmic drug at 1 year after a single ablation procedure	4 mm	1 yr	8	12	OR=1.03	0.30, 3.57	0.96			
			8 mm	1 yr	32	41	OR=1.18	0.47, 2.99	0.72			
			Chili	1 yr	35	50	Ref group					
Dixit 2008 US 18242535	Freedom from AF at 1 year off AAD	Secondary endpoint	4 mm	1 yr	8		OR=1.43	0.40, 5.11	0.6			
			8 mm	1 yr	27		OR=1.59	0.70, 3.59	0.3			
			Chili	1 yr	26		Ref group					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	6 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Male	**Dixit 2008 US 18242535**	**Long-term control of AF**	Complete freedom and/or >=90% reduction in AF burden either off or on previously ineffective antiarrhythmic drug at 1 year after a single ablation procedure	isolate all or arrhythmogenic PVs	1 yr	61	82	OR=1.45	0.52, 4.08	0.5			
Female					1 yr	14	21						
Paroxysmal AF	**Dixit 2008 US 18242535**	**Long-term control of AF**		isolate all or arrhythmogenic PVs	1 yr	59	75	OR=2.76	1.09, 7.01	0.032			
Not paroxysmal AF					1 yr	16	28						
Comorbidities	**Dixit 2008 US 18242535**	**Long-term control of AF**		isolate all or arrhythmogenic PVs	1 yr	41	58	OR=1.28	0.53, 3.11	0.6			
No comorbidities					1 yr	34	45						
Early AF recurrence (within 6 weeks)	**Dixit 2008 US 18242535**	**Long-term control of AF**		isolate all or arrhythmogenic PVs	1 yr	8	20	OR=0.14	0.05, 0.42	<.001			
no early AF recurrence					1 yr	65	79						
Male	**Dixit 2008 US 18242535**	**Freedom from AF at 1 year off AAD**	Secondary endpoint	isolate all or arrhythmogenic PVs	1 yr	50	82	OR=1.42	0.54, 3.73	0.5			
Female					1 yr	11	21						
Paroxysmal AF	**Dixit 2008 US 18242535**	**Freedom from AF at 1 year off AAD**		isolate all or arrhythmogenic PVs	1 yr	49	75	OR=2.53	1.04, 6.10	0.042			
Not paroxysmal AF					1 yr	12	28						
Comorbidities	**Dixit 2008**	**Freedom from AF**		isolate all or arrhythmogenic	1 yr	31	58	OR=1.38	0.56, 3.36	0.5			

No comorbidities	**US 18242535**	**at 1 year off AAD**		PVs	1 yr	30	45						
Early AF recurrence (within 6 weeks)	**Dixit 2008 US 18242535**	**Freedom from AF at 1 year off AAD**		isolate all or arrhythmogenic PVs	1 yr	2	20	OR=0.04	0.01, 0.20	<.001			
no early AF recurrence					1 yr	57	79						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Dixit 2008 US 18242535	Isolated all PVs (n=53)		0 (>=70% PV stenosis)	0	1 (2%)	1 (2%)		1 (2%)		
	Isolated arrhythmogenic PVs (n=52)		0	0	0	0		0		

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Dixit 2008 US 18242535	yes	nd	nd	Yes (2%)	Patients only	Yes	yes	Yes	yes	A
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	No				
Explanation for Overall Quality Grade:				As described above						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Dixit 2008 US 18242535		x	
Explanation for Applicability Grade:		Only 105 (42%) of 251 eligible subjects were randomized	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Dong Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Dong 2005 China 16117858		x			PVI vs. CPVA; KQ 1, 3	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Dong 2005 China 16117858	symptomatic AF, failed AAD			1 mo	first 50 cases of PVI or CPVA were excluded to exclude learning curve bias

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Dong 2005 China 16117858	nd	CPVA	68	68	56	76	6.6		3.77	67	C	moderate
		PVI	83	100	57	69	7.2		3.78	67		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Dong 2005 China 16117858	y	100% implied [electrical isolation of PVs assessed circular mapping catheter]	PVI group; CPVA group	n	PVI by "an ablation catheter" (Tip not specified)	nd	nd	nd
					irrigated tip (ThermoCool) in CPVA	nd	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Dong 2005 China 16117858	success	stable sinus rhythm without AADs	PVI	12.7 mo	50	83	60%					
			CPVA	7.2 mo	56	68	82%		<0.001			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Dong 2005 China 16117858										

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Dong 2005 China 16117858	n	NA	n	nd	n	n	y	n	n	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		n	n	n	y	n				
Explanation for Overall Quality Grade:				2 groups not entirely comparable (different AFs, different followup); no information on pts lost to followup as they were excluded						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Dong 2005 China 16117858		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Essebag Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Essebag, 2005 USA 16183686				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Essebag, 2005 USA 16183686	Any patients with AF who underwent PV isolation by RFA	nd		Nd. Patients with persistent/permanent AF or early relapse (<30 d) continued AADs.	• PV isolation was repeated in 6% of patients at a median of 5 moths (IQR, 2-7 moths) after the initial procedure. • Ablation for atrial flutter had been performed prior to PV isolation (initial procedure) in 20% of patients

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Essebag, 2005 USA 16183686	Canadian Institutes of Health Research (CIHR) and National Heart, Lung, and Blood Institute (NHLBI)	RFA (PV isolation)	102	59	53	74	nd	nd	4.5	56	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Essebag, 2005 USA 16183686	Yes	Nd (100% inferred) [entrance block (loss of PV potential) and exit block (failure to capture the LA by pacing (at 10 mA) 10–14 bipolar pairs of electrodes on a circumferential catheter positioned at the entrance of the PV)]	• LA: mitral isthmus line and/or posterior left line (in case AF/LA tachycardia was induced (n=21)) • RA: isthmus line (in case of a history of or inducible atrial flutter (52%))	Yes*	NaviStar (8 mm)	nd	52	nd

*Defined as induction of AF or left atrial tachycardia lasting > 10s by pacing at the RA and CS, and isoproterenol.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Essebag, 2005 USA 16183686	Freedom from AF	Asymptomatic and symptomatic atrial tachyarrhythmia consistent with AF lasting > 10 s beyond 30 days post-procedure period	RFA (PV isolation)	15**	nd	102	70% (at 6 mo) and 62% (at 12 mo)	nd	Nd			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**Median
Multivariate analyses by logistic regression identified non-inducibility (OR=4.3 (95% CI, 1.2-15.5 (P=0.027)), paroxysmal AF(OR=3.2 (95% CI, 1.1-10.0 (P=0.040)), and no valvular heart disease (OR=4.0 (95% CI, 1.0-16.2 (P=0.050)) as statistically significant factors to predict freedom from relapse at 6 mo, and non-inducibility (OR=3.8 (95% CI, 1.0-15.5 (P=0.047)), paroxysmal AF(OR=4.8 (95% CI, 1.4-16.3 (P=0.012)) at 12 mo. Non-inducibility, age, sex, hypertension, AF type, and valvular heart disease were taken into account a priori.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	30 days

*2-week transtelephonic event recorder and 24h Holter ECG at 1, 3, 6, and 12 months.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal	Essebag, 2005 USA 16183686	Freedom from AF	Asymptomatic and symptomatic atrial tachyarrhythmia consistent with AF lasting > 10 s beyond 30 days post-procedure period	PVI (ostial)	15*	nd	60	81% (at 6 mo) and 74% (at 12 mo)	nd	<0.001 (log-rank)			
Persistent or permanent							42	54% (at 6 mo) and 45% (at 12 mo)					
Paroxismal, non-inducible	Essebag, 2005 USA 16183686	Freedom from AF	Asymptomatic and symptomatic atrial tachyarrhythmia consistent with AF lasting > 10 s beyond 30 days post-procedure period	PVI (ostial)	15*	nd	34	88% (at 6mo) and 81% (at 12 mo)	nd	0.05 (log-rank)			
Paroxismal, inducible						nd	26	72% (at 6 mo) and 64% (at 12 mo)					
Persistent, non-inducible	Essebag, 2005 USA 16183686	Freedom from AF	Asymptomatic and symptomatic atrial tachyarrhythmia consistent with AF lasting > 10 s beyond 30 days post-procedure period	PVI (ostial)	15	nd	11	82% (at 6mo) and 65% (at 12 mo)	nd	0.30 (log-rank)			
Persistent, inducible						nd	22	45% (at 6 mo) and 41% (at 12 mo)					
PV isolation + additional lines	Essebag, 2005 USA 16183686	Freedom from AF	Asymptomatic and symptomatic atrial tachyarrhythmia consistent with AF lasting > 10 s beyond 30 days post-procedure period	PVI (ostial)	15*	Nd	15	57% (at 12 mo)	nd	0.52 (log-rank)			
PV isolation only						nd	87	50% (at 12 mo)					

Duplicate one row per outcome and per RFA intervention.

e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Median

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Essebag, 2005 USA 16183686	PVI (ostial)	15*	0/102	3/102 (3%)**	1/102 (1%)***	0/102	4/102 (4%)****	0/102	Nd	

*Median
**Two of them required drainage.
***TIA after 4h post-procedure.
****All the four patients required blood transfusion.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Essebag, 2005 USA 16183686	No	NA	NA	nd	nd	Nd/NA	Yes	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Nd**	Yes	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A
**Patients who underwent repeated procedure should be counted as event but not explicitly reported.

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Essebag, 2005 USA 16183686		Moderate	
Explanation for Applicability Grade:		Inclusion criteria seem broad, but the procedure was performed by a single operator.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Estner Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Estner 2006 Germany 16831837		x			PVI with or without NavX®; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Estner 2006 Germany 16831837	symptomatic AF, failed AADs		nd		non-concurrent comparison

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Estner 2006 Germany 16831837	nd	PVI	32	94	58	75	5.5		4.76	32.4	C	moderate
		PVI with NavX®	32	88	59	75	5.7		4.6	33.9		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Estner 2006 Germany 16831837	y	93.5% and 96.8% [dissociation of PV potentials from the left atrium]	group 1: PVI with conventional fluoroscopy group 2: PVI using NavX® - only catheter location and tracking was visualized, no 3D geometry was performed	n	4 mm irrigated (Celsius ThermoCool)	25-35	48	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Estner 2006 Germany 16831837	outcome 1	freedom from recurrence of symptomatic AF	PVI	10.0	27	31	87%					
			PVI with NavX®	9.5	28	31	90%		nd			
	outcome 2	sinus rhythm	PVI	10.0	21	31	68%					
			PVI with NavX®	9.5	23	31	74%		0.57			
	outcome 3	asymptomatic AF	PVI	10.0	6	31	19%					
			PVI with NavX®	9.5	5	31	16%		0.99			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	n		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Estner 2006 Germany 16831837	PVI									
	PVI with NavX®				1/32 (3.1%)					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Estner 2006 Germany 16831837	n	NA	NA	y	n	n	y (?)	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	y				
Explanation for Overall Quality Grade:		non-concurrent comparison, no statistical adjustment for potential confounders								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Estner 2006 Germany 16831837		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Fassini Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Fassini 2005 Italy 16302895	x				PVI vs. PVI + left mitral isthmus ablation; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Fassini 2005 Italy 1630289	drug refractory AF (amiodarone and IC)	nd	nd	6 mo (in those with permanent AF)	18% of patients had had previous ablations

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Fassini 2005 Italy 1630289	nd	PVI	92	67	55	80	nd	nd	4.26	56	B	moderate
		PVI + left mitral isthmus ablation	95									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Fassini 2005 Italy 1630289	y	100% [complete elimination of PV electrical activity]	Group 1: PVI Group 2: PVI +mitral isthmus line (bidirectional block in 72 (76%) + RFA in distal CS in 54 (75%)	n	irrigated tip	25-35	40	48 (PVI only group)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Fassini 2005 Italy 1630289	freedom from AF recurrence	maintenance of stable sinus rhythm after single procedure	PVI	12			53 ± 5%					
			PVI+MIL				71 ± 5%		0.01			
		continual use of AAD	PVI	12			56					
			PVI+MIL				50		NS			
		non-sustained AF	PVI	12	6	92						
			PVI+MIL		8	95			NS			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
paroxysmal AF	Fassini 2005 Italy 1630289	freedom from AF recurrence	maintenance of stable sinus rhythm	PVI	12			62 ± 6%					
				PVI+MIL				76 ± 6%		<0.05			
persistent AF	Fassini 2005 Italy 1630289	freedom from AF recurrence	maintenance of stable sinus rhythm	PVI				36 ± 9%					
				PVI+MIL				74 ± 9%		<0.01			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Fassini 2005 Italy 1630289	PVI	intra-procedural			TIA 1/92 (1.1%)					
	PVI+MIL	intra-procedural		1/95 (1%)						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Fassini 2005 Italy 1630289	y	nd	nd	nd	n	y	y	NA	n	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	n				
Explanation for Overall Quality Grade:		unclear how many patients completed followup at 12 mo; although ITT was performed; unclear what proportion of patients had permanent AF as they received 6 mo of AAD post treatment; this may have affected the findings								

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Fassini 2005 Italy 1630289		X	
Explanation for Applicability Grade:		relatively young population who failed at least 2 AAD (one must be amiodarone)	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
	unclear what proportion of patients had permanent AF as they received 6 mo of AAD post treatment; this may have affected the findings

Fiala Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Fiala 2008 Czech Rep 18684255				X	KQ2	EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Fiala 2008 Czech Rep 18684255	First ablation of persistent or paroxysmal AF	None	2002-2006	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Fiala 2008 Czech Rep 18684255	nd No disclosures	RFA	194	30	55	80	nd	nd	4.5	54	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Fiala 2008 Czech Rep 18684255	Yes	PV antrum encircling Endpoint was full elimination of all high frequency potentials within the encircled area validated by the ring catheter.	PLM (mitral) isthmus line Roof line LL-RL line PSM isthmus Septal line LAA septal line LA focal ablations (sites suspected or participating in the mechanism of organized AF or LAT) CS ablation (if LA tachycardia)	No	4 mm (NaviStar) or	50 W	56°	nd
					3.5 mm irrigated (NaviStar ThermoCool)	35 W	42°	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Unclear, not explicitly		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	3 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Long-lasting persistent AF (>6 mo)	Fiala 2008 Czech Rep 18684255	Repeat ablation		RFA	nd	43	100	43%					
Short-lasting persistent AF (<6 mo)						9	35	26%					
Paroxysmal						16	59	27%		nd			
Long-lasting persistent AF (>6 mo)	Fiala 2008 Czech Rep 18684255	Freedom of AF recurrence (after a single ablation, some on AAD)			31	50	100	50%					
Short-lasting persistent AF (<6 mo)					27	22	35	63%					
Paroxysmal					36	39	59	66%		nd			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
	nd									

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Fiala 2008 Czech Rep 18684255	No	NA	NA	Yes	NA	~Yes	Unclear	No	No (very unclear results data)	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Unclear	Unclear	Yes	No				
Explanation for Overall Quality Grade:				Unclear results data						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Forleo Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Forleo 2007 Italy 17636302		x		x	RFA in men vs. women; KQ 2, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Forleo 2007 Italy 17636302	symptomatic AF; failed AADs	age <18 or ≥75 y; any condition that would make survival unlikely for ≤1 y; previous RFA for AF	nd	1-3 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Forleo 2007 Italy 17636302	nd	PVI in men	150	61	57	100	3.9		4.06	57	C	moderate
		PVI in women	71	56	62	0	5		4.4	57.4		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Forleo 2007 Italy 17636302	y	99% [abolition of all PV potentials]	PVI + cavotricuspid isthmus ablation ± roof lines/mitral line	n	3.5 mm cooled tip	35	45	men – 34.5 women – 36.3

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Forleo 2007 Italy 17636302	success	free of arrhythmia (AF or left AT, ± AADs)	PVI in men	22.5 mo			82.7%					
			PVI in women				83.1%; HR 0.89	0.44-1.78	0.75			
	success	free of arrhythmia (AF or left AT, no AADs)	PVI in men	22.5 mo			74%					
			PVI in women				67.6%		NS			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Forleo 2007 Italy 17636302	QOL	change in SF-36 (physical)		PVI in men		nd	35.02	78.17		NS
				PVI in women		nd	33.03	82.19		
	QOL	change in SF-36 (mental)		PVI in men		nd	52.8	65.21		NS
				PVI in women		nd	51.07	68.73		

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Forleo 2007 Italy 17636302	PVI in men		1 moderate to severe (50%)	2/150 (1.3%)	2/150 strokes (after 16 mo, 25 mo); transient neurological events, 2/150 (1.3%);				mild pericardial effusion	4/150 (2.7%)
	PVI in women		1 moderate to severe (50%)	2/71 (2.8%)						1/71 (1.4%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Forleo 2007 Italy 17636302	n	NA	n	y	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	n	y				
Explanation for Overall Quality Grade:				no adjustment for potential confounders						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Forleo 2007 Italy 17636302		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Gerstenfeld Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Gerstenfeld 2006 US 16443531 2007 US 17081205				x		SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Gerstenfeld 2006 US 16443531	paroxysmal or persistent AF	nd	2001-2004	6 wk (paroxysmal AF) to 6 mo (persistent AF)	Data on ≤2 and >2 PV ablations have been merged into one cohort in this extraction.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Gerstenfeld 2006 US 16443531	nd	PVI	451	73	55	76	6.7		4.4	58	C	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Gerstenfeld 2006 US 16443531	y	[loss of high frequency signals and loss of atrial capture pacing]	PVs targeted for ablation if they initiated AF or provoked any atrial premature depolarizations; empiric 4-PV isolation in patients without identifiable triggers	n	4 mm, 8 mm, or cooled tip (Chilli – internal irrigation catheter)	nd	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Gerstenfeld 2006 US 16443531	AF Freedom after single procedure	no AF off AADs, a single isolated AF occurrence allowed	PVI	16.4 mo	284	450	63%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	nd		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	6 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Gerstenfeld 2006 US 16443531	PVI		3/449 (2 asymptomatic, 1 symptomatic required stent) (0.7%)		stroke or TIA, 4/449 (1 had persistent neurologic deficit) (0.9%)				pericardial effusion required drainage	6/449 (1.3%)
									jugular hematoma required intubation	1/449 (0.2%)
Gerstenfeld 2007 US 17081205	PVI	35	0.1% (symptomatic) 0.6% (>75% narrowing regardless of symptoms)	0.9%	0.5% (stroke) 0.2% (TIA)	1/1058 (0.1%)	0.8% (hematoma) 0.6% (pseudoaneurysm) 0.7% (AV fistula) 0.1% ()	2/1058 (0.2%) (1 from anaphylaxis after the procedure and 1 from AE fistula)	Cardiogenic shock	0.1%
									Radiation burn	0.1%
									Coronary air embolism	0.4%
									Anaphylaxis	1/1058 (0.1%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Gerstenfeld 2006 US 16443531	n	NA	n	y	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		n	y	y	n	y				
Explanation for Overall Quality Grade:				retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Gerstenfeld 2006 US 16443531			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Hachiya Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Hachiya 2007 Japan 17286569		x			Extensive Encircling PVI (EEPVI) with ATP vs. EEPVI without ATP (historical cohort); KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Hachiya 2007 Japan 17286569	paroxysmal or persistent AF	nd	2003-2005		non-concurrent comparison

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Hachiya 2007 Japan 17286569	nd	EEPVI+ATP	82	76	56	82	nd	nd	4.17	nd	C	Narrow
		EEPVI only	170	79	54	84	nd	nd	4.13	nd		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Hachiya 2007 Japan 17286569	y	58% (?) [elimination of PV potentials or lack of capture during pacing]	Inducibility: After successful EEPVI, provoke reconnection by ATP 30 mg during isoproterenol infusion. In those with reconnection, re-ablation followed by re-ATP.	y	8 mm	30-35	50	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Hachiya 2007 Japan 17286569	AF clinical recurrence	no AF and not on AAD	EEPVI+ATP	6 mo	60	82	73%					
			EEPVI only	6 mo	102	170	60%		0.04			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	n		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Hachiya 2007 Japan 17286569	EEPVI +ATP			1/82 (1.2%)						
	EEPVI only			nd						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Hachiya 2007 Japan 17286569	n	NA	NA		n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	y	y	n				
Explanation for Overall Quality Grade:				non-concurrent comparison, no adjustment for possible confounding factors						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Hachiya 2007 Japan 17286569	X		
Explanation for Applicability Grade:		details regarding study population not completely reported	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Haissaguerre Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Haissaguerre, 2004 France 15184286	X (not for our report purpose)				RCT of PVI vs. PVI+ mitral isthmus ablation (additional line)	MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Haissaguerre, 2004 France 15184286	Episodes of clinical AF persisting for ≥1 hour to minimize the chance of random termination of AF during ablation	None stated	nd	All antiarrhythmic drugs were stopped after ablation, except for patients with early recurrence of AF. These patients were offered further ablation during the index hospitalization or trial of antiarrhythmics for 1 month.	43% had structural heart disease

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Haissaguerre, 2004 France 15184286	Government and private	PVI: circumferential (Lasso) PVI plus cavotricuspid isthmus ablation PVI+MIA (mitral isthmus ablation): same as PVI group following additional left linear ablation between the left inferior PV (and contiguous root of the appendage) and the lateral mitral annulus	70	nd	53	74	5.1	nd	Parasternal: 4.3 Longitudinal 5.4 Transverse: 4.0	67	A; B for subgroup analysis	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Haissaguerre, 2004 France 15184286	yes	100% [total elimination or dissociation of the PV potentials]	PVI and CTI	Yes (inducibility was checked before ablation, after isolation of all PVs, and after MIA in those randomized to PVI+MIA group)**	4-mm Irrigated tip (Celsius ThermoCool, Biosense-Webster)	30 W (inside) and 40 W (outside the PV)	50	70*
			PVI+MIA + CTI (left linear ablation between the left inferior PV and contiguous root of the appendage and the lateral mitral annulus) (RF was also delivered in CS)			PVI: same as above MIA: 40 W; epicardially through the coronary sinus (when needed) with a power of 25 to 30 W	PVI: same as above MIA: 50	PVI: 70* MIA: 22

*all patients were lumped together when calculated the mean ablation time

**After PV isolation, sustained arrhythmia (AF persisted for ≥10 min) persisted or could be induced in 30 patient (30/70, 43%). After the additional left linear ablation, 8 patients (8/35, 23%) being inducible (AF in 5 left atrial flutter in 3).

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Haissaguerre, 2004 France 15184286	Arrhythmia free without the use of antiarrhythmics	Absence of arrhythmia (AF or flutter) beyond the 1st month without the use of antiarrhythmics	PVI	7	26	35			nd			
			PVI+MIA		29	35						

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes. Patients were hospitalized for 1 day at 1, 3, 6, and 12 months after the last procedure. Surface ECG and bipolar endocardial electrograms were continuously monitored and stored on a computer-based digital amplifier/recorder system.		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	Within 1 month after ablation

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up,mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Noninducibility of AF after ablation	Haissaguerre, 2004 France 15184286	Arrhythmia free without the use of antiarrhythmics	Absence of arrhythmia (AF or flutter) beyond the 1st month without the use of antiarrhythmics	PVI alone or PVI+MIA	7	40	46			0.03 (log-rank test)			
Inducibility of AF after ablation						15	24						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Haissaguerre, 2004 France 15184286	Yes (not for our report purpose)	nd	nd	0%	nd	yes (0% dropout)	yes	No (for subgroup analysis)	yes	A; B for subgroup analysis
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	no				
Explanation for Overall Quality Grade:				B for subgroup analysis because the analysis did not take into account patients received different procedures (PVI alone or PVI+MIA)						

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Haissaguerre, 2004 France 15184286		x	
Explanation for Applicability Grade:		Type of AF was not reported. N<100 per intervention	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Haissaguerre, 2004 France 15184286	15 patients with recurrent atrial arrhythmia, 4 had left atrial flutter and 11 had AF. 11 of these 15 patients underwent an additional procedure. The 3 previously noninducible patients showed PV recovery as compared with 4 of the 8 patients with persistent inducibility.

Hocini Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Hocini, 2005 France 16344401	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Hocini, 2005 France 16344401	Paroxysmal AFib	nd	Jan-Dec 2003	D/C “after ablation” if no “concurrent indications”	25/90 with structural heart disease

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Hocini, 2005 France 16344401	Govt and professional organizations (Lecture fees and advisory board for B-W etc.)	PVI alone	45	100	55	79	5.25 yr	nd	4.1	67%	C	Moderate
		PVI + roofline	45									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Hocini, 2005 France 16344401	Yes	100%	Wide circumferential Bidirectional cavotricuspid isthmus block	Yes	4 mm irrigated (Celsius ThermoCool)	30-35 W (L veins at their anterior aspect: 25 W)	50°	33
			Plus: LA roof joining superior PVs (with eval of complete linear block)					35

In the event of recurrent symptomatic or asymptomatic arrhythmia, patients were offered an additional ablation after a trial of drug therapy.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Hocini, 2005 France 16344401	Arrhythmia free	No atrial arrhythmia off AAD (symptomatic or asymptomatic)	PVI alone	15	31	45			.04			
			PVI+roofline	14	39	45						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Unclear	**If yes, how long was it?**	nd

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Hocini, 2005 France 16344401			1/90 at routine 12 mo CT (asymptomatic, 70%)	Pericardial tamponade 1/90*					R phrenic nerve injury 1/90**	

* During cavotricuspid isthmus ablation, at 38 W. Percutaneous drainage with no long term sequelae
** Complete recovery at 4 mo

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Hocini, 2005 France 16344401	Yes	nd	nd	Yes (0%)	nd	Yes (0%)	Yes	NA	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Unclear Redo's were done.	Yes	No				
Explanation for Overall Quality Grade:				Unclear about blanking. Unclear if outcome is after single procedure or includes repeats.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Hocini, 2005 France 16344401		Moderate	
Explanation for Applicability Grade:		Paroxysmal only	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Hsu 2004 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Hsu 2004 France 15575053		x	x			SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Hsu 2004 France 15575053	AF failed ≥2 AADs; ≥ NYHA class II with LVEF <45% CHF		2001-2004	none	58 pts matched for age, sex, and AF classification but without CHF were selected as controls

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Hsu 2004 France 15575053	governments	PVI ± LA linear lines	58 with CHF	9	56	88	6.7	100 (NYHA 2.3)	5.0	35	B	moderate
			58 with no CHG	9	56	88	6.6	0 (NYHA 1.3)	4.6	66		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Hsu 2004 France 15575053	y	[disappearance or dissociation of PV potentials]	PVI+/-LA linear ablations (roof line +/- mitral line) Linear ablation in "most" patients.	n	4 mm irrigated ThermoCool – external irrigation	25-30 (PVI); 40 (linear)	50	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Hsu 2004 France 15575053		sinus rhythm	PVI in pts with CHF (include repeat procedures), not on AADs	12 mo			69%					
			PVI in pts without CHF, not on AADs				71%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Hsu 2004 France 15575053	QOL	SF-36 - physical		PVI in CHF	12 mo				24 ± 21	<0.001
		SF-36 - mental		PVI in CHF	12 mo				21 ± 19	<0.001
	QOL	SF-36 - physical		PVI, no CHF	12 mo				18 ± 17	0.003
		SF-36 - mental		PVI, no CHF	12 mo				14 ± 19	0.004
	NYHA class ↓ (improvement)			PVI in CHF	12 mo		2.3	1.4		<0.001
				PVI, no CHF						NS
	LVEF increase			PVI in CHF	12 mo				21 ± 13	<0.001

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Hsu 2004 France 15575053	PVI in CHF			1/58 (1.7%)	1/58 (1.7%)				death from worsening CHF (with CHD) at 3 mo (AF recurred at 1 mo)	1/58 (1.7%)
	PVI no CHF			1/58 (1.7%)						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Hsu 2004 France 15575053	n	NA	n	y	n	n	y	?	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Hsu 2004 France 15575053	y	n	y	n				
Explanation for Overall Quality Grade:				cohort						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Hsu 2004 France 15575053		x	
Explanation for Applicability Grade:		applicable to pts with permanent AF with CHF	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Hsu 2005A Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Hsu 2005 (A) France 15683473				x	only cardiac tamponade events from retrospective cohort were extracted; KQ4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Hsu 2005 France 15683473	AF ablation procedures including initial and repeat		2002		

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Hsu 2005 France 15683473	y	90% [bidirectional mitral isthmus conduction block]	PVI + individualized LA ablation (mitral line, roof line or both) ± cavotricuspid isthmus (CTI) ablation		4 mm irrigated (Celsius)	PVI: 25-30	50	
						LA linear: 40-60		
						CTI: 45-50		

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Hsu 2005 France 15683473	PVI + individualized LA ablation + cavotricuspid isthmus (CTI) ablation			10/348 LA linear ablation procedures (2.9%)						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
		Was RFA Procedure Adequately Described?	Were the Recurrence Outcomes Fully Defined?	Was Success Rate After a Single Procedure (not including redo) Reported?	Was Asymptomatic AFib Screened For?	Was Compliance with Screening Reported?				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Hsu 2005B Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Hsu 2005 (B) France 15683473			x		only cardiac tamponade events from retrospective cohort were extracted	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Hsu 2005 France 15683473	AF ablation procedures including initial and repeat		2003		

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Hsu 2005 France 15683473	y	92% [bidirectional mitral isthmus conduction block]	PVI + individualized LA ablation (mitral line, roof line, or both) ± cavotricuspid isthmus (CTI) ablation		4 mm irrigated (Celsius)	PVI: 25-30	50	
						LA linear: ≤42		
						CTI: 45-50		

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Hsu 2005 France 15683473	procedural success											

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Hsu 2005 France 15683473	PVI + individualized LA ablation + cavotricuspid isthmus (CTI) ablation			4/398 LA linear ablation procedures (1.0%)						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Jais 2004 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Jais 2004 France 15520313		x				EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Jais 2004 France 15520313	Symptomatic, drug refractory paroxysmal AFib	LA thrombi	4-12/2001 (PVI and CTA) 4-12/2002 (PVI and CT+MIA)	nd (use implied)	Structural heart disease 24%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	
Jais 2004 France 15520313	nd	PV isolation Cavotricuspid ablation Mitral isthmus ablation	100	100	55	87	6	nd	4.6	71	C	
		PV isolation Cavotricuspid ablation	100									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Jais 2004 France 15520313	Yes	Endpoint: Isolation of all PVs was systematically performed.	WACA Cavotricuspid isthmus ablation Mitral isthmus ablation (endocardial and epicardial within CS)	No	4 mm irrigated (Celsius ThermoCool)	PV: 20-30 CTI: 50 MIA: 40-60 (42*)	50°	65
			WACA (PVI) CTIA					nd

* Initially 40-60. Reduced for safety reasons. See AE results.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Jais 2004 France 15520313	Recurrence of atrial arrhythmia	Not clearly defined	PV isolation Cavotricuspid ablation Mitral isthmus ablation	12 mo (implied)	32	100			.02			
			PV isolation Cavotricuspid ablation		49	100						
	Arrhythmia-free w/o AAD (including post-2nd or more procedure)		PV isolation Cavotricuspid ablation Mitral isthmus ablation	12 mo	87	100			.002			
			PV isolation Cavotricuspid ablation		69	100						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Screening done, but unclear if outcome includes ASx Afib		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
In patients with recurrent arrhythmia (unclear if mitral isthmus cohort alone or both cohorts), 36% had structural heart disease compared to 20% of those without recurrent arrhythmia (P=.02)
Multivariate analysis:
Only mitral isthmus ablation was associated with success without drugs: RR (AFib recurrence) 0.2 (0.1-0.4) P<.001

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Jais 2004 France 15520313	PV isolation Cavotricuspid ablation Mitral isthmus ablation	12 mo	0/136 (100+36 redo)	4/100*					Thromboembolic	0/136
									Coronary artery	0/136
	PV isolation Cavotricuspid ablation	nd								

***** 1 during CT isthmus ablation at 48 W
2 during endocardial RF delivery at the mitral isthmus at >50 W => In the last 25 patients power limited to 42 W.
1 attributed to catheter manipulation in the LA during mitral isthmus ablation

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Jais 2004 France 15520313	No	NA	NA	0%	No	NA	Yes	Unclear (multivariate analysis performed)	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes (partly)	Yes, but unclear how used	No				
Explanation for Overall Quality Grade:				Incomplete reporting of comparator cohort Structural heart disease analysis: unclear who analyzed Unclear if recurrence included asymptomatic AFib ND blanking period						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Jais 2004 France 15520313			
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Jais 2004 France 15520313	

Jais 2008 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Jais 2008 France, US, & Canada 19029470	y					TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Jais 2008 France, US, & Canada 19029470	>18 y Symptomatic paroxysmal AF >/=6 mon	• Contraindication to >2 AADs in different classes • Contraindication to oral anticoagulants • Contraindication to the discontinuation of oral anticoagulation • Intracardiac thrombus • AF from a potentially reversible cause • pregnancy	nd	none	• Up to 3 attempts to achieve freedom from arrhythmia (i.e., up to 2 repeat ablations) for RFA arm (n=23, 43%) and up to 4 attempts (i.e., up to 3 attempts for the modification of pharmacologic therapy such as altering drugs) for medical arm were allowed until 90 days from randomization (treatment stabilization period). • At the time of treatment failure during the follow-up period, crossover to the alternative therapy was allowed.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Jais 2008 France, US, & Canada 19029470	Biosense Webster, St. Jude Medical, Bard, Medtronic, Biotronik, Canada Research Chair in Electrophysiology and Adult Congenital Heart Disease, Canadian Institute of Health Research, Fonds de Recherche enSante, Boston Scientific, CryoCath Technologies	RFA (cPVI)	53	100	51	84	5.5 (median)	nd	4.0	64	B	Moderate
		Medical	59									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Jais 2008 France, US, & Canada 19029470	y	100% (LPVs), 98% (RSPV), 94% (RIPV) [nd]	Roof (17%) and Mitral isthmus lines(30%) (LA) Cavo-Tricuspid Isthmus line (64%) (RA) Targeted Foci (23%) (non-venous structure)	n	3.5- or 5-mm irrigated tip	Up to 35 W	Up to 50 Celsius	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Jais 2008 France, US, & Canada 19029470	Freedom from recurrent AF	Relapse of AF (at least 3 min by ECG or patients' report) beyond day 90 until 12 mon	RFA (cPVI)	12	46	52	89% (KM)	-	<0.0001 (log-rank)			
			Medical		13	55	23% (KM)	-				
Jais 2008 France, US, & Canada 19029470	Discontinuation of anticoagulation therapy	Discontinuation of anticoagulation therapy at 12 mon, (ITT analysis)	RFA (cPVI)	12	31	52	60%	-	0.02 (Fisher)			
			Medical		18	53	34%	-				

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
Patients in RFA arm received a mean of 1.8 procedures (median 2, range 1-3), those in medical arm received a mean of 2.5 drugs.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Y (some no)		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	90 days

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Jais 2008 France, US, & Canada 19029470	LAD	LAD at 12 mon (ITT analysis)	Cm	RFA (cPVI)	12	53	4.0	3.9	Nd	0.92 (at 12 mon only)
				Medical		59	4.0	3.9		
Jais 2008 France, US, & Canada 19029470	LVED	LVED at 12 mon (ITT analysis)	Cm	RFA (cPVI)	12	53	5.2	5.0	Nd	0.35 (at 12 mon only)
				Medical		59	5.1	5.1		
Jais 2008 France, US, & Canada	LVEF	LVEF at 12 mon (ITT analysis)	%	RFA (cPVI)	12	53	63	65	nd	0.99 (at 12 mon only)
				Medical		59	66	65		
Jais 2008 France, US, & Canada 19029470	QOL	SF36 physical component summary (ITT analysis)	Score	RFA (cPVI)	12	53	44.8	52.0	7.2	0.01 (at 12 mon only) 0.015 (net diff (GLM))
				Medical		59	43.0	48.9	6.0	
Jais 2008 France, US, & Canada 19029470	QOL	SF36 mental component summary (ITT analysis)	score	RFA (cPVI)	12	53	46.1	56.6	9.7	0.01 (at 12 mon only) 0.09 (net diff (GLM))
				Medical		59	44.0	51.9	9.1	

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Jais 2008 France, US, & Canada 19029470	RFA (cPVI)	12	1/155 (0.6%)stent	2/155 (1%)	0/155 (0/53)	0/155	0/155	0/155		
	Medical	12			0/59					

Unit of analysis was "procedure', not patient (n=53)
2 hypothyroidism and 2 death (not related with treatment) in ADD arm

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Jais 2008 France, US, & Canada 19029470	y	nd	nd	y	nd	y	y	n	n	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	N				
Explanation for Overall Quality Grade:				Poor reporting➔unclear methodology. Why 1 patient in RFA arm not evaluated? (discrepancy) outcome assessment after repeat procedure (43%)						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Jais 2008 France, US, & Canada 19029470		Moderate	
Explanation for Applicability Grade:		Only symptomatic paroxysmal AF	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Jais 2008 France, US, & Canada 19029470	Multiple repeat ablation was allowed during stabilization period ➔ may have resulted in better FFS in AF compared to other RCTs Would it be OK to include this study into meta-analyze this?

Kanj Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kanj, 2007 USA and Italy 17433955	X				Circumferential PV and additional lines ablation, comparison among three different catheter-tip-related strategies	TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kanj, 2007 USA and Italy 17433955	18-80 y Symptomatic AFib Failed at least one anti-arrhythmic	Previous PVI Previous esophageal or swallowing disorders	nd	2 mo (sotalol and dofetilide)	PVAI (pulmonary vein antrum isolation (ablation outside of PV ostia as WACA/LACA with PVI as endpoint)) was performed.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kanj, 2007 USA and Italy 17433955	nd	PVAI, 8 mm	59	nd	60	81	6	nd	4.2	54	B	Moderate
		PVAI, Irrigation 30-50 W	61									
		PVAI, Irrigation 10-35 W	60									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Kanj, 2007 USA and Italy 17433955	Yes	100 [No PV potentials along the antrum or inside the PV (Biosense LASSO), and dissociation of the PV from the LA]	RA-SVC junction ablation if no phrenic nerve capture during high-output pacing	No	8 mm conventional (Celsius)	30-70	55	nd
					3.5 mm Open irrigation (Thermo-Cool)	30-50	45	nd
						10-35	45	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Kanj, 2007 USA and Italy 17433955	Freedom from atrial arrhythmia	Any atrial arrhythmias by event recorder or implanted device after the discontinuation of AADs (2 mo period from the procedure) until 6 mos	PVAI, 8 mm	6	46	59	79%	nd	0.043 (Chi-squared)	nd	nd	nd
			PVAI, Irrigation 30-50 W		50	61	82%					
			PVAI, Irrigation 10-35 W		41	60	68%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	2 mo**

* Event record monitoring for at least 6 mo
** Patients with recurrent AFib during the 2 mo period were cardioverted

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kanj, 2007 USA and Italy 17433955	PVAI+ RA-SVC junction, 8 mm	0/59	0/59	TIA, 1/59 (2%)	Perforation, 0/59 Odynophagia or dysphagia, 3/59 (5%)	0/59	0/59	nd	nd
	PVAI+ RA-SVC junction, Irrigation 30-50 W	0/61	2/61 (3%)	0/61	Perforation, 0/60 Odynophagia or dysphagia, 11/61 (18%)	0/61	0/61	Pulmonary edema	2/61 (3%)
	PVAI+ RA-SVC junction, Irrigation 10-35 W	0/60	0/60	0/60	Perforation, 0/60 Odynophagia or dysphagia, 2/60 (3%)	0/60	0/60	nd	nd

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kanj, 2007 USA and Italy 17433955	Yes	Yes	nd	0%	nd	Yes/ nd	Yes	nd	No	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	nd**	Yes***	No*				
Explanation for Overall Quality Grade:				Some important methodological components of RCT are not reported/adopted.						

*observational study cannot be an A, retrospective study is always a C
** No report of re-procedure infers "yes"
*** Event record monitoring for at least 6 mo.
**** Descriptions in the Method section infers 100% compliance.
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Kanj, 2007 USA and Italy 17433955		X	
Explanation for Applicability Grade:		Inclusion criteria of patient are somewhat vague (refractory to only class I/III vs. digitalis, beta-blocker, or calcium-blocker also included?).	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Kanj, 2007 USA and Italy 17433955	• Few descriptions on how they implemented the RCT and analyzed the data. • The defined end point is “soft” but clearly defined (compliance not reported, though). • No dropouts until 6 mo should be intention-to-treatment analysis and non-time-to-event type analysis should be fine. • Minor discrepancy (typo): Freedom from any arrhythmia of 78% in text but 79% in Figure 2 • Unclear definition about “symptomatic AF” in inclusion criteria • All patients developing new odynophagia or dysphagia underwent chest CT, and upper GI endoscopy if the scan was normal.

Karch Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Karch 2005 Germany 15927974	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Karch 2005 Germany 15927974	Drug refractory AFib ≥2x/mo	Intracardiac thrombi, EF<35%, recent MI or cardiac surgery, previous ablation	Mar 2002-Dec 2003	No	A reablation procedure, with the use of the same technique as the first ablation, was offered to the patient in case of a symptomatic atrial fibrillation recurrence beyond the third month after the ablation procedure. Structural heart disease 57%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Karch 2005 Germany 15927974	Govt etc.	Circumferential RFA	50	89	60	64	4.5	nd	4.7	63%	B	
		Segmental RFA	50									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Karch 2005 Germany 15927974	Yes	Complete isolation not a target of procedure	WACA Line: L lower PV to MV annulus (mitral line)	No	8 mm (Navistar), 40 patients	max 50-70	55°	72
					and/or cooled 4 mm (Navistar thermocouple), 22 patients (ThermoCool – external irrigation)	max 35-50	48°	
		Goal: effective electric isolation	Segmental		Irrigated (Celsius, Thermo-Cool) external irrigation	max 30-35	48°	52

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Karch 2005 Germany 15927974	Freedom from atrial tachyarrhythmia (including pts w/2nd procedure)	>30 sec on 7 day Holter at 6 mo	Circumferential	6 mo	21	50			.02			
			Segmental		33	50						
	Freedom from atrial tachyarrhythmia (excluding pts w/2nd procedure)	(Success post 1 procedure)	Circumferential	6 mo	17	50						
			Segmental		27	50						
	Free of arrhythmia symptoms during 1-6 mo period		Circumferential	6 mo	27	50			<.01			
			Segmental		41	50						
	Reablation procedure	due to symptoms	Circumferential	3-6 mo	12	50			NS			
			Segmental		8	50						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Karch 2005 Germany 15927974	Circumferential		(>50%, Asymptomatic) 3/50 (6%) (3 PVs)	0/50	TIA 2/50 CVA 1/50				Pericardial effusion (mild, 3-8 mm)	22/50
	Segmental		6/50 (12%) NS (7 PVs)	0/50 NS	TIA 1/50 CVA 0/50 NS				P<.01	5/50

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Karch 2005 Germany 15927974	Yes	Yes	Yes	Yes (0%)	Yes	Yes	Yes	NA	Yes	
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Katritsis Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Katritsis 2008 Greece 18363086		x		x	KQ2, 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Katritsis 2008 Greece 18363086	PAF, no reablation in 1 y	repeat ablation for AF recurrence, AFL, or focal tachycardia		amiodarone for 6 wk	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Katritsis 2008 Greece 18363086	nd	ostial or antral PVI or WACA	90	100	55	83	nd	nd	4.1	nd	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Katritsis 2008 Greece 18363086	y	100% (implied) Segmental ostial/antral : abolition /dissociation of distal PVs, entrance/exit block	WACA	n	4 mm (ostial or antral)	40	52	25.9
					irrigated 4 mm (WACA)	30	46	25.1

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Katritsis 2008 Greece 18363086	Freedom from AF	symptom improvement; no EKG or Holter evidence of AF	ostial or antral PVI	12 mo	25	41	61%					
			WACA		33	49	67%		0.5			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	6 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
ablation time < median	Katritsis 2008 Greece 18363086	Freedom from AF	symptom improvement; no EKG or Holter evidence of AF after 1 ablation (AAD?)	ostial or antral PVI or WACA	12 mo			49%					
ablation time ≥ median								80%		0.002			
Freedom from AF	Katritsis 2008 Greece 18363086	ablation time		ostial or antral PVI or WACA	12 mo			27.2 min					
AF recurrence								22.3 min		<0.001			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Katritsis 2008 Greece 18363086	ostial or antral PVI or WACA	12 mo	0/90	2/90 (2.2%)		0/90				

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Katritsis 2008 Greece 18363086	n	NA	NA	nd	y	n	y	y	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	n				
Explanation for Overall Quality Grade:		retrospective; small sample size; unclear if a proportion of pts were on AADs at time of follow up								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Katritsis 2008 Greece 18363086	Cox proportional hazard model showed that for one minute increase in radiofrequency energy delivery there was a 16% reduction in the risk for recurrence of AF (HR=0.84, 95% CI: 0.77–0.90, p<0.001). This inverse relationship between radiofrequency energy delivery time and recurrence of AF remained (HR: 0.80, 95% CI: 0.72–0.87, p<0.001), even after adjustment for potential confounders such as age, sex, cause of AF, left atrial size and type of ablation technique (ostial–antral or circumferential).

Kettering Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kettering 2008 Germany 18507536		X		X	KQ3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kettering 2008 Germany 18507536	symptomatic PAF; failed 1 attempt at AAD	valve disease or CAD req'd surgery; left atrial thrombus; hyperthyroidism; Cr ≥ 2.0 mg/dL; severe concomitant illness	consecutive patients, but Group A (2004-2006), Group B (2005-2007)	No AAD except for amiodarone	Compared to historical cohort; 2nd procedure for 5% of the patients; 12% of patients on amiodarone during followup

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kettering 2008 Germany 18507536	nd	Group A: segmental PVI Group B: segmental PVI excluding sites if there were areas in close proximity to esophagus	Group A: 21; Group B: 22	100%	Group A: 59; Group B: 65	Group A: 76; Group B: 55	nd	nd	nd	Group A: 60; Group B: 59	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Kettering 2008 Germany 18507536	y	Group A: 67%; Group B: 55% (either no or dissociated PV potentials)		n	3.5 mm irrigated tip	20-40	43	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Kettering 2008 Germany 18507536	Freedom from AF recurrence		segmental PVI	6 mo	17	21	81%					
			segmental PVI with exclusion of sites if there were areas adjacent to esophagus	6 mo	18	22	82%		1.0			
			16/22 (73%) patients in group B: ablation strategy was modified significantly due to close proximity of PV to esophagus.									

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
No modification of segmental PVI	Kettering 2008 Germany 18507536	Freedom from AF recurrence		No modification of segmental PVI	6 mo	23	27	85%					
Modification of segmental PVI due to close proximity of PV to esophagus				Modification of segmental PVI due to close proximity of PV to esophagus	6 mo	12	16	75%		0.69			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kettering 2008 Germany 18507536			significant (≥50%) - zero events in both groups; moderate (<50%?) – 3/43							

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kettering 2008 Germany 18507536	n	NA	NA	NA	nd	y	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	n	y	NA				
Explanation for Overall Quality Grade:				enrollment dates are different between the 2 groups; 2 groups may not be comparable						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Khaykin Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Khaykin 2004 US 15851113				X		EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Khaykin 2004 US 15851113	AFib	LV dysfunction alone (without valve disease or history of prior cardiac surgery)	12/2000 – 12/2002		50% structural heart disease 26% with MV or AV disease 10% prior cardiac surgery

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Khaykin 2004 US 15851113	nd	PV antrum isolation	391	48%	56	78%	~7	24% LV dysfunction (EF<40%)	nd	nd	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Khaykin 2004 US 15851113	Yes	The goal of PV antrum isolation was abolition of all PV potentials as measured by circular mapping catheter.	WACA No lines	No	Cooled tip (EP Technologies) (Chilli – internal irrigation)	nd	First 160: 35° Rest per microbubbles	9.5 per PV

RESULTS (dichotomized or categorical outcomes)*

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Khaykin 2004 US 15851113	AFib recurrence	Incl asymptomatic ≥10 sec on Holter	PVI	10-18 mo (per subgroup)	54	336						
	Controlled on AAD	(subset of AFib recurrence)	PVI	10-18 mo (per subgroup)	12	336						
	2nd PVI performed	(subset of AFib recurrence)	PVI	10-18 mo (per subgroup)	42	336						
	On AAD post 2nd procedure		PVI	10-18 mo (per subgroup)	2	42						

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

* Also results data, subgroup data, and complications data for subgroups who had PVI with "no-bubbles" technique (n=144) and "bubbles" technique (n=192).

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	No (not stated)	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Lone AFib without LV dysfunction	Khaykin 2004 US 15851113	AFib recurrence	Incl asymptomatic ≥10 sec on Holter	PVI	18	31	194						
Valve disease (±LV dysfunction)					11	17	102						
Prior cardiac surgery (±LV dysfunction)					10	6	40						
Lone AFib without LV dysfunction		Controlled on AAD	(subset of AFib recurrence)	PVI	18	4	194						
Valve disease (±LV dysfunction)					11	5	102						
Prior cardiac surgery (±LV dysfunction)					10	3	40						
Lone AFib without LV dysfunction		2nd PVI performed	(subset of AFib recurrence)	PVI	18	27	194						
Valve disease (±LV dysfunction)					11	12	102						
Prior cardiac surgery (±LV dysfunction)					10	3	40						
Lone AFib without LV dysfunction		On AAD post 2nd procedure			18	0	27						
Valve disease (±LV dysfunction)					11	2	12						
Prior cardiac surgery (±LV dysfunction)					10	0	3						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Khaykin 2004 US 15851113	PVI		3/336 (0.9%) [≥70%, regardless of symptoms]	4/336 (1.1%)	1/336 (0.3%) [TIA 1/336 (0.3%)]					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Khaykin 2004 US 15851113	No	NA	NA	Unclear (numbers don't add up)	No	No	Poorly reported	No (beyond subgroups)	No (unclear reporting)	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:				Retrospective, with problems.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Kilicaslan 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kilicaslan 2005 US 15734612		x		x	PVI in pts with previous cardiac surgery vs. without; KQ 2, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kilicaslan 2005 US 15734612	Pts who had PVI	hx of AFL ablation; concomitant AFL ablation + PVI; intracardiac thrombi	2000-2003	2 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kilicaslan 2005 US 15734612	nd	PVI in pts with previous cardiac surgery	63	54	57	81	6.9		4.7	49	C	moderate
		PVI in pts without previous cardiac surgery	1062	57	55	80	6.6		4.4	54		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Kilicaslan 2005 US 15734612	y	100% [PV potentials surrounding the antrum were abolished.]	SVC also isolated Atrial flutter RFA (?# of pts)	n	8 mm	ND (Marrouche 2003 did not report settings for 8 mm)	ND	ND

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Kilicaslan 2005 US 15734612	recurrence	recurrence of AF	PVI in pts with previous cardiac surgery	17	13	63	21%					
			PVI in pts without previous cardiac surgery	18.3	201	1062	19%		0.31			
		recurrence of AFL after 2 mo	PVI in pts with previous cardiac surgery		21	63	33%					
			PVI in pts without previous cardiac surgery		43	1062	4%		<0.0001			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	8 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kilicaslan 2005 US 15734612	PVI in pts with previous cardiac surgery									
	PVI in pts without previous cardiac surgery		moderate or severe, 4/1062 (0.4%)		7/1062 (0.7%)				pericardial effusion	2/1062 (0.2%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kilicaslan 2005 US 15734612	n	NA	nd	NA	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		n	n	n	y	NA				
Explanation for Overall Quality Grade:				2 groups not totally comparable at baseline: larger LAD, lower LVEF, higher incidence of AFL before PVI, in pts with previous history of cardiac surgery						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Kilicaslan 2005 US 15734612		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Kilicaslan 2006 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kilicaslan 2006 US 16684021		X			microbubble titrated PVI vs. standard power limited PVI; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kilicaslan 2006 US 16684021	symptomatic, drug-refractory AF	intracardiac thrombi or spontaneous echo contrast; preexisting neurological deficits			only adverse events extracted; no clinical outcomes >6 mo reported; non-concurrent comparison

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kilicaslan 2006 US 16684021	nd	microbubble guided RFA	107	50	58	86	7.7		4.3	55	not rated	
		power limited RFA	95	52	56	80	7.6		4.2	54		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Kilicaslan 2006 US 16684021	y	100% [all PV potentials surrounding the vein were abolished]	PVAI using ICE guidance; SVC was also isolated (microbubble guided in group 1; power limited in group 2)	n	8 mm	30-70	55	nd
						45-50	55	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kilicaslan 2006 US 16684021	microbubble guided RFA				1/107 (0.9%)					
	power limited RFA				3/95 (3.1%)					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kilicaslan 2006 US 16684021	n	NA	nd	NA	n	n	y	n	y	NR
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	n	n	NA				
Explanation for Overall Quality Grade:				non-concurrent comparison						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Kilicaslan 2006 US 16684021		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Kistler 2006 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kistler, 2006 UK 16989651			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kistler, 2006 UK 16989651	Patients who underwent first catheter ablation for AF. All patients had symptomatic documented AF and had failed >2 AAD.	None	December 2003 to September 2005	None	Structural heart disease 19%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kistler, 2006 UK 16989651	Government, private, and industry	Wide encirclement PVI → Left atrial circumferential ablation → linear ablation (roof line and/or mitral line) and/or targeting of fractionated electrograms → cavotricuspid isthmus ablation RFA was guided by either 3D mapping or 3D mapping (CARTO or NavX system) with CT integration (Cartomerge™)	94	49	56	80	6	nd	4.4	nd	B	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Kistler, 2006 UK 16989651	YES	Right PVs: 95% Left PVs: 96% [no PV potential was detected] PVs were continuously assessed for EI using the circular mapping catheter.	Left atrial circumferential ablation (LACA) to all patients. If LACA is not successful, then further ablation was performed at the venoatrial junction. If AF continued following PVI, a combination of the following was performed: (1) roof line, (2) mitral isthmus line, and (3) complex fractionated electrograms – left and right atria were mapped systematically for fractionated potentials which were then targeted for ablation. If AF still continued, a cavotricuspid isthmus ablation was performed in all patients requiring internal cardioversion and where typical atrial flutter had been previously documented. Paroxysmal AF (n=46): 50% had cavotricuspid isthmus ablation Persistent/permanent AF (n=48): 89.5% had additional ablation (a combination of linear ablation at the LA roof, mitral isthmus, and cavotricuspid isthmus)	no	3.5 mm irrigated tip	LACA: 30 CTI: 50	LACA: 50 CTI: 60	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (clinical outcome was assessed on 7 day Holter monitor at 6 month)		
Was a blanking period (time when AFib episodes were not recorded) used?	no	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
3D mapping	Kistler, 2006 UK 16989651	Sinus rhythm	Freedom from AT/AF off antiarrhythmic medication	Wide encirclement PVI → Left atrial circumferential ablation → linear ablation (roof line and/or mitral line) and/or targeting of fractionated electrograms → cavotricuspid isthmus ablation	6.25	28	47			<.05			
3D mapping with CT integration					6	39	47						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kistler, 2006 UK 16989651	Wide encirclement PVI → Left atrial circumferential ablation → linear ablation (roof line and/or mitral line) and/or targeting of fractionated electrograms → cavotricuspid isthmus ablation								Pericardial effusions	2/94 (2%)*
									Intraoperative transient ischemic attack	1/94 (1%)**

*Both in 3D mapping group
**in the CT group

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kistler, 2006 UK 16989651	no	NA	NA	0	nd	Yes (0% dropout)	yes	no	yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		no	yes	no	yes	No				
Explanation for Overall Quality Grade:				Non-RCT. total ablation time was not reported. Not sure if the two groups of patients were comparable although all reported characteristics did not statistically significantly different.						

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Kistler, 2006 UK 16989651			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Kistler, 2006 UK 16989651	This study aimed to compare 3D Mapping to CT integration. The ablation procedures were not exactly the same between the groups although there was no statistical significant difference between groups. Among patients with recurrences, repeat procedures were performed in 30 patients (18 in the 3D mapping group and 12 in the CT group, p=0.2) and not in 11 (controlled on medication in 7, asymptomatic in 3, and death during follow-up in 1)

Kistler 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kistler, 2007 UK 17916142			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kistler, 2007 UK 17916142	Consecutive patients who underwent their first catheter ablation for AF. All patients had symptomatic documented AF and had failed or been intolerant of >1 antiarrhythmic drug.	None	2005 to 2006	None	21% structural heart disease

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kistler, 2007 UK 17916142	Government and private	Left atrial circumferential ablation; additional progressive linear ablation (12%) and further cardioversion (26%)	101	62	56	71	5.7	nd	4.6	nd	(AE data only)	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Kistler, 2007 UK 17916142	YES	Right superior PV: 100% Right inferior PV: 98% Left superior PV: 100% Left inferior PV: 100% [no PV potential was detected] PVs were continuously assessed for EI using the circular mapping catheter.	Left atrial circumferential ablation (LACA) for all patients. For 38 patients who remained in AF following completion of PVI, further ablation was performed: 12 patients received progressive AF organization (roof line and coronary sinus line; ablation within the CS if CS disconnection was not achieved) and 26 patients received cardioversion (cavotricuspid isthmus ablation) due to AF continued following linear ablation and targeting of fractionated electrograms. LACA for all 38 pts: roof line, CS line, CS RFA, CFAEs 12 pts: AT RFA 26 pts: CV and CTI RFA 25 (of 63 pts) in PAF group (i.e. separate from the above persistent group): CTI RFA	no	3.5 mm irrigated tip	LACA: 30 Cardioversion: 50	LACA: 50 Cardioversion: 50	206

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kistler, 2007 UK 17916142	Left atrial circumferential ablation; additional progressive linear ablation (12%) and further cardioversion (26%)	nd							Pericardial effusions*	2/101

*one requiring pericardiocentesis and one transient ischemic attack

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kistler, 2007 UK 17916142	n	NA	NA	0%	nd	Yes (0% dropout)	NA	NA	yes	
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes								
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Kistler, 2007 UK 17916142	No long-term outcomes; adverse events only. A total of 5 operators and “there were no systematic differences in the approach to ablation between operators”.

Kistler 2008 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kistler 2008 UK 18931059	X				KQ3b	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Kistler 2008 UK 18931059	symptomatic AF; failed ≥2 AADs	previous AF ablation	2006	none	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Kistler 2008 UK 18931059	World Congress of Cardiology	WACA ± CT integration	80	59	56	nd	6.3	nd	nd	nd	B	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Kistler 2008 UK 18931059	y	94% (electrical disconnection assessed by circular mapping)	WACA (encircle L and R PV in pairs); if AF continued, then a combination of the following: a) roof line; CS line, CS ablation; or AT activation map b) target CFAE; c) internal conversion with CTI ablation; also CTI in AFL pts	n	3.5 mm irrigated (Navistar Thermocool, Biosense Webster)	30	50	N/A

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Kistler 2008 UK 18931059	Primary: freedom from AF or atrial tachycardia	no AF or atrial tachycardia >30 s after a 4 wk blanking period, no AAD, single procedure	WACA without CT integration	6 mo	22	39	56%		0.65			
			WACA with CT integration		19	38	50%					
	Secondary: recurrent AF or atrial tachycardia		WACA without CT integration	12 mo	20	39	51%		0.65			
			WACA with CT integration		22	38	58%					
	reablation		WACA without CT integration	12 mo	14	39	36%		0.64			
			WACA with CT integration		16	38	42%					
	Secondary: sinus rhythm, no AADs		WACA without CT integration	13.6 mo	30	39	77%		0.61			
			WACA with CT integration		27	38	71%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	4 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)
Kistler 2008 UK 18931059	WACA without CT integration		1/40 (2.5%)						
	WACA with CT integration			2/39 (5.1%)					death (unrelated) 1/39 (2.6%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Kistler 2008 UK 18931059	y	nd	nd	y	y	n	y	NA	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	y				
Explanation for Overall Quality Grade:				small number of subjects; no power calculation						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Kottkamp 2004 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Kottkamp 2004 15312874; Hindricks 2005 Germany 16009793			x			EB/SI/AG

Some results and data come from Kottkamp, 2004 15312874

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Hindricks 2005 Germany 16009793	AF >18 mo; failed ≥1 AAD; 3 documented AF episodes with symptoms	none reported	nd	Amiodarone or flecainide for 3 months	only compared to pts with documented AF in a continuous 7-day ECG monitoring before RFA; 9% of pts had prior RFA

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Hindricks 2005 Germany 16009793	Biosense Webster (unrestricted educational grant) Swiss National Research Foundation (1 author) [From Kottkamp 2004 810]	circumferential + lines	114	84	54	71	5 (median)		4.0	62	B (Hindricks data) C (Kottkamp data)	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Hindricks 2005 Germany 16009793	Not required	Not goal, implied Demonstrated in <20% [Pacing within the circles with CARTO] (from Kottkamp, n=100)	Circumferential lesions around the L and R PVs. Linear lesion connecting the circular lesions (roof line) Linear lesion connecting the Left circular lesion with the mitral annulus (L atrial isthmus) R isthmus ablation 9% who had atrial flutter	No	8 mm (Navistar)	60 W max	60° target	33 min

The endpoint of the procedure was the completion of the proposed circular and linear lesions.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Kottkamp, 2004 Germany 15312874	Repeat procedure	for documented symptomatic AFib recurrences	RFA	Done at mean 7 mo	22*	100						
	Secondary atrial flutter procedure	for stable gap-related LA flutter	RFA	nd	5 (additional to 22 AFib repeats)	100						
	Thromboembolic event			12	0	100						
	Freedom from AFib	on 7-day ECG†		6 mo	52% 53% on AAD	100?						
				12 mo	63%	100?						
	Use of Antiarrhythmic drug†	Flecainide or amiodarone		6 mo	53%	100?						
				12 mo	40%	100?						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
* 1 patient had a 3rd procedure.
"In 8 patients (8%) with documented typical atrial flutter, RA isthmus ablation was performed during follow-up."
† Also data from 24 hour ECGs (lower rates of AFib detected). And data from 3 months, prior to ablation, post ablation.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes (recurrence data is at specific timepoints, not cumulative)	**If yes, how long was it?**	Up to timepoint

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Hindricks 2005 Germany 16009793		asymptomatic AF			baseline**	92	5			0.021
					6 mo	54		20		
		asymptomatic AF			baseline	92	5			0.05
					12 mo	25		9		
		symptomatic AF			baseline	92	35			0.078
					6 mo	54		14		
		symptomatic AF			baseline	92	5			0.07
					12 mo	25		5		
		symptomatic + asymptomatic AF			baseline	52	92			0.001
					6 mo	54		20		
		symptomatic + asymptomatic AF			baseline	52	92			0.001
					12 mo	25		11		

** only compared to pts with documented AF in a continuous 7-day ECG monitoring before RFA

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
	Hindricks 2005 Germany 16009793	There were no significant differences in patients with different AF perception with respect to age, sex, LVEF, LAD, LA appendage flow velocity, and AF duration.											

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal	Kottkamp, 2004 Germany 15312874	Oral anticoagulation			3 mo	77	80? (implied)						
					6 mo	67	80?						
					12 mo	59	80?						
Persistent					3 mo	nd							
					6 mo	66%	20?						
					12 mo	66%	20?						
Paroxysmal		Freedom from AFib	on 7-day ECG†		6 mo	55% 49% on AAD	80?						
					12 mo	74% 42% on AAD	80?						
Persistent					6 mo	38% 67% on AAD	20?						
					12 mo	22% 33% on AAD	20?						
Paroxysmal		Use of AAD	†		6 mo	49%	80?						
					12 mo	42%	80?						
Persistent					6 mo	67%	20?						
					12 mo	33%	20?						

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Paroxysmal	Kottkamp, 2004 Germany 15312874	AFib episode lasting >24 hr	Paroxysmal AFib existed at time of measurement			12 mo		13/61	1/33		.02 (pre-post)

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Kottkamp, 2004 Germany 15312874	RFA	nd	0/100						Major Bleeding (12 mo)	0/100

No other procedure-related complications were observed.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Hindricks 2005 Germany 16009793	n	NA	NA	y	NA (blinded to symptoms)	n	y	y	Yes (Hindricks) No (Kottkamp)	B (Hindricks data) C (Kottkamp data)
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	y	Yes (Kottkamp)	y	y				
Explanation for Overall Quality Grade:				cohort study; in Kottkamps: Unclear denominators throughout. Only %ages reported.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Hindricks 2005 Germany 16009793		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Krittayaphong Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Krittayaphong, 2003 Thailand 12866763	X				Circumferential PV and additional lines ablation with transient concurrent antiarrhythmics vs. Only (continuous) antiarrhythmics	TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Krittayaphong, 2003 Thailand 12866763	• M or F, 15-75 y • Symptomatic (> 6 mo) paroxysmal or persistent AFib • Refractory to at least 1 of class IA/IC, digitalis, beta-blocker, or Ca-blocker • No prior amiodarone	• Transient AFib or treatable cause • Bleeding disorder • Thyroid disorder • Previous stroke • Other comorbidity with less than 1-year life expectancy • Psychiatric disorder • Valvular heart diseases • Unwilling to participate	nd	3 mo (amiodarone 200 mg qd without loading dose)	Amiodarone arm: Loading dose: • 1200 mg qd (1 wk) • 600 mg qd (2 wks) Maintenance dose: • 200 mg qd

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Krittayaphong, 2003 Thailand 12866763	Faculty of Medicine Siriraj Hospital	RFA (WACA)	15	67	52	63	56	nd	3.9	63	C	Narrow
		Amiodarone	15									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Krittayaphong, 2003 Thailand 12866763	No	NA*	LA: WACA + mitral line RA: Cavotricuspid isthmus line, SVC-IVC, and mid RA horizontal line	No	8 mm (Navistar)	nd	55	212

*Only the assessment of the completeness of these lines was performed.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Krittayaphong, 2003 Thailand 12866763	Freedom from AF	Probability of AF free at 1 year (AF not clearly defined)	RFA (WACA)	12	11	14	79%	nd	0.018 (Log-rank)	nd	nd	nd
			Amiodarone		6	15	40%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
Relapse rates at 1 year were numerically reported in the paper but Freedom from RF was also presented in a K-M graph.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	nd**	**If yes, how long was it?**	nd

*Regular ECG (at clinic?) and 24 h ECG at 1, 3, 6 mo
** No description on a blanking period; however, no relapse cases reported in the RFA arm of the Kaplan-Meier graph during the first three-month period.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Krittayaphong, 2003 Thailand 12866763	Quality of life	SF-36, general health score	Score	RFA (WACA)	12	14	46	66		0.048 (ANOVA)
				Amiodarone	12	15	41	43		
Krittayaphong, 2003 Thailand 12866763	Quality of life	SF-36, physical fitness score	Score	RFA (WACA)	12	14	63	86		0.691 (ANOVA)
				Amiodarone	12	15	71	68		

Duplicate one row per outcome and per RFA intervention.
*Bar graph presented but no numerical data available.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Krittayaphong, 2003 Thailand 12866763	RFA (WACA with anterior linear lesion and cavotricuspid line ablation)	0/14	0/14 (0)	Cerebral infarction, 1/14 (7%)	0/14	Minor groin hematoma, 1/14 (7%)	Nd	Amiodarone-related*	3/14 (21%)
	Amiodarone						nd	Amiodarone-related**	7/15 (47%)

*Three patients had at least one adverse event during the first 3-month "concurrent" therapy period. Reports include GI adverse events (n=2), sinus node dysfunction (n=1), dizziness (n=1), and presyncope (n=1), meaning that some same patients might have had multiple adverse events. Grade/severity not provided.
**Seven patients had at least one adverse event. Reports include GI adverse events (n=6), corneal microdeposit (n=2), hypothyroidism (n=2), abnormal LFT (n=2), hyperthyroidism (n=1), and sinus node dysfunction (n=1), meaning that some same patients might have had multiple adverse events. Grade/severity not provided.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Krittayaphong, 2003 Thailand 12866763	Yes	nd	nd	Yes (7%)	nd	No	Yes	nd	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	nd**	Nd***	Yes****	No*****				
Explanation for Overall Quality Grade:				Poor description of the conduct of RCT and no ITT analysis.						

*observational study cannot be an A, retrospective study is always a C
** Not defined but reported as freedom from Afib only.
*** not clearly defined, but no reports on re-procedure infers "yes"
**** Regular ECG (at clinic?) and 24 h ECG at 1, 3, 6 mo
***** Method section infers 100% compliance.

N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Krittayaphong, 2003 Thailand 12866763	X		
Explanation for Applicability Grade:		N<30	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Krittayaphong, 2003 Thailand 12866763	• Few/unclear descriptions on how they implemented the RCT and analyzed the data. • Unclear about post procedure blanking period. • No ITT analysis; they excluded a patient who failed the procedure of RFA from analysis • Probably no blinded outcome assessment of the "soft" outcome with relatively scanty (1, 3, 6, 12 mo) follow-up timings (survival curve infers this). • Only 15 per arm. • Also included class I/III antiarrhythmic naïve patients (only failures of digi, beta-blocker, or Ca-blocker), meaning some of them (number not presented) underwent RFA almost as first line therapy, which might have affected the results. • Cannot apply the results to those with valvular diseases. The same may be true in psychiatric population.

Lakkireddy Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Lakkireddy 2005 US 16360082		x	x		Patients with pacemaker or ICD vs. patients without; KQ 2, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Lakkireddy 2005 US 16360082	Symptomatic drug resistant AF	Left atrial clots	2000-2003	8 wk	In group 1: 81% pacemakers and 19% defibrillators

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Lakkireddy 2005 US 16360082	nd	RFA in pts with pacemaker or ICD	86	58	60	70	2.6		4.55	48.6	C	moderate
		RFA in pts without pacemaker or ICD	86	60	60	70	3.8		4.39	52.4		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Lakkireddy 2005 US 16360082	y		SVC also isolated in those with sharp high-frequency potentials without phrenic nerve pacing		8 mm or 4 mm cool-tip (Chilli internal irrigation)	50	50	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Lakkireddy 2005 US 16360082	success	Freedom from AF recurrence	RFA in pts with pacemaker or ICD	12 mo			81%					
			RFA in pts without pacemaker or ICD				79%		0.73			
	Weight in kg is the only significant independent predictor of cumulative recurrence (95%CI 1.013-1.055, P=0.002)											

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Lakkireddy 2005 US 16360082	RFA in pts with pacemaker or ICD		Significant (>70%), 2%		1%				Pulmonary edema	1%
									Symptomatic mode switch (pertains only to this group)	12/86 (14%)
									Asymptomatic mode switch	2/86 (2.3%)
	RFA in pts without pacemaker or ICD		Significant (>70%), 1%		1%				Pulmonary edema	0%

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Lakkireddy 2005 US 16360082	N	NA	NA	Nd	N	N	Y	N	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	N	Y	n				
Explanation for Overall Quality Grade:		Baseline characteristics not totally comparable, higher DM and CAD rates in pts with pacemakers or ICD; followup rate unclear								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Lemola Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Lemola 2006 US 16843185		x			CPVA vs. Electrogram guided ablation (EGA); KQ 3	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Lemola 2006 US 16843185	Paroxysmal or persistent AF		nd		CPVA pts overlaps with Oral 2003

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Lemola 2006 US 16843185	government	CPVA	42	57	57	83	7		4.4	58	C	moderate
		EGA	42	60	57	83	6		4.2	56		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Lemola 2006 US 16843185	n		AF induced by rapid atrial pacing at onset in 38 pts in NSR. CPVA (including mitral line and roof line) Electrogram guided ablation (EGA) – focal ablation at sites of complex electrograms (CFAEs); linear ablation not performed, end point was termination of AF and non-inducibility	Yes in EGA	8 mm			42 35

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Lemola 2006 US 16843185	success	Freedom from symptomatic or asymptomatic AF, not on AADs, after a single ablation	CPVA	9 mo	28	42	67%					
			EGA		30	42	71%		0.6			

Duplicate one row per outcome and per RFA intervention

* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	6 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Lemola 2006 US 16843185										

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Lemola 2006 US 16843185	n	NA	Nd	Y	N	N	Y	N	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Y	Y	Y	Y	y				
Explanation for Overall Quality Grade:				Unclear how patients were selected into the respective groups						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Lemola 2006 US 16843185		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Li Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Li 2008 China 18577822				x		EB/AG

PROBABLE OVERLAP WITH OTHER STUDIES FROM BEIJING ANZHEN HOSPITAL (319, 275, 458, 603, 528)

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Li 2008 China 18577822	Chronic AF			Amiodarone, propafenone, or sotalol for 2 months	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Li 2008 China 18577822	Gov't	RFA	92	0	59	76	5.6	nd	4.2	60	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Li 2008 China 18577822	Yes	Circumferential PV ablation (Goal – electrical isolation of all PVs)	CFAE targeting "critical isthmus" causing any Aflutter or macro-reentrant atrial tachycardia	No	nd	nd	nd	nd

RESULTS (dichotomized or categorical outcomes) No reporting of total # with recurrent AF, only among those with early recurrence

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Li 2008 China 18577822			0/92	0/92		0/92				

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
		Was RFA Procedure Adequately Described?	Were the Recurrence Outcomes Fully Defined?	Was Success Rate After a Single Procedure (not including redo) Reported?	Was Asymptomatic AFib Screened For?	Was Compliance with Screening Reported?				C
Explanation for Overall Quality Grade:		Poor, incomplete reporting throughout.								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Liu 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Liu, 2005 China 16336813			X			EB/AG

Almost definite partial overlap with separately extracted Tang 2006 275, Ma 2006 458, Dong 2005 603.

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Liu, 2005 China 16336813	Highly symptomatic AFib, multiple AAD, paroxysmal or persistent	none	9/2004-6/2005	Yes (1 mo)	39% had HTN and structural heart disease

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Liu, 2005 China 16336813	Government	Circumferential PV ablation	130	70%	58	73%	7.1 yr	nd	3.8 cm	67%	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Liu, 2005 China 16336813	Yes	100% [nd]	(They used the term CPVA…but is essentially equivalent to WACA except that PV isolation was explicitly specified as an endpoint)	No, from Methods (but they do mention induced AT in Results)	Irrigated 3.5 mm (ThermoCool)	35 W max	43° target	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Liu, 2005 China 16336813	Persistent recurrent atrial tachyarrhythmia	After 2 months, atrial tachycardia alone, AFib alone, or AT and AFib. Derived from convoluted reporting. Text data used (different from Table) 52=ATa w/in 2 mo 22=spontaneous resolution of ATa	CPVA	Unclear. Mean resolution occurred at about 3 mo	30 (52-22=30)	130						
	Repeat ablation			nd	21	130						
	Symptom free after 2nd ablation			6	116	130						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Initial yes. Post-2nd ablation no		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes (essentially)	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Liu, 2005 China 16336813	CPVA		1/130 (0.8%) (50% stenosis, asymptomatic)	1/130 (0.8%) (not defined, no long term sequelae)	1/130 (0.8%) (no long term sequelae)					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Liu, 2005 China 16336813	No	NA	NA	yes (0%)	nd	y	no (poor outcome chosen)	incomplete	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Incompletely	Yes, though not used throughout	No				
Explanation for Overall Quality Grade:		Results poorly reported. Text does not match Table data (23 vs 25, 14 vs 19)								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Liu 2006a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Liu 2006 China 17062959	X				stepwise PVI (SPVI) vs. CPVI; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Liu 2006 China 17062959	20-80 y; NYHA I or II; ≥9 mo followup; failed multiple AADs	LAD >55mm; LVEF <35%; prior AF ablation; contraindication to anticoagulation; presence of LA thrombus	nd	2 mo	included only patients with ≥9 mo followup; excluded initial 50 cases (to avoid learning curve bias); first time ablation

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Liu 2006 China 17062959	government	stepwise PVI	55	100%	58	66	5	nd	3.8	63.6	C	moderate
		circumferential PVI (CPVI)	55									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Liu 2006 China 17062959	y	100% [elimination or dissociation of PV potentials assessed by Lasso catheter]	SPVI + linear ablation along LA roof in persistent or inducible sustained AF; mitral annulus isthmus line ablation in those with inducible AF refractory to LA roof ablation (transthoracic cardioversion in those who failed); endpoint is non-inducibility of AF Def of inducibility: AF>10 min; linear lesions were also tested for block. CPVI; RF applied for 30 s at each site until the maximal local electrogram amplitude decreased by >70% or <0.1 mV; endpoint is continuity of the circular lesions and PVI verified by circumferential PV mapping	y	4 mm irrigated tip	30	43	63
				n	3.5 mm irrigated tip	~30	~43	59

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Liu 2006 China 17062959	successful clinical outcome	absence of atrial tachyarrhythmias relapse (defined as any symptomatic AT, regardless of duration; and any asymptomatic AT >10 min) without the use of AADs during the 3-9 mo after the last procedure	SPVI	9 mo	43	55	78%					
			CPVI		46	55	84%		0.63			
	repeat procedure		SPVI	3-5 mo of initial procedure	7	55	13%					
					5	55	9%		nd			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	3 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Liu 2006 China 17062959	SPVI		asymptomatic right superior PV stenosis, 1/55 (1.8%)						subcutaneous hematoma	3/55 (5.5%)
									requiring transfusion	1/55 (1.8%)
	CPVI		asymptomatic right superior PV stenosis, 1/55 (1.8%)						subcutaneous hematoma	4/55 (7.3%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Liu 2006 China 17062959	y	y	n	nd	n	n	y	NA	n	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	n				
Explanation for Overall Quality Grade:				unclear what the initial total enrollment was, since the first 50 was not counted and only those who completed 9 mo of followup since last procedure were included in the final sample						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Liu 2006 China 17062959		X	
Explanation for Applicability Grade:		n=55 in each arm	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Liu 2006b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Liu 2006 China 17239094	X				aggressive CPVA vs. modified CPVA (CPVA + segmental PV ostia ablation); KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Liu 2006 China 17239094	20-80 y; NYHA I or II; ≥6 mo followup; failed multiple AADs	LAD >55mm; LVEF <35%; prior AF ablation; contraindication to anticoagulation; presence of LA thrombus	2004-2005	3 mo	included only patients with residual PV conduction; with ≥6 mo followup; first time ablation

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Liu 2006 China 17239094	government	aggressive CPVA	50	75%	57	69	6.7	nd	3.9	64.5	B	moderate
		modified CPVA	50									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Liu 2006 China 17239094	y	96% [isolation confirmed by circumferential mapping] in a-CPVA and 100% in m-CPVA	In patients with residual PV conduction after initial CPVA, then 1. aggressive CPVA: supplementary ablations along the CPVA lines close to the earliest ipsilateral PV spikes; additional conduction gap considered if PV activation sequence changed after one gap was closed or 2. modified CPVA: sites with earliest activation in each PV perimeter were targeted during SR or CS pacing Also, in patients with AFL before or during the procedure, tricuspid annulus isthmus ablation was performed to achieve a bidirectional conduction block.	n	3.5 mm irrigated tip	35	43	58

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Liu 2006 China 17239094	successful outcome	absence of atrial tachyarrhythmias relapse (defined as any symptomatic AT, regardless of duration; and any asymptomatic AT >5 min) without the use of AADs beyond the first 3 mo after the initial procedure	a-CPVA	13 mo (?)	41	50	82%					
			m-CPVA		29	50	58%		0.01			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	3 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
	Liu 2006 China 17239094												
modified CPVA predicted late AT recurrence (RR 0.318; 95% CI 0.123-0.821; P=0.02)													

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Liu 2006 China 17239094	a-CPVA			1/50 (2%)					subcutaneous hematoma requiring transfusion	1/50 (2%)
	m-CPVA		asymptomatic single PV stenosis (>50% reduction in diameter) 2/50 (4%)		1/50 (2%)					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Liu 2006 China 17239094	y	y	n	nd	n	n	y	NA	n	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	?	y	n				
Explanation for Overall Quality Grade:				unclear if re-dos were counted in success rate						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Liu 2006 China 17062959		X	
Explanation for Applicability Grade:		n=50 in each arm	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Ma Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Ma, 2006 China 17199954			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Ma, 2006 China 17199954	Nonvalvular AF, age <80 years, function of heart (NYHA I-II0, refractory to >2 AAD, no severe structural heart disease; no history of stroke in the previous half year	Age<20, LA thrombus identified by transesophageal echocardiography, severe impairment of liver function or kidney function, be hyper susceptible to warfarin, thyroid disorder; other severe disease (such as malignant tumor)	Since September 2004	Oral amiodarone (in 26 patients, 25%) or propafenone (in 27 patients, 25%) was taken after ablation. Among them, 16 patients took oral amiodarone for >3 months (patients with chronic AF or those whose PVs had not been isolated completed).	16% persistent AF 15% permanent AF

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Ma, 2006 China 17199954	nd	Linear ablation of LA guided by both Carto and double lasso catheters	106	73.6	51.4	77	7.1	nd	nd	nd	B	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Ma, 2006 China 17199954	yes	88.7% [absence of all PV spikes detected by the 2 Lasso catheters within the ipsilateral PVs, or dissociation of PVPs (fibrillation in PVs, while sinus rhythm in atria) for >30 minutes]	"Circumferential lines of ablation" Regions in LA with fragmented potentials were also ablated in patients with persistent or permanent AF (31%). External cardioversion was performed if the patients still presented with atrial fibrillation after the complete isolation of PVs. Additionally, linear ablation of the cavotricuspid isthmus was performed until bidirectional block was acquired at the isthmus if the patient had previous history of atrial flutter.	no	3.5-mm irrigated tip (ThermoCool Navi-Star, Biosense Webster, USA)	30-40	43-45	25.4

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Ma, 2006 China 17199954	Success of ablation	No recurrence of atrial tachyarrhythmias according to the symptoms, ECG and Holter monitoring during the followup periods from the 4th month of post ablation procedure to current time	Linear ablation of LA guided by both Carto and double lasso catheters	11.5	62	87						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	yes		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	3 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Ma, 2006 China 17199954	Linear ablation of LA guided by both Carto and double lasso catheters		0	2/106 (1.9%)	0			0	Atrioesophageal fistula	0

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Ma, 2006 China 17199954	no	NA	NA	18%	nd	no	yes	no	no	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	No				
Explanation for Overall Quality Grade:		Incomplete reporting of patients characteristics. Descriptive analyses only.								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Ma, 2006 China 17199954			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Ma, 2006 China 17199954	Long-term clinical outcomes assessed in 87 (82%) patients who had follow-up >3 months. During followup, 9 patients underwent a second ablation procedure for the recurrence of atrial tachyarrhythmia and all of them had acquired PVPs isolation. After the 2nd ablation procedure, there have been (6.2+-3.7) months (1-14 months) during which no recurrence of atrial tachyarrhythmias has been observed.

Macle Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Macle, 2002 France 12475093				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Macle, 2002 France 12475093	Symptomatic drug-refractory AF	nd	nd	nd	37 patients had undergone cavo-tricuspid isthmus line previously

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Macle, 2002 France 12475093	nd	Ostial PVI + additional lines	136	90	52	80	7.0	nd	nd	nd	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Macle, 2002 France 12475093	Yes	100% [Abolition or dissociation of all PV potentials recorded within the PV]	• Cavo-tricuspid isthmus line (all) • Non-PV foci (if induced) • Other linear lines (for persistent AF only): roof line, line between ipsilateral PVs, and mitral isthmus line	Yes	4 mm irrigated-tip (Celcius Thermo-Cool)	25-30*	50	36.9**

*Ablation energy was delivered at 25 W at the right inferior PV only whereas 30 W was used for the other PVs.
**Only ablation time for PVIs was taken into account.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Macle, 2002 France 12475093	Cure without AAD	Freedom from AF recurrence (no detailed definition on recurrence (but symptoms suspected of AF were considered recurrence) and post-procedure blanking period)	Ostial PVI + additional lines	8.8	90	136	66%					
Macle, 2002 France 12475093	Cure with/without AAD	Freedom from AF recurrence (no detailed definition on recurrence (but symptoms suspected of AF were considered recurrence) and post-procedure blanking period)	Ostial PVI + additional lines	8.8	110	136	81%					
Macle, 2002 France 12475093	Re-procedure	At least one re-procedure	Ostial PVI + additional lines	8.8?	67	136	49%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
Most likely crude estimates

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Nd		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Macle, 2002 France 12475093	Ostial PVI + additional lines	8.8	0/136*	nd	0/136	nd	nd	nd		

*50% narrowing by PV angiography was reported in one patient.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Macle, 2002 France 12475093	No	NA	NA	nd	nd	Nd/NA	No	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Probably no	nd	NA				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Macle, 2002 France 12475093			Wide
Explanation for Applicability Grade:		No exclusion criteria. Should have patient spectrum similar to clinical practice.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Mansour Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Mansour, 2004 USA 15149421				X	Retrospective comparison between segmental ostial PVI and circumferential extraostial approach	TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Mansour, 2004 USA 15149421	Paroxysmal or persistent symptomatic drug-refractory AF	nd	09/2000-12/2002	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Mansour, 2004 USA 15149421	nd	Segmental ostial PVI	40	81	54	85	nd	nd	4.0	Nd*	C	Narrow
		Circumferential extraostial PVI	40									

*13% of patients (10/80) had EF<40%

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Mansour, 2004 USA 15149421	Yes (Segmental ostial PVI)	90% [Entrance block]	nd	No	nd	25-30	50	44
	Yes (Circumferential extraostial PVI)	100% [Entrance block during sinus/paced-LA rhythm and exit block in PV pacing]	Mitral isthmus line*			50	60	71

*Only if patients were ablated during AF or AF still showed some organization after completion of the circumferential PVI (n=12).

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Mansour, 2004 USA 15149421	Relapse free	Free from AF (no explicit definition) recurrence during follow-up (Kaplan-Meier at unclear time point)	Segmental ostial PVI	21	24	40	60%		nd			
			Circumferential extraostial PVI	11	30	40	75%					
Mansour, 2004 USA 15149421	Repeat procedure	Patients who required a repeat procedure (reason not explicitly provided) during follow-up (crude estimate?)	Segmental ostial PVI	21	6	40	15%		nd			
			Circumferential extraostial PVI	11	4	40	10%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No		
Was a blanking period (time when AFib episodes were not recorded) used?	No	**If yes, how long was it?**	NA

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Mansour, 2004 USA 15149421	Segmental ostial PVI	21	0/40****	2/40 (5%)	1/40 (3%)*	nd	0/40	Nd		
	Circumferential extraostial PVI	11	0/40****	1/40 (3%)	1/40 (3%)**	nd	2/40 (5%)***	nd		

* Symptoms (left-sided hemipararesis) appeared 10 h after the procedure. This patient had patent foramen oval.
** Symptoms (alexia) appeared 10 h after the procedure.
***Significant femoral vascular complication requiring vascular repair.
****Only patients who needed a repeat procedure underwent a MRI evaluation.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Mansour, 2004 USA 15149421	No	NA	NA	nd	nd	nd	Yes	No	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Nd	No	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Mansour, 2004 USA 15149421	X		
Explanation for Applicability Grade:		N<30 per intervention	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Mantovan Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Mantovan 2005 Italy 16403059		X			anatomical vs. integrated approach; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Mantovan 2005 Italy 16403059	drug refractory AF	intracardiac thrombi	nd	6 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Mantovan 2005 Italy 16403059	nd	anatomical	30	65	54	85	4.2	nd	4.3	60	C	moderate
		integrated	30									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Mantovan 2005 Italy 16403059	no in anatomical; yes in integrated	100% in integrated group; endpoint [elimination or dissociation of distal PV potentials leading to no PV muscle conduction distal to the ablation site]	Anatomical – circumferential lines around each PV at >5 mm from the PV ostia; no linear lesions Integrated – anatomical plus assessment of PV potentials with further ablation if there were residual PV potentials	n	3.5 mm irrigated tip (ThermoCool – external irrigation)	40	nd	43
						30 (at or inside the ostium)	nd	42

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Mantovan 2005 Italy 16403059	primary endpoint (stable sinus rhythm)	freedom from recurrent AF – no symptomatic AF, no asymptomatic sustained AF (>30 s)	anatomical	15.1	17	30	RR 1.78	1.07-2.09	<0.02			
			integrated	15.9	25	30						
		sinus rhythm without AAD	anatomical		4	30	13%		0.002			
			integrated		16	30	53%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Mantovan 2005 Italy 16403059	anatomical		asymptomatic PV stenosis by TEE, 1/30 (3.3%)							
	integrated								pericardial effusion requiring drainage	1/30 (3.3%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Mantovan 2005 Italy 16403059	n	NA	NA	y	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	y				
Explanation for Overall Quality Grade:				unclear if the success rate included redo						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Mantovan 2005 Italy 16403059		x	
Explanation for Applicability Grade:		N=30 in each group; relatively young patients	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
	unclear how successful the procedure was as majority of the patients remained on AAD

Marrouche 2003 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Marrouche, 2003 USA 12756153				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Marrouche, 2003 USA 12756153	nd	nd	12/2000-05/2002	Nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Marrouche, 2003 USA 12756153	nd	Ostial PVI	315	51	54	78	6.0	nd	4.2	Nd	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Marrouche, 2003 USA 12756153	Yes	88-100%* [abolition of all ostial PV potentials]	nd	nd	4 mm cooled-tip EP TECHNOLOGIES	Nd**	35**	nd

*PV-based data were presented. Unclear if these data showed %success (assuming that all four PVs were tried) or % performed (assuming 100% success)

**Energy delivery was titrated 5-watt upward/downward monitoring microbubbles by ICE in 152 patients. In this group, energy delivery ranged from 20 to 50 watts with 20 to 50 temperature at the ablated sites.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Marrouche, 2003 USA 12756153	Freedom from recurrent AF**	Freedom from recurrence after 8-week blanking period. Definition of AF recurrence not explicitly provided.	Ostial PVI	13	271	315	86%					

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

**Recurrence rate was reported in the text.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	8 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
No ICE (Group 1)	Marrouche, 2003 USA 12756153	Freedom from recurrent AF	Freedom from recurrence after 8-week blanking period. Definition of AF recurrence not explicitly provided.	Ostial PVI	21	45	56	80		0.009 (Group 1 vs. 3, Cox??) 0.08 (Group 2 vs. 3, ?)			
ICE without microbubble assessment (Group 2)					14	89	107	83					
ICE with microbubble assessment (Group 3)					9	137	152	90					
No ICE (Group 1)	Marrouche, 2003 USA 12756153	Freedom from recurrent AF	Freedom from recurrence after 8-week blanking period. Definition of AF recurrence not explicitly provided.	Ostial PVI	21	45	56	80		0.01 (?)			
ICE (Group 2+3)					11	226	259	87					
ICE without microbubble assessment (Group 2)	Marrouche, 2003 USA 12756153	Chronic Success	Unclear	Ostial PVI	14	Nd	107	80		0.009 (log-rank?)			
ICE with microbubble assessment (Group 3)					9	nd	152	90					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
Discrepancies of adopted statistical tests (Cox regression without specifying covariates were mainly described in the text, whereas log-rank was inferred in the methods and graphs).

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Marrouche, 2003 USA 12756153	Ostial PVI	13	5/315 (2%)	nd	5/315 (2%)*	nd	nd	nd		

No patient who underwent microbubbles assessment by ICE (Group 3) developed severe (>60%) PV stenosis or stroke (P<0.05, compared with Group 1(?) per report).
* Three of these five patients developed TIA.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Marrouche, 2003 USA 12756153	No	NA	NA	nd	nd	nd	?	?	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	No	Inferred yes	No				
Explanation for Overall Quality Grade:				Retrospective study with many discrepancies on methodology applied						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Marrouche, 2003 USA 12756153		Moderate	
Explanation for Applicability Grade:		Should have been categorized as wide with detailed inclusion/exclusion criteria reported…	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Marrouche 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Marrouche, 2007 Germany 17490437	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Post RFA Anti-Arrhythmics (Time)	Enrollment Years	Other Important Characteristics
Marrouche, 2007 Germany 17490437	Symptomatic AFib, for PV antrum isolation	nd	None (implied)	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Marrouche, 2007 Germany 17490437	1 researcher: BARD (German engineering company)	Open Irrigation RF, 3.5 mm (Thermo-cool or Navistar-Thermo-Cool) with ICE	26	62%	54	75%	5.0 yr	53%	4.3 cm	nd	B	Narrow
		8 mm (Navistar or Celsius DS) with ICE and microbubble	27									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Marrouche, 2007 Germany 17490437	Yes	100% Lasso used [electrical disconnection of the PV-antra from the left atrium]	Isolation of the SVC from the RA	No (nd)	Irrigation RF	Max 50 (Mean 43)	50° (Mean 45°)	5.1 min
					8 mm	Min 20 (Mean 44)	nd (Mean 49°)	9.2 min

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Marrouche, 2007 Germany 17490437	Recurrence atrial arrhythmia (late)	AFib or AFlutter	Irrigated	14	5	26			NS			
			8 mm	14	6	27						
	2nd isolation procedure		Irrigated	14	2	26			NS			
			8 mm	14	2	27						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes, implied*	**If yes, how long was it?**	8 weeks

* Late recurrence (14 mo) rates were lower than early recurrence (8 wk) rates.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Marrouche, 2007 Germany 17490437	Irrigated	3 mo	0/26						LA-esophageal fistulae	0/26
	8 mm	3 mo	0/27							0/27
	Irrigated								Dyspepsia with esophageal wall changes (within 2 wk)	0/26
	8 mm									1/27

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Marrouche, 2007 Germany 17490437	Yes	nd	nd	Yes (0%)	nd	Yes (no dropouts)	Yes	NA	Yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Not explicitly	Yes	Yes	No				
Explanation for Overall Quality Grade:				Study design features lacking. Recurrence outcome definition not explicit. N<30 per arm						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Marrouche, 2007 Germany 17490437	Narrow		
Explanation for Applicability Grade:		N<30 per arm	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Marrouche, 2007 Germany 17490437	Also data on esophageal ulcers etc., all of which healed without incident. Endoscopy was done in all. Also data on Early AFib recurrences (8 wk) Small N. Clearly reported, but few study method details.

Marsan Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Marsan 2008 Netherlands 18805109				X		EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Marsan 2008 Netherlands 18805109	Symptomatic, drug refractory AF	nd	<2007	3 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Marsan 2008 Netherlands 18805109	nd	RFA	57	75	56	77	4.6	nd	nd	57	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Marsan 2008 Netherlands 18805109	Y	Goal (PVI confirmed by entrance block)	no	Y	4 mm irrigated (ThermoCool)	30	50°	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Marsan 2008 Netherlands 18805109	AF Recurrence	>3 min Sxic or >30 sec on ECG/Holter	RFA	7.9	19	57	33%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Y		
Was a blanking period (time when AFib episodes were not recorded) used?	Y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
PAF	Marsan 2008 Netherlands 18805109	AF Recurrence	>3 min Sxic or >30 sec on ECG/Holter	RFA	7.9	11	45	24%		<.05			
Persistent						8	12	75%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Marsan 2008 Netherlands 18805109										

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Marsan 2008 Netherlands 18805109	N	NA	NA	N	NA	Y	Y	Y	Y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Y	Y	Y	Y	N				
Explanation for Overall Quality Grade:				**Retrospective**						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Martinek Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Martinek 2007 Austria 17897124		X			RFA with multislice CT vs. without; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Martinek 2007 Austria 17897124	symptomatic drug-refractory AF	nd	2005		Non-concurrent comparison (first 53 patients compared with second 47 patients over a period of 7 mo)

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Martinek 2007 Austria 17897124	nd	RFA with conventional electroanatomic mapping (Carto XP)	53	59	56	85	6.5	nd	4.8	55	C	moderate
		RFA with multislice CT integration with Carto MERGE	47									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Martinek 2007 Austria 17897124	y	100% [complete electrical disconnection]	LA circumferential ablation with further linear lesions (roof, mitral isthmus, and inferior line) or focal RF applications at areas with CFAE if AF could not be terminated	n	4mm irrigated tip (ThermoCool)	30	48	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Martinek 2007 Austria 17897124	full success	free of arrhythmias without class IC or class III AAD	Carto XP	6 mo	26	53						
			Carto Merge		36	47						
	success on AAD	no symptomatic recurrences, on AAD	Carto XP		10	53						
			Carto Merge		4	47						
	failure	no clinical benefits, with AF episodes	Carto XP		17	53						
			Carto Merge		7	47						
	overall success	full success + success on AAD	Carto XP		36	53	67.9%					
			Carto Merge		40	47	85.1%		0.018			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal AF		overall success		Carto XP	6 mo	23	31						
				Carto Merge		23	28						
Persistent/permanent AF		overall success		Carto XP	6 mo	13	22						
				Carto Merge		17	19			0.197 (paroxysmal vs. persistent/ permanent)			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Success did not vary between patients receiving their first RFCA or having repeated procedures (P=0.199).											

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Martinek 2007 Austria 17897124	Carto XP		>50% stenosis, 3/53 (5.7%)		TIA, 1/53 (1.9%); major stroke, 1/53 (1.9%)					
	Carto Merge				TIA, 1/47 (2.1%)				right phrenic n. injury	1/47 (2.1%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Martinek 2007 Austria 17897124	n	NA	NA	y	n	n	y	y(?)	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	n				
Explanation for Overall Quality Grade:				non-randomized; non-concurrent comparison						

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Martinek 2007 Austria 17897124		X	
Explanation for Applicability Grade:		relatively few patients, patients relatively young with normal ejection fraction	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Matiello Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Matiello 2008 Spain 18515285		X			Three intervention groups (non-concurrent comparisons)	MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Matiello 2008 Spain 18515285	Patients with documented symptomatic refractory paroxysmal, persistent, and permanent AF	Age<18 or >75 years, anteroposterior left anterior descending artery and transthoracic echocardiography>55 mm, presence of left anterior thrombus on transesophageal echo, and the presence of a mechanical prosthetic heart valve	nd	Previous AAD was maintained for >1 month in order to manage early recurrences and then discontinued if there were no recurrences 1-3 months after ablation	Persistent AF: 24% Permanent AF: 14%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Matiello 2008 Spain 18515285	Government	First 90 patients – 8-mm tip catheter, next 42 patients – saline cooled-tip catheter (Celsius ThermoCool) at 45°C and 30 W power output; the remaining 89 patients - saline cooled-tip catheter (Celsius ThermoCool) at 45°C and 40 W power output	221	62	52	76	nd	nd	4.1	nd	C	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Matiello 2008 Spain 18515285	yes	Anatomical approach [The endpoint was the disappearance of the local electrogram inside the whole surrounded areas]	LA roof, post vwall Mitral isthmus ablation was anatomically performed by creating an RF line from the posterolateral aspet of the left-sided encircling lesions to the mitral valve	no	Group 1: 8-mm	50	55	No breakdown by groups. Total ablation time = 2197 +- 944 s
					Group 2: irrigated tip	30	45	
					Group 3: irrigated tip	40	45	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Matiello 2008 Spain 18515285	Arrhythmia free after a single procedure	At 1 year follow-up, on or off AADs. A total of 7 (8%), 4 (10%), and 13 (15%) of the patients of each group were taking 1 AAD despite they had no recurrences beyond the blanking period.	Group 1: 8-mm	12	53%	90			nd			
			Group 2: irrigated tip (30 W)	12	35%	42						
			Group 3: irrigated tip (40 W)	12	55%	89						
	Arrhythmia recurrence	Implied including repeated procedure, on or off AADs	Group 1: 8-mm	20	32%	90			0.03 (group 2 vs. group1 or group 3)			
			Group 2: irrigated tip (30 W)	14	55%	42						
			Group 3: irrigated tip (40 W)	9	40%	89			0.37 (group 1 vs. group 3)			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	yes		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	3 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Catheter tips	Matiello 2008 Spain 18515285	Arrhythmia recurrence	Implied including repeated procedure, on or off AADs	Group 1: 8-mm Group 2: irrigated tip (30 W) Group 3: irrigated tip (40 W)	Group 1: 20 Group 2: 14 Group 3: 9			Only irrigated tip (30 W) was a significant predictor HR=1.713*	1.02-2.90	0.045			
Anteroposterior atrial diameter								HR= 1.105*	1.05-1.19	0.001			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Unclear univariate or multivariate analyses. Variables that were not significant predictors were not reported.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Matiello 2008 Spain 18515285	Group 1: 8-mm	20	0 (>50% narrowing)	1/90 (1%)					Dysphagia	0
									Transient vascular accident	1/90 (1%)
									pericarditis	4/90 (4%)
									Transient ST elevation	0
	Group 2: irrigated tip (30 W)	14	0	0					dysphagia	0
									Transient vascular accident	1/131 (0.8%)
									pericarditis	1/131 (0.8%)
									Transient ST elevation	1/131 (0.8%)
	Group 3: irrigated tip (40 W)	**9**	0	0					dysphagia	1/89 (1%)
									Transient vascular accident	2/89 (2%)
									pericarditis	3/89 (3%)
									Transient ST elevation	2/89 (2%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Matiello 2008 Spain 18515285	no	NA	no	nd	nd	nd	yes	no	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	no	unclear	yes	no				
Explanation for Overall Quality Grade:				Non-concurrent groups. Poor and discrepant reporting.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Matiello 2008 Spain 18515285			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Matiello 2008 Spain 18515285	Unclear univariate or multivariate analyses for results of clinical predictors of arrhythmia recurrence. Variables that were not significant predictors were not reported. Discrepant reporting of sample sizes in the tables..

Matsuo Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Matsuo, 2007 Japan 17506857				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Matsuo, 2007 Japan 17506857	Symptomatic drug-refractory AF	nd	04/2003-05/2006 04/2003-01/2005: ostial PVI only 01/2005-05/2006: ostial PVI + additional ablation targeting dormant PV conduction	None except for recurrence within a week after the procedure	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Matsuo, 2007 Japan 17506857	nd	Ostial PVI ± additional ablation	148	65	53	86	4.7	nd	3.8	66	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Matsuo, 2007 Japan 17506857	Yes	100% inferred (except for PVs with diameter less than 12 mm) and those without arrhythmogenicity [Bidirectional conduction block between the LA and PV]	Additional ablation of the earliest PV activation if ATP- or CS pacing-induced dormant PV conduction	Yes	8 mm (nd)	30-35*	50*	31 min**

*When the ablation site was proximate to the esophagus, the power and the target temperatures was lowered to 25 W and 45 ºC, respectively.
**Difference between ostial PVI only and ostial PVI + additional ablation was 2.1 min (30.7 vs.32.8, P<0.05)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	No	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
No additional ablation	Matsuo, 2007 Japan 17506857	Freedom from AF after the first procedure	Recurrence of AF was defined as sustained AF (>1 min) without AAD during the entire follow-up evaluated by the symptoms, regular ECG, and Holter ECG. Blanking period unclear.	Ostial PVI without or with additional ablation	20	56	94	60%		<0.05 (log-rank)			
Additional ablation						43	54	80%					
No additional ablation	Matsuo, 2007 Japan 17506857	Repeat procedure after the first procedure	Not explicitly described	Ostial PVI without or with additional ablation	5.6	36	94	38%		<0.05 (log-rank)			
Additional ablation						9	54	17%					
No additional ablation	Matsuo, 2007 Japan 17506857	Freedom from AF after the second procedure	Recurrence of AF was defined as sustained AF (>1 min) without AAD during the entire follow-up evaluated by the symptoms, regular ECG, and Holter ECG. Blanking period unclear.	Ostial PVI without or with additional ablation	?	29	36	81%		nd			
Additional ablation						6	9	67%					
No additional ablation	Matsuo, 2007 Japan 17506857	Maintenance of NSR after the last procedure	Maintenance of NSR without AAD. Otherwise, not explicitly described.	Ostial PVI without or with additional ablation	20?	85	94	90%		nd			
Additional ablation						49	54	91%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Matsuo, 2007 Japan 17506857	Ostial PVI ± additional ablation	20	2/148 (1%)*	1/148 (1%)**	nd	nd	nd	Nd		

*Asymptomatic PV stenosis (50-75% narrowing)
**Another one patient developed moderate pericardial effusion, which resolved without pericardiocentesis.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Matsuo, 2007 Japan 17506857	No	NA	NA	nd	nd	NA	Yes	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Matsuo, 2007 Japan 17506857			Wide
Explanation for Applicability Grade:		No exclusion criteria.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Miyazaki Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Miyazaki 2008 Japan 18362429				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Miyazaki 2008 Japan 18362429	Drug refractory paroxysmal or chronic AF	Patients who could not complete all the questionnaires	nd	3 mo (chronic AF only)	LAD and LVEF were significantly worse for chronic group (P<0.01)

Chronic AF: lasting >6 mo despite the use of any AADs
Paroxysmal AF: AF spontaneously converting to normal sinus rhythm with or without AAD

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Miyazaki 2008 Japan 18362429	nd	CPVI	86	71	59	79	nd	nd	4.0	65	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Miyazaki 2008 Japan 18362429	yes	100% [The elimination of all PV potentials]	LA: WACA Roof line (2% vs. 12%) Mitral-isthmus line (0% vs. 56%) RA: Cavo-tricuspid isthmus line (100% for both) Other: SVC isolation (5% vs. 28%) Focal ablation (5% vs. 8%)	no	8 mm (Japan Lifeline)	35 (LA posterior wall), 40 (anterior aspect of PV)	55	nd

In the parentheses, patients with paroxysmal AF vs. chronic AF

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal	Miyazaki 2008 Japan 18362429	Free from recurrence	Free from recurrence (by symptoms, ECG, or Holter ECG)	CPVI	6	48	61	76%					
Chronic	Miyazaki 2008 Japan 18362429	Free from recurrence	Free from recurrence (by symptoms, ECG, or Holter ECG)	CPVI	6	15	25	60%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Paroxysmal AF (without recurrence)	Miyazaki 2008 Japan 18362429	Frequency of symptoms	AFQLQ	score	CPVI	6	48	13.8	21.7	7.9	Nd
Paroxysmal AF (without recurrence)	Miyazaki 2008 Japan 18362429	Severity of symptoms	AFQLQ	score	CPVI	6	48	11.3	16.7	5.4	Nd
Paroxysmal AF (without recurrence)	Miyazaki 2008 Japan 18362429	Limitations of activity and mental anxiety	AFQLQ	score	CPVI	6	48	33.3	51.4	18.1	Nd
Chronic AF (without recurrence)	Miyazaki 2008 Japan 18362429	Frequency of symptoms	AFQLQ	score	CPVI	6	15	13.5	22.8	9.3	Nd
Chronic AF (without recurrence)	Miyazaki 2008 Japan 18362429	Severity of symptoms	AFQLQ	score	CPVI	6	15	12.5	16.9	4.4	Nd
Chronic AF (without recurrence)	Miyazaki 2008 Japan 18362429	Limitations of activity and mental anxiety	AFQLQ	score	CPVI	6	15	37.6	51.9	14.3	Nd

Duplicate one row per outcome and per RFA intervention.
e.g. Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Miyazaki 2008 Japan 18362429										

Not reported.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Miyazaki 2008 Japan 18362429	n	na	na	Yes?/nd	nd	nd	nd	nd	no	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	no	yes	yes	nd				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Miyazaki 2008 Japan 18362429		Moderate	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Nilsson 2006a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Nilsson 2006 Denmark 17043070		x			high output/short duration RF vs. low output/long duration RF; first 45 compared with second 45 patients; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Nilsson 2006 Denmark 17043070	patients with paroxysmal or persistent AF, failed AAD and had one segmental PVI	EF<20%; NYHA class IV; prior ablation; significant valve disease; <18 yr; congenital heart disease	nd	1 mo	possibly overlap with the ostial PVI arm in the Nilsson 2006 RCT

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Nilsson 2006 Denmark 17043070	industry	low output	45	71	51	80	6.4	9			C	moderate
		high output	45	57	55	67	4.6	4.4				

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Nilsson 2006 Denmark 17043070	y	96% [no potential] segmental ostial PVI		nd	5 mm irrigated	30	50	36
						45	55	19

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Nilsson 2006 Denmark 17043070	outcome 1	stable SR with no symptomatic recurrent AF	low output	15			74%					
			high output				76%		NS			
	outcome 2	did not need additional AAD	low out put	15			54%					
			high output				56%		NS			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	n		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Nilsson 2006 Denmark 17043070	low output		0		TIA, 1/45 (2.2%)					
	high output		0		TIA, 1/45 (2.2%)					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Nilsson 2006 Denmark 17043070	n	NA	NA	NA	n	n	y	n	n	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	n	NA				
Explanation for Overall Quality Grade:				retrospective; no adjustment for possible confounding						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Nilsson 2006 Denmark 17043070	possible that some of the patients in the high output group were also the same ones in the RCT of ostial vs. extra ostial study (UI 16923426)

Nilsson 2006b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Miyazaki 2008 Japan 18362429				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Miyazaki 2008 Japan 18362429	Drug refractory paroxysmal or chronic AF	Patients who could not complete all the questionnaires	nd	3 mo (chronic AF only)	LAD and LVEF were significantly worse for chronic group (P<0.01)

Chronic AF: lasting >6 mo despite the use of any AADs
Paroxysmal AF: AF spontaneously converting to normal sinus rhythm with or without AAD

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Miyazaki 2008 Japan 18362429	nd	CPVI	86	71	59	79	nd	nd	4.0	65	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Miyazaki 2008 Japan 18362429	yes	100% [The elimination of all PV potentials]	LA: WACA Roof line (2% vs. 12%) Mitral-isthmus line (0% vs. 56%) RA: Cavo-tricuspid isthmus line (100% for both) Other: SVC isolation (5% vs. 28%) Focal ablation (5% vs. 8%)	no	8 mm (Japan Lifeline)	35 (LA posterior wall), 40 (anterior aspect of PV)	55	nd

In the parentheses, patients with paroxysmal AF vs. chronic AF

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal	Miyazaki 2008 Japan 18362429	Free from recurrence	Free from recurrence (by symptoms, ECG, or Holter ECG)	CPVI	6	48	61	76%					
Chronic	Miyazaki 2008 Japan 18362429	Free from recurrence	Free from recurrence (by symptoms, ECG, or Holter ECG)	CPVI	6	15	25	60%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Paroxysmal AF (without recurrence)	Miyazaki 2008 Japan 18362429	Frequency of symptoms	AFQLQ	score	CPVI	6	48	13.8	21.7	7.9	Nd
Paroxysmal AF (without recurrence)	Miyazaki 2008 Japan 18362429	Severity of symptoms	AFQLQ	score	CPVI	6	48	11.3	16.7	5.4	Nd
Paroxysmal AF (without recurrence)	Miyazaki 2008 Japan 18362429	Limitations of activity and mental anxiety	AFQLQ	score	CPVI	6	48	33.3	51.4	18.1	Nd
Chronic AF (without recurrence)	Miyazaki 2008 Japan 18362429	Frequency of symptoms	AFQLQ	score	CPVI	6	15	13.5	22.8	9.3	Nd
Chronic AF (without recurrence)	Miyazaki 2008 Japan 18362429	Severity of symptoms	AFQLQ	score	CPVI	6	15	12.5	16.9	4.4	Nd
Chronic AF (without recurrence)	Miyazaki 2008 Japan 18362429	Limitations of activity and mental anxiety	AFQLQ	score	CPVI	6	15	37.6	51.9	14.3	Nd

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Miyazaki 2008 Japan 18362429										

Not reported.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Miyazaki 2008 Japan 18362429	n	na	na	Yes?/nd	nd	nd	nd	nd	no	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	no	yes	yes	nd				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Miyazaki 2008 Japan 18362429		Moderate	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Okada Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Okada 2007 Japan 17397672		x (retrospective)			PVI vs. CPVA; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Okada 2007 Japan 17397672	symptomatic paroxysmal AF, failed AADs (excluding amiodarone)		nd		essentially a cohort study

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Okada 2007 Japan 17397672	nd	PVI	50	100	58	84	5	nd	3.41	67	C	moderate
		CPVA	27									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Okada 2007 Japan 17397672	y	96.5% of veins in PVI; 99% of veins in CPVA [complete electrical dissociation and non-inducibility]	group 1: PVI group 2: CPVA	y	8 mm	30-40	55	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Okada 2007 Japan 17397672	outcome 1	free of symptomatic paroxysmal AF and no AADs	PVI	6 mo	25	50	50%					
			CPVA		24	27	89%		<0.001			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	n		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Okada 2007 Japan 17397672	PVI		significant PV stenosis (asymptomatic), 2/50 (4%)							
	CPVA		significant PV stenosis (asymptomatic), 1/27 (3.7%)							

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Okada 2007 Japan 17397672	n	NA	nd	y	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	n				
Explanation for Overall Quality Grade:				essentially a cohort study with no adjustment for potential confounders						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Okada 2007 Japan 17397672		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Oral 2003 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral, 2003 US 14557355	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral, 2003 US 14557355	Symptomatic paroxysmal AFib	CHF, EF<35%, LAD>5.5 cm, previous ablation	nd	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Oral, 2003 US 14557355	Ellen and Robert Thompson Atrial Fibrillation Research Fund	PVI segmental ostial oblation (4 mm)	40	100%	52	78%	7 yr	0%	4.0	56%	B	
		PVI LA ablation (8 mm)	40									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Oral, 2003 US 14557355	Yes	100% Inferred	None (Only segmental ostial RFA)	No	4 mm (EP Technologies)	35 W max	52° target	18 min
			WACA Posterior LA line connecting circles Mitral isthmus line		8 mm (Navistar)	60 W max	55° target	42 min

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Oral, 2003 US 14557355	Freedom from recurrent AFib	Absence of symptomatic AFib off AAD (without repeat procedure)	Segmental	6 mo	27 (67%)	40			.02 (log rank)			
			LA Ablation	6 mo	35* (88%)	40						
	AFib recurrence	symptomatic	Segmental	6 mo	13	40						
			LA Ablation	6 mo	4*	40						
	Repeat ablation		Segmental	6 mo	7	40						
			LA Ablation	6 mo	0	40						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
* Unclear about extra patient (35+4=39)
ALSO DATA ON FREEDOM FROM AFIB AFTER REPEAT PROCEDURE.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Oral, 2003 US 14557355			No complications (other than AFL) No PV stenosis							

PREDICTORS OF OUTCOMES

Multivariable Cox regression

LAD (presumably larger) and use of segmental ostial ablation were independent predictors of recurrent PAF (P<.01, both).

Age, sex, symptom duration, symptom frequency, structural heart disease, LVEF were NS (>.05)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral, 2003 US 14557355	Yes	nd	nd	Yes (0%)	nd	Yes (0%)	Yes	Yes	No There seems to be a missing recurrent patient	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	No	No				
Explanation for Overall Quality Grade:				Symptomatic. Missing patient (35+4=39, not 40; 88%+10%=98%).						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral, 2003 US 14557355		Moderate	
Explanation for Applicability Grade:		Paroxysmal only.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Oral 2004a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral, 2004 US 15089987				X		TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral, 2004 US 15089987	Symptomatic, drug-refractory paroxysmal AF	nd	nd	nd	The left superior, left inferior, and right superior PVs were targeted in all patients, but the right inferior PV was targeted in only 41% of patients.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Oral, 2004 US 15089987	Ellen and Robert Thompson Atrial Fibrillation Research Fund	Segmental ostial ablation	188	100	53	81	7.4	nd	3.9	0.55	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Oral, 2004 US 15089987	yes	96%* [nd]	nd	No	nd	nd	nd	nd

*Unit of analysis is most likely to be PV, not individual patient.

Of note, the methods refer to previous articles. I don't think that we can assume the same catheter tip. So, leaving the above blank is likely the correct thing to do.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 mo

*An event recorder was provided only to patients with symptoms.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up,mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Vagotonic paroxysmal AF	Oral, 2004 US 15089987	Freedom from recurrent AF	Freedom from symptomatic AF relapse at 1 year	Segmental ostial ablation	15	nd	22	50%	nd	-			
Adrenergic paroxysmal AF				Segmental ostial ablation		nd	30	83%	nd	0.02 (?)			
Random episode paroxysmal AF				Segmental ostial ablation		nd	136	69%	nd	0.05 (?)			
Vagotonic paroxysmal AF	Oral, 2004 US 15089987	Freedom from recurrent AF	Symptomatic AF	Segmental ostial ablation	15	nd	22	nd	nd	0.04, 0.07, and 0.3* (Log-rank)			
Adrenergic paroxysmal AF						nd	30						
Random episode paroxysmal AF						nd	136						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Vagotonic vs. adrenergic, vagotonic vs. random, and random vs. adrenergic, respectively.
PREDICTORS OF OUTCOMES
Multivariable Cox regression
Vagotonic AF was the only independent predictors of recurrent PAF (P=0.03).
Age, sex, symptom duration, symptom frequency, structural heart disease, LVEF, and LAD were NS (>.05)

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

No AEs reported.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral, 2004 US 15089987	No	NA	NA	Yes (0%)	nd	nd	Yes**	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	No	nd	No	NA				
Explanation for Overall Quality Grade:				Retrospective study						

*observational study cannot be an A, retrospective study is always a C

**Variable (especially statistical test is unclear about freedom of relapse AF at 1year)

N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral, 2004 US 15089987		X	
Explanation for Applicability Grade:		Only paroxysmal AF included. Clearly not applicable to other categories.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Oral, 2004 US 15089987	Overlap of 40 patients of the SOA arm in the Oral 2003 (RefID964, RCT of SOA vs. LACA) cannot completely be excluded but this study was considered to be independent.

Oral 2004b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral 2004 US 15505091	X					TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral, 2004 US 15505091	Symptomatic, drug-resistant, paroxysmal AF inducible by atrial pacing	nd	nd	Class I or III (8 to 12 weeks)	Only patients with non-terminated or inducible AF after LACA were randomly assigned to no further ablation or additional ablation, which was repeated until AF was terminated and not inducible. Patients whose AF was terminated with LACA and not inducible were observed without further interventions.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Oral, 2004 US 15505091	Ellen and Robert Thompson Atrial Fibrillation Research Fund; (Biosense-Webster (consultant))	LACA only (terminated and non-inducible group)	40	100	55	80	7	nd	4.3	57	B	Moderate
		LACA + additional ablation (non-terminated or inducible group)	30									
		LACA only (non-terminated or inducible group)	30									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Oral, 2004 US 15505091	Yes	Nd (100% inferred) [>80% reduction in the local electrogram amplitude or reaching the predefined total ablation time of 40 sec. Additional RFAs performed within the circles wherever the local electrogram amplitude showed >0.2 mV]	LACA Posterior LA lines connecting circles and mitral isthmus line (all patients) LA septum (n=23), roof (n=14), posterior mitral annulus (n=7), anterior wall (n=21), and other additional lines (only patients assigned to the LACA + additional ablation arm)	Yes	8 mm (Navistar)	70 W max	55° target	43 min (LACA only) 25 min (additional lines)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Oral, 2004 US 15505091	Freedom from recurrent AF	Freedom from AF relapse in the absence of AAD at 6 mo	LACA only (terminated and non-inducible group)	8	Nd	70	85%	Nd	0.02 (Log-rank)	nd	nd	nd
			LACA + additional ablation (non-terminated or inducible group)									
			LACA only (non-terminated or inducible group)	8	nd	30	67%	Nd				
Oral, 2004 US 15505091	Re-procedure	Nd	LACA only (terminated and non-inducible group)	8	0	100	0%	nd				
			LACA + additional ablation (non-terminated or inducible group)									
			LACA only (non-terminated or inducible group)									

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	6 weeks

*An event recorder was provided only to patients with symptoms.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Oral, 2004 US 15505091	LACA only (terminated and non-inducible group)	8	nd	nd	nd	nd	nd	nd	Atrial Flutter	21/100 (21%)
	LACA + additional ablation (non-terminated or inducible group)									
	LACA only (non-terminated or inducible group)									

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral, 2004 US 15505091	Yes	nd	nd	Yes (0%)	nd	Yes	Yes	nd	Yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Yes	No	NA				
Explanation for Overall Quality Grade:				No clear description on how they conduct the study. Only symptomatic relapse taken into account. Non randomized arm combined with a randomized arm in analysis, possibly making the results less straightforward. N<100						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral, 2004 US 15505091		X	
Explanation for Applicability Grade:		Only paroxysmal AF included. Clearly not applicable to other categories.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Oral, 2004 US 15505091	40 patients of LACA only look quite similar to the LACA arm in the Oral 2003 (RefID964, RCT of segmental ostial ablation vs. LACA) but the max energy used (70W vs. 60W in the RCT) and the adoption of inducibility to check procedure endpoint is different; thus, this is considered to be distinct.

Oral 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral 2005 US 16253904	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral 2005 US 16253904	Chronic AFib	>75 yr, EF<25%, LA thrombus, LAD >6.5 cm	nd	Amiodarone 200 mg/d x 8-12 wk	Chronic AFib = ≥6 mo, no intervening SR, recurred within 1 mo after cardioversion Structural heart disease 16%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Oral 2005 US 16253904	Ellen and Robert Thompson Atrial Fibrillation Research Fund	LA circumferential ablation	40	0%	53.5	84	4.5 yr	nd	4.8 cm	53%	C	Moderate
		Nonencircling linear ablation	40									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Oral 2005 US 16253904	Yes (voltage abatement, WACA)	nd	WACA Lines in the posterior LA between encircling lesions* Line in the mitral isthmus	No, implied**	8 mm quadripolar (Navistar)	70* max	55° target*	46 min
	No (lines only)	NA	Lines along the LA roof, septum, anterior wall, mitral isthmus, and atrial aspect of mitral annulus. Lines transected areas with complex electrograms. 3-5 lines (total) per patient	Yes (rapid atrial pacing)				35 min P=.01

*To minimize atrioesophageal fistula, posterior line moved to the LA roof, power limited to 40-50 W, target temperature lowered to 45-50°

** In both if AF terminated during ablation, rapid atrial pacing was performed. (However) Termination and noninducibility of AF were not designated endpts of either ablation strategy.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Oral 2005 US 16253904	AFib recurrence	Confirmed symptomatic (implied)	LACA	10	15	40			0.7			
			Segmental		20	40						
	AFL (no AFib)	Confirmed symptomatic (implied)	LACA	10	6	40			0.8			
			Segmental		7	40						
	"Freedom from recurrent AFib and AFL off AAD, 6 mo post-8 wk blanking" *	Confirmed symptomatic (implied)	LACA	10*	19	40			0.2			
			Segmental		13	40						
	Repeat ablation for AFib		LACA	at 8±5 mo	7 (of 15 w/AFib)	40			NS, implied			
			Segmental		11 (or 20)	40						
	Repeat ablation for AFib or AFL		LACA	nd	13	40						
			Segmental		15**	40						

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

* Primary outcome was "Freedom from recurrent AFib and AFL off AAD, 6 mo post-8 wk blanking" to be measured at 8 months (2 mo blanking + 6 mo), but results report recurrence of AFib and AFl data at a mean f/up of 10±3 mo.

** Plus one patient scheduled to undergo repeat ablation, at the time of writing

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	No, implied		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	8 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Oral 2005 US 16253904	Both	10	No complications							

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral 2005 US 16253904	Yes	nd	nd	0%	nd	Y (all included)	Yes	NA	Yes, but Timing of reported primary outcome different than data reported	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	No. An event recorder used for symptoms	No				
Explanation for Overall Quality Grade:		Study stopped early, Asymptomatic AFib apparently not recorded								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral 2005 US 16253904		Moderate	
Explanation for Applicability Grade:		Size, (excluded >75 yr)	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Oral 2005 US 16253904	Original assumptions yielded a power estimation of 74 patients in each group. An interim analysis post 40 patients in each group suggested a power estimation of 365 patients in each group. Therefore “a point of futility was reached” and enrollment was stopped.

Oral 2006a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral, 2006 USA and Italy 16510747	X				Circumferential PV and additional lines ablation with transient concurrent anti-arrhythmics vs. Only transient AAD (crossover permitted)	TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral, 2006 USA and Italy 16510747	Chronic AFib*	• Age < 18 or > 70 years • Left atrial diameter > 55 mm • Left ventricular ejection fraction < 30 percent • Contraindication to amiodarone therapy or anticoagulation with warfarin • Presence of a mechanical prosthetic valve • History of a cerebrovascular accident • Presence of left atrial thrombus on transesophageal echocardiography • Prior attempt at catheter or surgical ablation for AFib	11/2002-02/2004	Amiodarone 200 mg per day (3 mo)	• Amiodarone 200 mg per day (plus cardioversion at 6 weeks for most of the patients) was also discontinued at 3 mo in the control arm. • Cross-over design: 53 patients in the drug arm (77%) underwent RFA after relapse.

* Chronic AFib was defined as AFib that had been present for more than six moths without intervening spontaneous episodes of sinus rhythm and that recurred within one week after cardioversion.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Oral, 2006 USA and Italy 16510747	Ellen and Robert Thompson Fibrillarion Research Fund*	LACA + additional lines	77	0	56	65	4.5	nd	4.5	55	B	Narrow
		Amiodarone (for only 3 mo)	69									

*Other conflict of interest includes Ablation Frontier, Biosense Webster, St. Jude Medical, Guidant, and Medtronic.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Oral, 2006 USA and Italy 16510747	Yes	Nd (100% inferred) [Local electrogram amplitude 0.2 mV or less]	Encircling lesions of PVs Roof line Mitral isthmus line Cavotricuspid isthmus line*	No	8 mm (Navistar)	70	55	37**

*Performed in only 55 patients at the discretion of the operators. Unclear as to whether these 55 patients were only those in the RFA arm.
**Time for only circumferential PV ablation

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Oral, 2006 USA and Italy 16510747	Maintaining Sinus rhythm	In sinus rhythm and free from AF or atrial flutter in the absence of AAD at 12 mo**	LACA + additional lines	12	57	77	74%	Nd	<0.001 (Fisher's)	nd	nd	nd
			Amiodarone for 3 mo only	12	3	69	4%**					
					40	69	58%**		0.05 (Fisher's)			
Oral, 2006 USA and Italy 16510747	Re-intervention	Re-procedure of ablation due to relapse of AF or atrial flutter	LACA + additional lines	12	25	77	32%					

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

**The way to analyze the outcome seems quite different from other studies. Also, crossover to RFA in relapsed patients was allowed. It is unclear why relapse free (AF only instead of AF + Aflutter?) crude % without AAD for AAD arm is reported as 58% (40/69) in contrast with the 4% in analysis similar to others.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	Nd/no	**If yes, how long was it?**	NA

*Event monitor for one year to record the rhythm for 3 min at least 5 days/week or if symptoms, regular ECG and echocardiogram at 3, 6, and12 mo.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Oral, 2006 USA and Italy 16510747	LAD size*	LAD size at 12 mo	cm	LACA + additional lines	12	77	4.5	4.0	Nd	<0.001 (t-test)*
				Amiodarone for 3 mo only	12	69	4.5	4.5		
Oral, 2006 USA and Italy 16510747	LVEF*	LVEF at 12 mo	%	LACA + additional lines	12	77	55	62	nd	<0.001 (t-test)*
				Amiodarone for 3 mo only	12	69	56	55		

Duplicate one row per outcome and per RFA intervention.
*Only measured size at 12 mo was considered, not the difference between before procedure (baseline) and after 12 mo (final).

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Oral, 2006 USA and Italy 16510747	LACA + additional lines	12	0	0	0	0	0	0	Atypical atrial flutter*	5/77 (6%)
									Sick sinus syndrome**	1/77 (1%)
									Pneumonia**	1/77 (1%)
	Amiodarone (for only 3 mo)	0	0	0	0	0	0	0	Sick sinus syndrome**	1/69 (1%)

*The authors inferred that these atypical atrial flutters were associated with ablation procedure.

**The authors considered these adverse events to be unrelated with either ablation procedure or anti-arrhythmics. All the reported patients with SSS needed a permanent pacemaker, and the patients developing pneumonia, who had nonischemic cardiomyopathy, died of the pneumonia.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral, 2006 USA and Italy 16510747	Yes	nd	nd	Yes, 0%	Yes	Yes	Yes	No	No#	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes**	No	Yes***	Yes****				
Explanation for Overall Quality Grade:				Some item not reported and possible confounders not adjusted.						

*observational study cannot be an A, retrospective study is always a C
See rhythm control part (some unclear reporting's)
** More than three seconds recorded by event monitor evaluated by blinded interpreters.
***Event monitor for one year to record the rhythm for 3 min at least 5 days/week or if symptoms, regular ECG and echocardiogram at 3, 6, and12 mo.
****Compliance of 85%.
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral, 2006 USA and Italy 16510747	X		
Explanation for Applicability Grade:	Only patients with chronic Afib.		

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Oral, 2006 USA and Italy 16510747	• Re-procedure in 25 patients (32%) in the RFA arm and crossover RFA in 53 patients (77%) in the control arm. • Crossover design. • The way investigators calculated freedom from arrhythmia appears unique. • One patient in the RFA arm and 25 patients in the control arm continued amiodarone after the predefined period.

Oral 2006b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral, 2006 USA 16606789				X	A cohort study of Individualized stepwise RFA approach	TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral, 2006 USA 16606789	Symptomatic paroxysmal AF	Prior ablation	nd	8 weeks*	

*Only 90 out of 153 patients (59%) due to either prior use or early relapse.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Applicability
Oral, 2006 USA 16606789	Ablation Frontiers (founder, stockholder, and consultant) and Biosense-Webster (consultant)	Tailored stepwise RFA*	153	100	56	72	7	nd	4.1	57	

*1) PVI, targeted ablation of arrythmogenic fascicle, or WACA/LACA of tachycardia-inducible PV(s) by pacing in the PV(s), 2) Ablation of CFAEs in the LA, CS, and/or SVC if AF is still inducible by atrial pacing.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Oral, 2006 USA 16606789	No	NA **	Ostial (focal or segmental) ablation or WACA/LACA (as a first step) CFAEs in the LA, CS, and/or SVC (as a second step)	Yes*	8 mm (Navistar)	35 (CS and critical sites near the esophagus in the LA) 70 (LA in general)	45 (critical sites near the esophagus in the LA) 50 (CS and LA in general)	32

*Endpoint of the procedure. **Although complete isolation of PVS was not a required endpoint elimination of all PV tachycardias was required.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Oral, 2006 USA 16606789	Freedom from AF and atrial flutter	Absence of recurrent AF or atrial flutter (not fully defined) in the absence of AAD from 8-week blanking period in which some took AAD)	Tailored stepwise RFA	11	118	153	77%**					
Oral, 2006 USA 16606789	Repeat procedure	Not fully defined	Tailored stepwise RFA	11	28	153	18%**					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**Most likely crude estimates (no mention about K-M method).

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	8 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
AF non-inducible after procedure	Oral, 2006 USA 16606789	Freedom from AF and atrial flutter	Absence of recurrent AF or atrial flutter (not fully defined) in the absence of AAD from 8-week blanking period in which some took AAD)	Tailored stepwise RFA	11	(77)	88	88%*	Nd	0.003 (Chi-squared)			
AF inducible after procedure						(43)	65	66%*	Nd				

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Should be crude estimates (no mention about K-M method).

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Oral, 2006 USA 16606789	Tailored stepwise RFA	11	nd	2/180* (1%)	2/180* (1%)**	nd	nd	nd	nd	

*180 procedures including 153 first procedures and 27 second procedures for relapse in total 153 patients.
**Transient neurological events without any sequelae at discharge.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral, 2006 USA 16606789	No	NA	NA	Unclear**	nd	nd	No	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Yes	Yes	Yes (30%)				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A
**Explicitly stated as "no patient was lost to follow-up"; however, follow-up period was reported as 11 months with the SD of 4months.

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral, 2006 USA 16606789		Moderate	
Explanation for Applicability Grade:		Only those with paroxysmal AF	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Oral 2006c Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Oral, 2006 US 16908760				X		TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Oral, 2006 US 16908760	Patients with AF who underwent LA-RFA at the University of Michigan Medical Center from January 2003 to July 2005	nd	01/2003-07/2005	ADD discontinued at 2 to 3 mo after ablation unless the patients were still having AF	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Oral, 2006 US 16908760	Ablation Frontiers (stockholder and consultant), Biosense-Webster (consultant)	LACA or "tailored" approach*	755	65	55	76	6	nd	4.3	0.56	C	Wide

*1) PVI, targeted ablation of arrythmogenic fascicle, or LACA of tachycardia-inducible PV(s) by pacing in the PV(s), 2) Ablation of CFAEs in the LA, CS, and/or SVC if AF is still inducible by atrial pacing.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Oral, 2006 US 16908760	Nd	Nd [nd]	Nd Circumferential PV ablation N 603 Left atrial RFA N 226	nd	nd	nd	nd	nd

Details were described above (per previous reports).

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Oral, 2006 US 16908760	Early ischemic stroke	Ischemic stroke with in 30 days from RFA	LACA or "tailored" approach	25	7	755	0.9%	nd	nd	nd	nd	Nd
Oral, 2006 US 16908760	Late ischemic stroke	Ischemic stroke after 30 days from RFA**	LACA or "tailored" approach	25	1	755	0.1%	nd	nd	nd	nd	Nd
Oral, 2006 US 16908760	Hemorrhagic stroke	Hemorrhagic stroke after RFA***	LACA or "tailored" approach	25	2	755	0.3%	nd	nd	nd	nd	Nd

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
** Renal infarct case (n=1) was excluded
***Developed at 1 and 3 mo.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	2 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
1 or more risk factors for thromboembolic events	Oral, 2006 US 16908760	Freedom from thromboembolic events	Freedom from thromboembolic events at 1 year from RFA	LACA or "tailored" approach	25	6	411	99%	Nd	0.69 (Log-rank)**			
No risk factor for thromboembolic events	Oral, 2006 US 16908760	Freedom from thromboembolic events	Freedom from thromboembolic events at 1 year from RFA*	LACA or "tailored" approach	25	3	344	99%	Nd				
Paroxysmal AF	Oral, 2006 US 16908760	Freedom from relapse (1y)	Freedom from relapse of AF or atrial flutter in the absence of AAD at 1 year from RFA	LACA or "tailored" approach	25	nd	490	77%	Nd	0.001 (Log-rank)			
Chronic AF	Oral, 2006 US 16908760	Freedom from relapse (1y)	Freedom from relapse of AF or atrial flutter in the absence of AAD at 1 year from RFA	LACA or "tailored" approach	25	nd	265	66%	Nd				
Paroxysmal AF	Oral, 2006 US 16908760	Freedom from relapse (2y)	Freedom from relapse of AF or atrial flutter in the absence of AAD at 2 year from RFA	LACA or "tailored" approach	25	nd	490	73%	Nd	nd			
Chronic AF	Oral, 2006 US 16908760	Freedom from relapse (2y)	Freedom from relapse of AF or atrial flutter in the absence of AAD at 2 year from RFA	LACA or "tailored" approach	25	nd	265	62%	Nd				
Paroxysmal AF	Oral, 2006 US 16908760	Freedom from relapse (2y)	Freedom from relapse of AF only in the absence of AAD at 2 year from RFA	LACA or "tailored" approach	25	nd	490	77%***	Nd	0.01 (Log-rank)			

Chronic AF	Oral, 2006 US 16908760	Freedom from relapse (2y)	Freedom from relapse of AF only in the absence of AAD at 2 year from RFA	LACA or "tailored" approach	25	nd	265	68%***	Nd				

Duplicate one row per outcome and per RFA intervention.
* Only one renal infarct case was included. Not freedom from stroke.
** Compared with hypothetical control group extrapolated from Framingham cohort.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
***Relapse rates were reported in the paper but converted.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Oral, 2006 US 16908760	LACA or "tailored" approach	25	nd	nd	10/755 (1%)*	nd	nd	nd		

* 7 early ischemic strokes (<30 days), 1 late ischemic stroke (>30 days), and 2 hemorrhagic strokes (at 1 and 3 mo) were reported (see the results section).

AVOIDING ANTICOAGULATION (maybe not relevant question in this study; not compared to ADD per final work plan)
Cox regression analysis found age>65 and prior stroke/TIA were independent factors not to predict discontinuation of anticoagulation therapy ($p<0.001$)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Oral, 2006 US 16908760	No	NA	NA	No**	Nd/NA	Nd/NA	Yes	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	Yes	Nd**	Yes	No				
Explanation for Overall Quality Grade:				Retrospective design						

*observational study cannot be an A, retrospective study is always a C
**reported minimum follow-up period was 10 mo.
***Inferred yes as definition of outcome was freedom from recurrent AF (and atrial flutter).
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Oral, 2006 US 16908760			X
Explanation for Applicability Grade:		755 patients probably from the institutional registry including paroxysmal and chronic	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Oral, 2006 US 16908760	Unclear if there is overlap with studies from the University of Michigan Medical Center (at least Oral 2003 (Ref ID 964), Oral 2006 (Ref ID 483), and Oral 2006 (Ref ID 459)

Pak Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Pak 2008 Korea 18284506		x			KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Pak 2008 Korea 18284506	PAF; identified arrhythmogenic PVs	PAF with bilateral or non-detectable arrhythmogenic PVs; non-PV foci; and others	nd	none; AADs in those with recurrences after 2 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Pak 2008 Korea 18284506	Frontier R&D grant	selective or all 4 PVI	77	100	52	74	5		3.9	57	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Pak 2008 Korea 18284506	y	Selective PVI only in PV with triggering AF vs. PVI in all 4 PVs (elimination of all potentials confirmed)		y	5 mm (EP Technology)	35	55	51 (Se) vs. 127 (all 4)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Pak 2008 Korea 18284506	Freedom from AF recurrence (after 1 ablation, not on AAD?)		Selective PVI	39 mo (total followup duration)	26	42	62%					
			All 4 PVI		26	35	74%		NS			
	Reablation		Selective PVI		13	42	31%					
			All 4 PVI		8	35	23%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Pak 2008 Korea 18284506	Selective PVI		60% stenosis, 1/42 (2.4%)		TIA, 1/42 (2.4%)					
	All PVI			2/35 (5.7%)						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Pak 2008 Korea 18284506	n	NA	NA	y	nd	n	y	n	n	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	n				
Explanation for Overall Quality Grade:		C; unclear how patients were selected into respective groups								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Pappone 2003 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Pappone, 2003 Italy 12875749				X*	Circumferential PV ablation vs. Medical management	TT/AG

*Patients' data were "prospectively' recorded (but most likely analyzed retrospectively). Also, includes Pappone 2001 (RefID 1211) and Pappone 2001 (RefID 1230)

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Pappone, 2003 Italy 12875749	• Two or more previous ineffective trials with antiarrhythmic drugs • More than 2 AF-related hospital admissions during the 2 years before entering the study • Two or more years of AAD treatment	• Contraindication to anticoagulation • New York Heart Association functional class IV • Myocardial infarction or cardiac surgery within the past three moths • Sick sinus syndrome or atrioventricular conduction disturbances without an artificial pacemaker • Ventricular tachyarrhythmias • Thyroid dysfunction • Unsuccessful cardioversion to SR by drugs and/or electroshock	01/1998-03/2001	3 mo (only 115 patients (20%) who had in-hospital Afib and/or needed DC cardioversion after the procedure were prescribed)	"RFA" group had less favorable patient profiles than "medical" group: longer duration of AFib (5.5 years vs. 3.6 years, p<0.001) and more AADs tried (3.1 vs. 2.3, P<0.001).

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Pappone, 2003 Italy 12875749	nd	Circumferential PV ablation	589	70	65	58	4.6*	Nd**	4.6	54	C	Moderate
		Medical	582									

*Significantly different (5.5 for RFA and 3.6 for Medical, p<0.001(t-test)).
**Mean NYHA class 1.3 for RFA and 1.2 for medical.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Pappone, 2003 Italy 12875749	Yes	Nd (100% inferred)* [Elimination of PV ostial potentials and absence of discrete electrical activity inside the lesion during pacing outside the ablation line, or voltage abatement inside and around the encircled areas]	Nd**	No	nd	Nd***	Nd****	59

See Pappone et al. Circulation 1999, 2000, and 2001for more details per report.
* 75% for post-procedure remapping (1: low peak-to-peak bipolar potentials (<0.1 mV) inside the lesion and 2: a local activation time > 30 ms between contiguous points lying in the same axial plane across the line) although the target to terminate energy delivery was reduction of the local potential amplitude by 80% (Pappone 2001 (RefID 1230)) and 82% for electrical activity (< 0.01 mV) in which unit of analysis was each PV (Pappone 2001 (RefID 1211))
** None (Pappone 2001 (RefID 1230))
*** 50 W (Pappone 2001 (RefID 1211))
****60 ºC (Pappone 2001 (RefID 1211 and RefID 1230))

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Pappone, 2003 Italy 12875749	AF-free survival	Symptomatic AF lasting more than 10 min confirmed by ECG	Circumferential PV ablation	30**	469	589	HR=0.30***	0.24-0.37	<0.001	nd	nd	nd
			Medical	30**	242	582						
Pappone, 2003 Italy 12875749	Congestive heart failure	nd	Circumferential PV ablation	30**	32	589	Nd****	nd	nd	nd	nd	nd
			Medical	30**	57	582						
Pappone, 2003 Italy 12875749	Stroke	TIA, ischemic stroke, and hemorrhagic stroke	Circumferential PV ablation	30**	14	589	Nd****	nd	nd	nd	nd	nd
			Medical	30**	49	582						
Pappone, 2003 Italy 12875749	Overall survival	Survival from any cause of death	Circumferential PV ablation	30**	551#	589	Nd*****	nd	<0.001	nd	nd	nd
			Medical	30**	499#	582						
Pappone, 2003 Italy 12875749	Adverse event-free survival	Survival free from any adverse event (unclear about how death was dealt with)	Circumferential PV ablation	30**	523#	589	HR=0.45******	0.31-0.64	<0.001	nd	nd	nd
			Medical	30**	484#	582						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**Median
***Freedom from recurrent AF at 1, 2, and 3 years were: 84%, 79%, and 78% for ablation, respectively, and 61%, 47%, and 37% for medical management, respectively.
****Neither crude estimate nor Kaplan-Meier estimate reported.
*****Overall survival at 1, 2, and 3 years were: 98%, 95%, and 92% for ablation, respectively, and 96%, 90%, and 86% for medical management, respectively.
******Adverse event-free survival at 1, 2, and 3 years were: 97%, 94%, and 91% for ablation, respectively, and 93%, 87%, and 81% for medical management, respectively.
#Either death or adverse event was reported in the paper.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	No	**If yes, how long was it?**	

*Standard ECG, echocardiogram, and Holter at 1, 3, 6, 9, and 12, 18, 24… mo or on symptom. Also, transtelephonic monitoring.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Pappone, 2003 Italy 12875749	Arrhythmia burden	The number of relapse episodes after the first recurrence	Times/patient-year	RFA	nd	Nd	0	2.1	RR=0.38 (95%CI, 0.32-0.56) (Poisson distribution)	nd
				Medical	Nd	nd	0	5.4		
Pappone, 2003 Italy 12875749	QOL	SF-36, physical component summary score	Score	RFA	12	109	39	49	Nd	Nd*
				Medical	12	102	40	41		
Pappone, 2003 Italy 12875749	QOL	SF-36, mental component summary score	Score	RFA	12	109	42	50	nd	Nd*
				Medical	12	102	42	43		

Duplicate one row per outcome and per RFA intervention.
*Adjusted p<0.01 (statistical test unclear)

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
LAD > 4.5 cm	Pappone, 2003 Italy 12875749	Recurrence	Symptomatic episode lasting more than 10 min confirmed by ECG	RFA	30**	nd	nd	nd	nd	nd	HR=3.37	2.19-5.19	
Reduced encircled ablation area	Pappone, 2003 Italy 12875749	Recurrence	Symptomatic episode lasting more than 10 min confirmed by ECG	RFA	30**	nd	nd	nd	nd	nd	HR=3.58	2.41-5.32	

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Recurrent Afib	Pappone, 2003 Italy 12875749	Changes in hospitalization	Changes in hospitalization rates from 2 years before entering the study	Times/patient-year	RFA	nd	Nd	Nd	Nd	-0.7 (95%CI, -1.9 to 0.2)*	0.04*
					Medical	nd	nd	Nd	Nd	0.5 (95%CI, -0.7 to 2.8)*	0.43*
Non-recurrence	Pappone, 2003 Italy 12875749	Changes in hospitalization	Changes in hospitalization rates from 2 years before entering the study	Times/patient-year	RFA	nd	Nd	Nd	Nd	-1.8 (95%CI, -4.7 to –0.7)*	<0.001*
					Medical	nd	nd	nd	Nd	-1.2 (-2.9 to –0.8)*	0.01*
Recurrent Afib	Pappone, 2003 Italy 12875749	Changes in LAD size	Changes in LAD size between before and after therapy	cm	RFA	nd	Nd	Nd	Nd	-0.5 (95%CI, -1.0 to 0.1)*	Nd*
					Medical	nd	nd	Nd	Nd	-0.2 (95%CI, -0.5 to 0.1)*	Nd*
Non-recurrence	Pappone, 2003 Italy 12875749	Changes in LAD size	Changes in LAD size between before and after therapy	cm	RFA	nd	Nd	Nd	Nd	-1.1 (95%CI, -1.5 to -0.8)*	<0.01*
					Medical	nd	nd	nd	Nd	-0.3 (95%CI, -0.5 to –0.04)*	<0.01*

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Difference between before and after therapy in each subgroup in each therapy, not net difference between RFA and medical.
Although this is not a subgroup analysis (but rather one of the data explorations by multiple univariate analyses), in patients with permanent AF, those without relapse had statistically significantly smaller LAD than those with relapse at baseline and follow-up (<0.001 for both; however, statistically significance not shown in the other report (Pappone 2001 (RefID1211))). Age, AF duration, number of patients with structural heart disease, and EF had no statistically significant difference between relapse (+) group and relapse (-) group. (Pappone 2001 (RefID1230)).

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Pappone, 2003 Italy 12875749	RFA	30*	0	4/589 (1%)	0	nd	nd	nd		

*Median

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Pappone, 2003 Italy 12875749	No	NA	NA	Yes, 2%	nd	NA	Yes	Yes**	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	Yes	Nd (inferred yes)	Yes	No				
Explanation for Overall Quality Grade:				Observational study						

*observational study cannot be an A, retrospective study is always a C

**Some (not for recurrence of AFib, etc.)

N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Pappone, 2003 Italy 12875749		X	
Explanation for Applicability Grade:		Unclear about why included patients were sent to this institution	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Pappone, 2003 Italy 12875749	A large multi-center observational (retrospective case series) study. Survival and morbidity were mainly featured (some of which did not apply to our focused question). Unclear about blanking period.

Pappone 2004a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Pappone, 2004 Italy 14707026				X		TT/AG

NOTE: should partially overlap the Pappone 2003 (RefID 1015), which includes the Pappone 2001 and 2001 (RefID 1211 and 1230)

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Pappone, 2004 Italy 14707026	Paroxysmal AF	Sinus node disease, AV block, or permanent pacing 5% premature complexes on Holter monitoring Recent myocardial infarction (< 6 moths) LVEF < 45%. Beta-blocker therapy, Diabetes mellitus, renal failure, or thyroid dysfunction	01/1999-04/2002	Nd	297 (63%) out of 470 consecutive patients with paroxysmal AF who underwent circumferential PV ablation

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Pappone, 2004 Italy 14707026	nd	Circumferential PV ablation	297	100	49	nd	7.0	nd	3.9	58	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Pappone, 2004 Italy 14707026	nd	nd	CPVA Two additional LA lines - posterior LA and Mitral isthmus line Ablation of autonomic targets (only if identified)* (n=102) Pts with h/o AFL - RFA	nd	nd	40-85	60	61

*Vagal target sites were identified through the induction of vagal reflex during ablation, at which RF energy was delivered until such reflexes were abolished or for up to 30 seconds. Complete denervation was achieved in 98% (100/102). CPVA details previously described (2001 article).

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Pappone, 2004 Italy 14707026	Freedom from recurrent AF	AF lasted at least 30 sec, after 1 week blanking period	Circumferential PV ablation	12	267	297	90%	nd	nd	nd	nd	Nd

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 week

*Transtelephonic ECG once monthly until 12 mo.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Circumferential PV ablation + denervation	Pappone, 2004 Italy 14707026	Freedom from recurrent AF	AF lasted at least 30 sec, after 1 week blanking period	Circumferential PV ablation + denervation	12	101	102	99%	nd	<0.001 (log-rank)	nd	nd	Nd
Circumferential PV ablation only				Circumferential PV ablation only	12	166	195	85%	nd		nd	nd	Nd

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
Success of denervation (complete denervation) and %LA isolation were two statistically significant predictive factors to predict success of ablation (no relapse) in multivariate analysis by the Cox regression (p=0.025, HR=0.025 (95% CI, 0.014-0.750) and p<0.001, HR=0.72 (CI, 0.66-0.80), respectively). Age, Sex, AF duration, EF, LAD, %LA isolation, complete denervation, and structural heart disease were the analyzed covariates.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

Not reported

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Pappone, 2004 Italy 14707026	No	NA	NA	Yes (0%)	NA	NA	Yes	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	Yes	Nd**	Yes	No				
Explanation for Overall Quality Grade:				Observational study						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A
**Data on prior procedure or re-procedure not provided; thus unclear.

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Pappone, 2004 Italy 14707026		Moderate	
Explanation for Applicability Grade:		297 (63%) out of 470 consecutive patients with paroxysmal AF who underwent circumferential PVI; thus some patients were excluded.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Pappone 2004b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Pappone 2004 Italy 15520310	x				Circumferential Pulmonary Vein Ablation (CPVA) vs. modified CPVA; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Pappone 2004 Italy 15520310	18-70 y; symptomatic AF; NYHA I or II	Left atrial size>55 mm; LVEF <30%; recent MI; preexisting atrial tachycardia (AT) or flutter; and others	1/2002-1/2003	none	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Pappone 2004 Italy 15520310	nd	CPVA	280	63%	56.5	52	7.2	nd (?)	3.95	nd	A	moderate
		CPVA-mod	280									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Pappone 2004 Italy 15520310	n		CPVA: encircling lines at a distance >15 mm from PV ostia when possible with ipsilateral intravenous lines CPVA-mod: above + 2 additional lines (posterior LA connecting the contralateral superior & inferior PVs; along mitral isthmus between inferior aspect of left encircling line and the mitral annulus) Endpoint was voltage abatement of the local atrial electrogram by 80% or <0.1 mV. Completion of connecting lines assessed pre and post ablation activation and voltage maps.	n	8 mm	100	60	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Pappone 2004 Italy 15520310	primary	freedom from symptomatic incessant AT (continuous sequence of atrial activation; activation times >90% of the tachycardia cycle length; demonstration of entrainment by pacing)	CPVA	12 mo	252	280	90%					
			CPVA-mod		269	280	96%		0.005 (log rank)			
	secondary	freedom from recurrent AF	CPVA	12 mo			85.7%					
			CPVA-mod				87.1%		0.57			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	6 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
The presence of multiple gaps (gaps in a single PV were defined as a single gap and as multiple gaps if >1 PV) and chronic AF were the strongest predictors of AT: CPVA adj HR 3.84 (95%CI 1.86- 7.89); multiple gaps adj HR 25.19 (95%CI 11.01-57.30); chronic AF adj HR 22.28 (6.72-73.87); all P<0.001													

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Pappone 2004 Italy 15520310	CPVA		0/280	2/280 (0.7%)	0/280				access site hematoma	3/280 (1.1%)
	CPVA-mod		0/280	2/280 (0.7%)	0/280				access site hematoma	2/280 (0.7%)
	CPVA or CPVA-mod								AT leading to syncope	8/560 (1.4%)
	CPVA or CPVA-mod								AT leading to syncope leading to cardioversion	5/560 (0.9%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Pappone 2004 Italy 15520310	y	y	y	y	y	y	y	NA	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	unclear	y	y				
Explanation for Overall Quality Grade:		result included patients with reablation								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Pappone 2004 Italy 15520310		X	
Explanation for Applicability Grade:		relatively young patients, NYHA I or II	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Pappone 2006 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Pappone 2006 Italy 17161267	X				CPVA vs. AAD; KQ 1, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Pappone 2006 Italy 17161267	Paroxysmal AF with failed AADs; >18 or <70 y; creatinine <1.5 mg/dL; AF history > 6 mo; AF > 2 episodes/mo in the last 6 mo	LAD >65 mm; LVEF <35%; CHF>NYHA class II; prior amiodarone, flecainide, or sotalol; prior catheter or surgical ablation; and others (see text)	2005	6 wk	patients could be considered for crossover to CPVA after 2 trials of AAD

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Pappone 2006 Italy 17161267	nd	circumferential pulmonary vein ablation	99	100%	56	67	6	nd	3.9	61	B	moderate
		flecainide 100 mg q12h; sotalol 80 mg q8h; amiodarone 200 mg/d (maintenance dose)	99									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Pappone 2006 Italy 17161267	n*	assessed completeness across mitral isthmus lines (?) Yes – as previously described	circumferential pulmonary vein ablation (CPVA) (Including roof and mitral line) + cavotricuspid isthmus ablation (right sided empiric atrial flutter ablation)	n	8 mm (50)	60-100	50-65	35
					irrigated 3.5 mm (49)	25-40	35-40	

*Of note, pre and post ablation bipolar voltage maps of LA performed. (as previously described)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Pappone 2006 Italy 17161267	primary end point (Kaplan-Meier analysis)	freedom from documented recurrent atrial tachyarrhythmia (lasted ≥ 30 s)	CPVA	12 mo	85	99	86%					
			AAD	12 mo	24	99	22%		<0.001			
"Among patients assigned to CPVA, 9 summed up 24 hospital admissions for cardiovascular causes, including repeat procedures. In the ADD group, 167 cardiovascular event-related hospital admissions occurred, not including the hospitalizations for crossover to CPVA (p<0.001)."												

Duplicate one row per outcome and per RFA intervention.

* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	6 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
No independent predictors of AF recurrences were found in the ablation group.													
LVEF (HR 1.08, 95% CI 1.03-1.13, P=0.003); HTN (HR 2.31, 95% CI 1.34-3.97, P=0.003); AF duration (HR 1.03, 95%CI 1.01-1.11, P=0.015) were independent predictors of drug failure in AAD group.													

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Pappone 2006 Italy 17161267	8 mm CPVA				mild TIA 1/99 (1%)					
	irrigated tip CPVA								small pericardial effusion	1/99 (1%)
	flecainide								pro-arrhythmia	3/33 (9%)
	amiodarone								thyroid dysfunction	7/33 (2.1%)
	sotalol								sexual dysfunction	11/33 (33%)
									permanent drug withdrawal 2º to adverse events	23/99 (23%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Pappone 2006 Italy 17161267	y	nd	nd	y	n	n	y	NA	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	n				
Explanation for Overall Quality Grade:		No descriptions on appropriate randomization technique and allocation concealment								

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Pappone 2006 Italy 17161267		x	
Explanation for Applicability Grade:		relatively young patients with low NYHA classification	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Piorkowski Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Piorkowski 2008 Germany 18684284					"case-control study": patients (controls) treated with circumferential left atrial PV ablation between October 2004 and December 2005 were matched with subsequent patients (cases) ablated between Jan 2006 and October 2006	MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Piorkowski 2008 Germany 18684284	Patients (controls) treated with circumferential left atrial PV ablation between October 2004 and December 2005 using a conventional nonsteerable transseptal sheath (Mullins; Cook Inc., Bloomington, IN, USA) were matched with subsequent patients (cases) ablated between Jan 2006 and October 2006 with a similar line concept but mapping and ablation performed with a manually controlled steerable sheath (Agilis, St. Jude Medical, St. Paul, MN, USA). The matching criteria included patient's age, patient's gender, paroxysmal or persistent AF, duration of AF history, previous AF ablations, and underlying cardiac disease.	nd	Controls: October 2004 and December 2005 Cases: Jan 2006 and October 2006	AAD was discontinued and patients received a beta-blocker (if tolerated) after ablation. In case of early postinterventional AF recurrences within the 2 postinterventional in hospital days, cardioversion was performed and AADs (flecainide or amiodarone) were added for at least 3 months. Afterward the medication was adapted on an individual basis.	Persistent AF=20% Lone AF=53% Prior AF ablation=12%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Piorkowski 2008 Germany 18684284	nd	circumferential left atrial PV ablation using a conventional nonsteerable transseptal sheath (controls) or a manually controlled steerable sheath (cases)	166	80	55	73	4.4	nd	3.7	61	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Piorkowski 2008 Germany 18684284	yes	100% [endpoint of the procedure was the completion of the intended lesion lines with either complete PVI or conduction delay into the PVs]	In patients with persistent AF, additional ablation lines were placed between the circular lesions and along the roof of the left atrium as well as between the circular lesion and the mitral annulus	no	Irrigated tip (F-Type, Navi-Star ThermoCool, Biosense Webster)	Standard: 40 At the posterior LA near to the esophagus: 25 At the anterior aspects of circumferential ablation: 50	Standard: 50	Cases: 42 min Controls: 40 min

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Piorkowski 2008 Germany 18684284	AF recurrences	On or off AADs. Exclude repeat procedures	circumferential left atrial PV ablation using a manually controlled steerable sheath (cases)	6	19	79			0.0009			
			circumferential left atrial PV ablation using a conventional nonsteerable transseptal sheath (controls)	6	35	83						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	yes		
Was a blanking period (time when AFib episodes were not recorded) used?	no	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Piorkowski 2008 Germany 18684284	circumferential left atrial PV ablation using a conventional nonsteerable transseptal sheath (controls) or a manually controlled steerable sheath (cases)		0	2/166 (1.2%)		0	Vascular access complications = 3/166 (1.8%)		Phrenic nerve palsy	0
									Thromboembolic event	1/166 (0.6%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Piorkowski 2008 Germany 18684284	no	NA	NA	yes	nd	no	yes	yes	yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	no				
Explanation for Overall Quality Grade:				Prospective study, non-concurrent control so cannot exclude learning effects						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Piorkowski 2008 Germany 18684284		x	
Explanation for Applicability Grade:		Matching controls	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Piorkowski 2008 Germany 18684284	4 of the 83 patients (4.8%) underwent reablation between 3 and 6 months of follow-up. They were excluded from the analyses at 6 month of follow-up. The original study compared AE between cases and controls. However the rates of AE reported in this form were re-calculated using all 166 patients (both cases and controls).

Proclemer Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Proclemer 2008 Italy 18667447				X (only PVI data were extracted; AVJ did not meet inclusion criterion)	KQ 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Proclemer 2008 Italy 18667447	drug refractory AF		2002-2006	AAD for 3 mo; continued past 3 mo in those with AF recurrences	only used data on adverse events

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Proclemer 2008 Italy 18667447	nd	PVI	144	65	56	75	nd	NYHA III-IV: 6%		59	not rated	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Proclemer 2008 Italy 18667447	y (implied)	ostial PVI	CVT ablation in pts with AFL	n	3.5 mm irrigated (7% used 4 mm tip)	40	45	39

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Proclemer 2008 Italy 18667447	Freedom from symptomatic AF	Freedom from symptomatic AF (14% had redo and 40% on AAD)	PVI	25 mo (median)	113	144	78%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Proclemer 2008 Italy 18667447	ostial PVI	25 mo (median)		5/144 (3.5%)	0/144 (0%)			0/144 (0%)	metabolic coma At 5 mo (unrelated to PVI)	1/144 (0.7%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Proclemer 2008 Italy 18667447	n	NA	NA	NA	n	n	y	n	n	
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	`n	n	y	n				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Richter Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Richter, 2008 Richter, 2006 Austria 18328850 17038349				X (no concurrent comparative groups; comparing 2 cohorts with different recruitment periods)		MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Richter, 2008 Richter, 2006 Austria 18328850 17038349	Patients undergoing catheter ablation of either symptomatic drug-resistant paroxysmal or persistent AF.	Pregnancy, ongoing infections, intracardiac thrombosis, inadequate anticoagulation prior to admission, contraindications to anticoagulation, history of MI or cardiac surgery within the last 3 months, and refusal to give informed consent. Received RFA but excluded from analyses: Post-ablation stimulation test could not be carried out because of inability to achieve stable sinus rhythm despite repeat transthoracic cardioversion after ablation or respiratory failure precluding continuation of the procedure.	May 2002 to April 2004 (Lasso) After April 2004 (CARTO)	Class I or III antiarrhythmic drugs (amiodarone, sotalol, flecainide, and propafenone), if present before ablation, were continued for ≥3 months	Structural heart disease= 22% Mean BMI= 26.6

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Richter, 2008 Richter, 2006 Austria 18328850 17038349	No financial support for this study	Lasso-guided PVI (n=83)	234*	92	57	72	6.1	nd	4.5	61	C	Wide
		CARTO-guided WACA (n=151)		57								

*No breakdown patient characteristics per intervention was reported

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Richter, 2008 Richter, 2006 Austria 18328850 17038349	yes	Lasso-guided RFA (n=83): 100% [elimination of all ostial vein potentials and complete entrance block into PVs]	none	yes	4 mm tip (Biosense Webster Inc.)	30	55	22
	yes	CARTO-guided RFA (n=151): 100% [80% reduction in the amplitude of the local bipolar electrogram or a total of 40 s of energy delivery]	WACA, Roof line and mitral isthmus line 37 patients with a history or inductility of isthmus-dependent right atrial flutter also underwent ablation of the cavotricuspid isthmus	yes	8 mm tip (Navistar, Biosense Webster Inc.)	50	55	32

Inducible if duration greater than 1 minute.
AF> 5 min DCCV

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Richter, 2006 Austria 17038349	Freedom from recurrent AF		Lasso-guided RFA	6	53	83						
			CARTO-guided RFA	6	91	151						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (24 or 48 hr Holter monitoring at follow-up visits)		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Early recurrence of AF (within the first 48 hours after ablation)	Richter, 2008 Austria 18328850	AF-free survival analysis	Multivariate Cox regression analysis (variables included early recurrence of AF, type of AF, sex, age, BMI, antiarrhythmic drug use during follow up, applied ablation technique, structural heart disease, LVEF, left atrial size)	Lasso- or CARTO-guided RFA	12.7			HR: 2.29	1.54-3.42	<.001	2.17	1.45-3.25	<.001
Type of AF (paroxysmal vs. persistent AF)								HR: 1.94	1.28-2.93	.002	1.79	1.19-2.69	.006
Sex								HR: 0.9	0.57-1.41	.65	nd	nd	ns
Age								HR: 0.99	0.98-1.01	.48	nd	nd	ns
BMI								HR: 1	0.95-1.05	.92	nd	nd	ns
Antiarrhythmic drug use during follow-up (class I or III)								HR: 0.81	0.53-1.27	.33	nd	nd	ns
Applied ablation technique								HR: 1.27	0.83-1.95	.28	nd	nd	ns
Structural heart disease								HR: 0.93	0.57-1.53	.79	nd	nd	ns
LVEF								HR: 0.97	0.59-1.6	.92	nd	nd	ns
Left atrial size								HR: 1	0.97-1.03	.98	nd	nd	Ns
Type of AF (paroxysmal vs. persistent AF)	Richter, 2006 Austria 17038349	AF-free survival analysis	Multivariate Cox regression analysis (variables included type of AF, inducibility of AF, sex, age, BMI, antiarrhythmic drug use during	Lasso- or CARTO-guided RFA	12.7			HR: 1.94	1.28-2.93	.002	1.77	1.17-2.67	.007
Inducibility of AF (inducibility of AF > duration of 1 min)								HR: 2.32	1.56-3.47	<.001	2.19	1.46-3.27	<.001
Sex								Same as data reported					

Age			follow up, applied ablation technique, structural heart disease, LVEF, left atrial size)					in Richter, 2008 Austria 18328850 (above)					
BMI													
Antiarrhythmic drug use during follow-up (class I or III)													
Applied ablation technique													
Structural heart disease													
LVEF													
Left atrial size													
Paroxysmal AF	Richter, 2008 Austria 18328850	Freedom from recurrent AF		Lasso- or CARTO-guided RFA	12.7	105	165			nd			
Persistent AF						31	69						
Paroxysmal AF with early AF recurrence	Richter, 2008 Austria 18328850	Ablation failure	Long-term AF recurrence	Lasso- or CARTO-guided RFA	12.7	30	64	HR: 2.05	1.24-3.41	.005			
Paroxysmal AF without early AF recurrence						30	101						
Persistent AF with early AF recurrence	Richter, 2008 Austria 18328850	Ablation failure	Long-term AF recurrence	Lasso- or CARTO-guided RFA	12.7	25	37	HR: 2.35	1.2-4.6	.013			
Persistent AF without early AF recurrence						13	32						
Early AF recurrence	Richter, 2008 Austria 18328850	Ablation failure	Long-term AF recurrence	Lasso-guided RFA	12.7	17	31	HR: 2.29	1.16-4.55	.017			
Without early AF recurrence						16	52						
Early AF recurrence	Richter, 2008 Austria	Ablation failure	Long-term AF recurrence	CARTO-guided RFA	12.7	38	70	HR: 2.25	1.39-3.69	.001			

Without early AF recurrence	18328850					27	81						
Paroxysmal AF	Richter, 2006 Austria 17038349	Freedom from recurrent AF		Lasso-guided RFA	6	51	76			nd			
Persistent AF						2	7						
Paroxysmal AF	Richter, 2006 Austria 17038349	Freedom from recurrent AF		CARTO-guided RFA	6	60	89			nd			
Persistent AF						31	62						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Richter, 2008 Richter, 2006 Austria 18328850 17038349	no	NA	NA	Yes (assumed)	nd	Yes (0% dropout)	yes	yes	yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	no	yes	no				
Explanation for Overall Quality Grade:				Retrospective. Lasso and CARTO groups were not comparable. However, multivariate analyses controlling for ablation techniques and other confounders are useful.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Richter, 2008 Richter, 2006 Austria 18328850 17038349			x
Explanation for Applicability Grade:		Wide for CARTO group only. Moderate (due to 92% paroxysmal AF and N<100) for Lesso group (but should be excluded, see reviewer's comment). Wide for both groups combined.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Richter, 2008 Richter, 2006 Austria 18328850 17038349	No breakdown patient characteristics per intervention were reported. Much more patients in Lasso group were paroxysmal AF than CARTO group (92 vs. 57%). Data applied to Lasso-guided group only should be excluded for our review purpose because 4-mm tip was used in this group.

Rossillo Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Rossillo, 2008 Italy 18268419		X				MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Rossillo, 2008 Italy 18268419	PVI group: consecutive patients who were referred for ablation of symptomatic drug-refractory AF AAD: age-, sex- and heart disease-matched patients with persistent AF who underwent electrical cardioversion between May 2002 and July 2003. *The risk for stroke (% of medium- and high-risk patients) are similar in both groups.	None reported	PVI group: 2002 to 2004 AAD: 2002 to 2003	PVI group: no patients received anti-arrhythmic drugs unless arrhythmic recurrences developed during follow-up Controls: all patients were pre-treated with anti-arrhythmic drug, and the treatment was continued or stopped during follow-up according to the referring physician's indications. 29 (34%) patients stopped anti-arrhythmic drug Rx at least 1 month after electrical cardioversion.	19% vs. 6% (PVI vs. AAD) were low risk for stroke (i.e. age<65, no HTN, DM, CHF or previous CVA), p<0.01

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Rossillo, 2008 Italy 18268419	nd	PVI	85 PVI group	32**	62	84	8 (range 1-24)	72% high risk for stroke*	4.4	58	C	moderate
			85 AAD group	0	62	84	unknown	76% high risk for stroke*	4.2	56		

*High risk: age>65, plus hypertension or diabetes or CHF or previous cerebrovascular accident
**51% persistent AF; 18% permanent AF

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Rossillo, 2008 Italy 18268419	yes	100% [all 4 pulmonary veins were disconnected (Lasso)]*	72 pts: SVC isolation	no	8 mm tip catheter (Biosense-Webster)	Energy was controlled by progressively increasing power until scattered microbubbles were observed by ICE	nd	nd

*In addition, complete electrical isolation of the superior vena cava was achieved in 72 patients (85%). The other 13 patients, disconnection was not possible owing to stimulation of the phrenic nerve or proximity of the sinus node to the ablation site.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Rossillo, 2008 Italy 18268419	Stable sinus rhythm	nd	PVI	15	70**	85			nd			
			AAD (antiarrhythmic Rx; electrical cardioversion)	16	34	85						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**In 10 patients, a previous ineffective anti-arrhythmic drug was necessary to maintain stable sinus rhythm

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes, asymptomatic AF was evaluated by means of monthly 24-h Holter recording during the first 3 months of follow-up and daily pulse check.		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	8 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Rossillo, 2008 Italy 18268419	PVI	15			1/85 (1%)*					
	AAD (anti-arrhythmic Rx; electrical cardioversion)	16			5/85 (5.8%)**			1/85 (1%)***		

*stoke occurred just after electrical cardioversion at the end of the PVI procedure in a 74-year-old patient with permanent AF and history of transient ischemic attack
**Intraprocedural stroke (not related to anti-arrhythmic drug discontinuation) is not considered in the analysis. The difference in stroke event between cases and controls were statistically significant (0/84 vs. 5/85, p=0.03). In 2 of the 5 patients had stoke among the controls, the stroke was fatal. See specific comment section for the characteristics of these 5 patients who has stoke.
***one patient with stroke happened <30 days and died from the stroke

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Rossillo, 2008 Italy 18268419	no	NA	NA	nd	nd	nd	no	no	no	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		no	yes	no	yes	no				
Explanation for Overall Quality Grade:				Week study design for clinical outcomes, PVI and AAD groups were not comparable, poor reporting (except for the adverse events); statistical analyses for adverse events only						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Rossillo, 2008 Italy 18268419		x	
Explanation for Applicability Grade:		Mixed types of AF patients for AF but n<100	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Rossillo, 2008 Italy 18268419	Clinical characteristics of the patients with stroke

Patient	Group	Age	Gender	Time to Stoke	Rx	ECG at recovery	Death
1	AAD	70	Female	<30 days	Warfarin	AF	Yes
2	AAD	64	Male	>30 days	Aspirin	AF	No
3	AAD	70	Female	>30 days	Warfarin	Sinus rhythm	No
4	AAD	71	Female	>30 days	Warfarin	AF	No
5	AAD	73	Male	>30 days	Aspirin	Sinus rhythm	Yes

Rotter 2005a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Rotter,2005 France 16403060				X (data were collected prospectively per report)	Only adverse events-related data were relevant to our project.	TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Rotter,2005 France 16403060	• Symptomatic drug-refractory paroxysmal AF • Paroxysmal AF • Duration of episode <7 days • No previous ablation for AF • No use of amiodarone (< 3 mo)	nd	nd	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Rotter,2005 France 16403060	•Swiss National Foundation for Scientific Research •Neil Hamilton Fairley and Ralph Reader Fellowship •National Health and Medical Research Council •National Heart Foundation of Australia	PV antrum? ablation + additional lines	181	100	54	85	6	nd	4.2	68	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Rotter,2005 France 16403060	Yes	100% [nd]	Cavo-tricuspid isthmus line (n=181)* Mitral isthmus line (n=57)* Roof line (n=58)*	Yes	3.5 mm irrigated-tip (Celsius ThermoCool or Navistar)	25-35 (PV antrum ablation) 35-40 (additional lines)	50	59**

*Not mutually excusive

**Difference between with and without additional substrate modification was 20 min (69 and 49, respectively, P<0.001)

Inducibility – three predefined sites: midcoronary sinus, left and right atrial appendage. Patients with AF > 10 min and pts with persisting AF

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
No clinical results of interest reported except for adverse events.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Rotter,2005 France 16403060	PV antrum? ablation + additional lines	nd	nd	2/181 (1%)*	nd	nd	nd	Nd		

*Both two cases underwent additional substrate modification.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Rotter,2005 France 16403060	No	NA	NA	nd	nd	nd	NA	NA	NA	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	NA	NA	NA	NA				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Rotter,2005 France 16403060			Wide
Explanation for Applicability Grade:		Only paroxysmal AF	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Rotter 2005b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Rotter 2005 France 15741228	y				Primary endpoint is the reduction of fluoroscopy time by 30%	TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Rotter 2005 France 15741228	Drug refractory symptomatic AF	nd	nd		

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Rotter 2005 France 15741228	Swiss National Foundation for Scientific Research, National Health Research Council of Australia, National Heart Foundation of Australia	Fluoroscopy-guided PVAI	37	Nd[#]	52	88	nd	nd	4.3	66	B	Moderate
		Fluoroscopy+NavX-guided PVAI	35									

Persistent AF was reported as 7%, otherwise, unclear.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min[#]
Rotter 2005 France 15741228	y	Elimination or dissociation of the PV potentials as determined by circumferential mapping	Roof-line (LA) if persistent or inducible sustained AF after PVAI (n=18 for NavX arm and n=21 for fluoroscopy arm)	y	4 mm irrigated	25-35 (PVAI), 35-40 (Roof-line)	50	33 for PVAI and 10.2 for Roof-line (NavX arm)
								35 for PVAI and 12.8 for Roof-line (fluoroscopy arm)

P=0.3 (PVAI) and P=0.2 (Roof-line), respectively, between the two arms.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Rotter 2005 France 15741228	Freedom from arrhythmia	Any atrial arrhythmia after single procedure (7 of each arms with AAD)	Fluoroscopy-guided PVAI	6.2	29	37	78% (KM)		0.87 (Log-rank)			
			Fluoroscopy+NavX-guided PVAI	7.2	26	35	74% (KM)					
Rotter 2005 France 15741228	Reprocedure	Nd	PVAI	6.7	17	72	24% (Crude?)					
Rotter 2005 France 15741228	"Arrhythmia free"	Any atrial arrhythmia after necessary procedures (mean 1.24 procedure) with or without AAD	PVAI	6.7	65	72	90% (Crude?)					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Y		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Rotter 2005 France 15741228	PVAI	6.7	No events observed							

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Rotter 2005 France 15741228	y	nd	nd	y	nd	y	y	n	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	y	y	N				
Explanation for Overall Quality Grade:		Poor reporting on methodology and definition used downgraded the rating.								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Rotter 2005 France 15741228		Moderate	
Explanation for Applicability Grade:		Inclusion criteria were not fully reported.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Saad Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Saad 2003 USA 12693885				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Saad 2003 USA 12693885	Symptomatic drug-refractory AF	nd	nd	nd	May overlap other studies conducted at the Cleveland Clinic Foundation

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Saad 2003 USA 12693885	none	Ostial PVI	335	52	54	78	5.4	nd	4.2	53	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Saad 2003 USA 12693885	Yes*	Nd [entrance block]	nd	nd	4 mm 8 mm (Biosense Webster) Cooled-tip (Chilli)	nd	nd	nd

*Ablation energy for PVI was delivered inside the PVs (during only early period) or at the PV-LA junction identified by ICE or PV angiography (vast majority). For patients who underwent electroanatomical mapping, only elimination of ectopic activity initiating AF, instead of PVI, was considered procedure endpoint in some patients. In patients in whom the electro anatomic system was used, only the superior PVs were targeted unless firing from other veins was noted.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Circular mapping-guided	Saad 2003 USA 12693885	Cure	Cure of AF after the first procedure without AAD (detailed definition of relapse and blanking period unclear)	Ostial PVI	6 mo	212	264	80%					
Circular mapping-guided	Saad 2003 USA 12693885	Cure	Cure of AF after the last procedure without AAD (detailed definition of relapse and blanking period unclear)	Ostial PVI	6 mo	243	264	92%		nd			
Electro anatomically guided						21	71	30%					
Circular mapping-guided	Saad 2003 USA 12693885	Re-procedure	Second procedure (details unclear)	Ostial PVI	6 mo	35	264						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (inferred)		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	NA

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Saad 2003 USA 12693885	Ostial PVI	5.2	18/335 (5%)*	nd	nd	nd	nd	nd		

*All patients developed at least one severe stenosis (>70%) by CT. Eight patients (44%) were asymptomatic.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Saad 2003 USA 12693885	No	NA	NA	Yes (inferred)	nd	nd	nd	nd	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	No	Yes	Yes (inferred)	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Saad 2003 USA 12693885			Wide
Explanation for Applicability Grade:		No clear exclusion criteria, inferring wide applicability.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Sauer 2006a Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Sauer, 2006 US 16945795			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Sauer, 2006 US 16945795	All patients referred to UPHS for ablation of symptomatic drug refractory AF	None	Nov 2000 to Aug 2004	6 weeks for paroxysmal AF patients; 6 months for persistent and permanent AF patients	Persistent AF: 33% Permanent AF: 5% CAD: 11.6%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Sauer, 2006 US 16945795	nd	PVI	424	60	53.5	76	nd	nd	4.4	59	B	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Sauer, 2006 US 16945795	yes	100% [elimination of all provocable AF triggers, Lasso]	nd	yes	4-mm (74%) or 8-mm tip (26%) NaviStar mapping/ablation catheter (Biosense Webster, Diamond Bar, CA)	4-mm: 50 8-mm: 70	50-52	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Sauer, 2006 US 16945795	AF cure	No recurrent AF and no use of any AAD	PVI	21.7	243	424						
	Maintenance of sinus rhythm after a single procedure	Including those who continued previously ineffective AAD	PVI	21.7	301	424						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	no		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	6 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Acute PV reconnection (conduction entry or exit was observed at any time during the procedure after initial vein disconnection)	Sauer, 2006 US 16945795	AF cure	No recurrent AF and no use of any AAD	PVI	21.7	119	213			0.97			
No acute PV reconnection						124	211						
Acute PV reconnection	Sauer, 2006 US 16945795	Maintenance of sinus rhythm after a single procedure	Including those who continued previously ineffective AAD	PVI	21.7	153	213			0.52			
No acute PV reconnection						148	211						
Acute PV reconnection	Sauer, 2006 US 16945795	AF control	AF cure and no recurrent AF on AADs that were previously ineffective	PVI	21.7						RR= 1.27	0.83-1.93	0.28
No acute PV reconnection													

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Sauer, 2006 US 16945795	mo	NA	NA	0%	nd	yes	yes	yes	yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	no	No				
Explanation for Overall Quality Grade:				Data were prospectively collected but post hoc analyses						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Sauer, 2006 US 16945795			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Sauer, 2006 US 16945795	Data were prospectively collected. 4-mm tip catheter was used in most patients but no separate analyses for 8-mm

Sauer 2006b Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Sauer, 2006 US 16831982			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Sauer, 2006 US 16831982	Patients referred to UPHS	nd	Nov 1998 to March 2005	6 weeks for paroxysmal AF patients; 6 months for persistent and permanent AF patients. Typically class IC drug if patient was without structural heart disease or sotalol if they had heart disease	Persistent AF: 35% Permanent AF: 4% CAD: 9%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Sauer, 2006 US 16831982	nd	PVI	629	61	54.6	73	6.9	1.9	4.4	58	C	wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Sauer, 2006 US 16831982	yes	100% [isolation of all PVs was performed if no trigger identified. Entry and exit block confirmed]	AVNRT was ablated if discovered to be an AF trigger.	yes	nd (~70% 4mm; ~30% 8mm inferred from other articles in the same cohort)	nd	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Sauer, 2006 US 16945795	Freedom from AF	No recurrent AF without use of any AAD	PVI	21.4	350	624						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	no		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	6 weeks

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Patients with atrioventricular nodal reentrant tachycardia (AVNRT)	Sauer, 2006 US 16945795	Freedom from AF	No recurrent AF without use of any AAD	PVI	21.4	21	24***			<.01	OR=3.58	1.31-6.18	0.03
Patients without AVNRT						329	602						
Patients with atrioventricular nodal reentrant tachycardia (AVNRT)	Sauer, 2006 US 16945795	Maintenance of sinus rhythm after a single procedure	Including those who continued previously ineffective AAD	PVI	21.4	21	24***						
Patients without AVNRT						427	602			0.12			

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Sauer, 2006 US 16831982	PVI (~70% 4-mm tip; ~30% 8-mm tip)								"major complications"	2.5%

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Sauer, 2006 US 16945795	no	NA	NA	0	nd	yes	yes	yes	no	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		no	yes	yes	no	no				
Explanation for Overall Quality Grade:		Data were prospectively collected but post hoc analyses. Ablation procedure was not described in detail.								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Sauer, 2006 US 16945795			x
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Schwartzman Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Schwartzman 2003 US 14574043		x			KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Years of enrollment	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Schwartzman 2003 US 14574043	symptomatic drug resistant AF; ≥ 3 episodes of sustained AF solely from PV myocardium during EP study	inadequate number of sustained AF; extra-venous origin	nd		non-concurrent comparison; last group (vestibule encircling) had significantly smaller proportion of patients with prior amiodarone therapy

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Schwartzman 2003 US 14574043	nd	focal	47	nd	55	81	nd	nd	4.0	56	C	narrow
		vein encircling	42									
		vestibule encircling	23									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Schwartzman 2003 US 14574043	y	100% of all patients in vein encircling and vestibule encircling group [entrance block during sinus rhythm]		y	nd	30	50	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Schwartzman 2003 US 14574043	clinical success	absence of detectable AF without type I or III AAD in the 6th post-procedure mo	focal	6 mo			47%					
			vein encircling				69%					
			vestibule encircling				87%		<0.05			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	n		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Schwartzman 2003 US 14574043	focal or vein encircling or vestibule encircling	6 mo					femoral pseudoaneurysm, 3/112 (2.7%); AV fistula, 2/112 (1.8%);		femoral bleeding requiring transfusion	1/112 (0.9%)
									transient non-cardiogenic pulmonary edema	1/112 (0.9%)
	focal								*stenosis of targeted zone	4/47 (9%)
	vein encircling								stenosis of targeted zone	2/42 (5%)
	vestibule encircling								stenosis of targeted zone	0/23

*"Significant" stenosis of targeted zone.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Schwartzman 2003 US 14574043	n	NA	NA	nd	n	n	y	n	n	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		no	no	no	yes(?)	no				
Explanation for Overall Quality Grade:				incomplete reporting; non-concurrent comparison; not totally comparable baseline characteristics						

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Schwartzman 2003 US 14574043	X		
Explanation for Applicability Grade:		relatively few patients; single center experience	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Shah Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Shah 2007 Switzerland 17655668		x				EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Shah 2007 Switzerland 17655668	Drug refractory symptomatic AFib	LA thrombi	nd	No, unless recurrence	15% structural heart disease

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	
Shah 2007 Switzerland 17655668	Medtronic, Biosense Webster, Guidant (and consultancy for others)	PVI Linear LA ablation PRN	113	64%	56	81	6 yr		4.3	<40%: 6%		
		PVI Linear LA ablation PRN Cavotricuspid isthmus (CTI) ablation	75	85% (P<.001)					4.0 (P=.02)			

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Shah 2007 Switzerland 17655668	Yes	100%	Supplemental LA lines if persistent or permanent AFib or AFib after PV isolation: L to R superior PV ostia (roof line); L inferior PV ostium to posterolateral mitral annulus (mitral line) (9 patients)	No (except for Aflutter if necessary)	Irrigated 7F (ThermoCool)	35	nd	43
			Also CT isthmus ablation Supplemental LA lines in 48 patients					48

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Shah 2007 Switzerland 17655668	AFib recurrence	unclear (probably including asymptomatic holter AFib)	PVI	30 (16-55 range)	28% (32)	113			NS			
			PVI + CTI ablation		25% (19)	75						
	AFib-free survival	Off AAD	PVI	30 (16-55 range)		113			NS by KM plot			
			PVI + CTI ablation			75						
	SR without AFib, Aflutter, or AAD at end of followup	(including additional ablations)	PVI	30 (16-55 range)	79% (89)	113			NS			
			PVI + CTI ablation		82% (61.5)	75						
	SR without AFib or AAD at end of followup	(including additional ablations)	PVI	30 (16-55 range)	84% (95)	113			NS			
			PVI + CTI ablation		88% (66)	75						
	Arrhythmia free (including on AAD) at end of followup	(including additional ablations)	PVI	30 (16-55 range)	86% (97)	113			NS			
			PVI + CTI ablation		89% (67)	75						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Shah 2007 Switzerland 17655668	PVI	30 (16-55 range)	2.6% (3/113, 150 procedures) >50%, asymptomatic, no treatment	0.8% (1/113, 150 procedures)					Embolic events (not defined	0.8% (1/113, 150 procedures)
	PVI + CTI ablation		0% (0/75, 98 procedures)	2.6% (2/75, 98 procedures)						0% (0/75, 98 procedures)

NS for all comparisons

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Shah 2007 Switzerland 17655668	No	NA	NA	Yes	No	Yes	Yes	No	No	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No (unclear if asymptomatic included)	Yes	Yes	No				
Explanation for Overall Quality Grade:				Reported % not n, which led to 1 discrepancy						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Shah 2007 Switzerland 17655668	4 lost to follow-up and 2 died of noncardiac, nonembolic causes. ITT analysis implied

Sheikh Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Sheikh, 2006 US 17318445	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Sheikh, 2006 US 17318445	AFib refractory to AAD	Prior ablation Chronic or persistent AFib	nd	AAD x 1 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Sheikh, 2006 US 17318445	nd	PVI	50	100%	59	63	nd	nd	4.1	54	C	Moderate
		PVI+ ablation lines	50									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Sheikh, 2006 US 17318445	Yes	Yes Lasso used in first 20 pts and then basket catheter used in 80 until PVs were electrically silent.	WACA WACA + Lines: Left inferior PV to the MV annulus Connecting superior PVs (roof line)	No	nd	nd	Goal: 50-55°	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Sheikh, 2006 US 17318445	NSR off AAD		PVI alone	9 mo	14 (41-27**)	50						
			PVI+ Lines		14 (45-31)	50						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
3 patients with post-procedure AFL (within first 3 months, implied) had AFL ablation.
** # in NSR minus # using AAD

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Only partially*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	3 mo

* Holters done only if symptomatic or if rhythm strip in clinic was suggestive.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Sheikh, 2006 US 17318445	PVI alone		0/50	1/50 (2%) surgical pericardial window	1/50 (2%) TIA				Small pericardial effusion with pericarditis, resolved with Rx	1/50
	PVI+ Lines		0/50	0/50						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Sheikh, 2006 US 17318445	Yes	nd	nd	Yes (0%)	No (nd)	Yes	Yes	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No Catheter tip not described	Yes	Essentially (AFL ablation was done)	Only partially	No				
Explanation for Overall Quality Grade:				Unknown catheter. Only partial assessment for asymptomatic AFib						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
		Moderate	
Explanation for Applicability Grade:		Small	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Shimano Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Shimano 2008 Japan 18550508			X			EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Shimano 2008 Japan 18550508	Paroxysmal or persistent AF	Valvular heart disease, HD, previous RFA	2004-2005	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Shimano 2008 Japan 18550508	Gov't and Foundation	RFA	62	69%	59	77	4.8		4.0	63	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Shimano 2008 Japan 18550508	Yes	Ostial, guided by lasso catheter complete elimination of electrical conduction into PV		Yes	nd	30W	55°	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Shimano 2008 Japan 18550508	Recurrent AF	(unclear how maintenance on AAD counted)	RFA	2.1 yr	15	62	24%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	No?	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
	nd									

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Shimano 2008 Japan 18550508	No	NA	NA	Yes	NA	~Yes	OK	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	No	Yes	Yes	No				
Explanation for Overall Quality Grade:				Unclear procedure and outcome.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Spragg Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Spragg 2008 US 18462327				X		EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Spragg 2008 US 18462327	Catheter ablation for AF	None	2001-2007	n/a	only complications

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Spragg 2008 US 18462327	nd Senior author does industry consulting	RFA	517 (641 procedures)	54%	57	78	nd	nd	4.7	57	B	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Spragg 2008 US 18462327	Yes (endpoint since 2004)	2001-03: Segmental ablation targeting PV ostia (17%) 2003-07: Wide, circumferential linear ablation (83%)		No	8 mm (38%) or 4 mm irrigated (62%)	Segmental: 50W (target) Wide: 30 W anterior, 20 W posterior	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	NA		
Was a blanking period (time when AFib episodes were not recorded) used?	NA	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Spragg 2008 US 18462327	RFA		1/641* (0.2%)	8/641* (1.2%)	7/641* (1.1%)	0/641*	"Vascular injury" 11/641* (1.7%) 4 required surgery	0/641*	Hemothorax	1/641* (0.2%)
									Heart block	1/641* (0.2%)
									Lung injury	1/641* (0.2%)
									MV injury	1/641* (0.2%)

* 641 procedures in 517 patients
There are analyses of temporal trends and of complication predictors

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Spragg 2008 US 18462327	No	NA	NA	No	NA	~Yes	OK	No	Yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		OK	NA	NA	NA	NA				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Spragg 2008 US 18462327			
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Spragg 2008 US 18462327	

Sra Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Sra 2007 US 17284262	x					MC

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Sra 2007 US 17284262	Documented, symptomatic AF prior to the procedure; refractory to >1 AAD.	nd	nd	All AADs were discontinued within the 1st month	8 patients (5 in CT-fluoro guided group) had undergone 1 prior catheter ablation procedure for AF. Structural heart disease=26%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Sra 2007 US 17284262	nd	RFA with or without the CT-fluoro guidance system	50	64	55	82	3.5	nd	4.5	47	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Sra 2007 US 17284262	yes	100% [no PV potentials]	For both groups, in the LA: (1) roof line, (2) circumferentially around the left and right PV antrum posteriorly, (3) mitral annulus to left inferior PV, and (4) anteriorly. For patients in persistent AF, the catheter was dragged along the posterior mitral annulus. Cavo-tricuspid lesions were also delivered in patients with inducible isthmus-dependent right atrial flutter and in those with persistent AF. Cardioversion was used to convert to sinus rhythm if AF still present after ablation.	no	nd	30-35	50-55	CT-fluoro-guided: 86 min Control: 95 min P=0.18

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Sra 2007 US 17284262	Free of AF	No recurrence of AF or atrial flutter after a single ablation (unclear on or off AADs)	CT-fluoro-guided RFA (3D)	9	21	25			nd			
			RFA without CT-fluoro-guided	9	16	25						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	1 month

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Persistent AF	Sra 2007 US 17284262	Free of AF	No recurrence of AF or atrial flutter after a single ablation	RFA with or without the CT-fluoro guidance system	9	12	18			nd			
Paroxysmal AF					9	25	32						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Sra 2007 US 17284262	yes	nd	nd	0%	nd	NA	no	no	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	no				
Explanation for Overall Quality Grade:				no information on use of AAD after the 1st month (blanking period); 8 patients (5 in CT-fluoro-guided group) had undergone 1 prior entering to the study.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Sra 2007 US 17284262		x	
Explanation for Applicability Grade:		8 patients (5 in CT-fluoro-guided group) had undergone 1 prior entering to the study.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Sra 2007 US 17284262	8 patients (5 in CT-fluoro-guided group) had undergone 1 prior entering to the study. 8 patients (2 in CT-fluoro-guided group) have undergone a 2nd procedure since their last follow-up.

Stabile Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Stabile, 2006 Italy 16214831	X				Circumferential PV and additional lines ablation with continuous concurrent anti-arrhythmics vs. only (continuous) anti-arrhythmics	TT/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Stabile, 2006 Italy 16214831	Paroxysmal* or persistent** AFib Intolerant of AADs or refractory to two or more anti-arrhythmics	• Age < 18 or > 80 years • Permanent AFib*** • AFib secondary to a transient or correctable abnormality, including electrolyte imbalance, trauma, recent surgery, infection, toxic ingestion, and endocrinopathy • Persistence of AFib episodes triggered by another uniform arrhythmia (i.e. atrial flutter or atrial tachycardia) despite previous supraventricular tachycardia ablation • Intra-atrial thrombus, tumor, or other abnormality precluding catheter insertion • Wolff–Parkinson–White syndrome • Heart failure with NYHA class III or IV or EF ≤ 35% • Unstable angina or acute myocardial infarction within 3 moths • Cardiac revascularization or other cardiac surgery within 6 moths or with prior atrial surgery • Renal failure requiring dialysis, or hepatic failure • An implanted device (pacemaker or cardioverter-defibrillator) • Left atrial diameter > 60 mm.	02/2002-06/2003	Continued	

*Paroxysmal AFib was defined as the occurrence, in the previous 6 moths, of one or more episodes of AFib a moth, each lasting more than 60 min but less than 7 days, with all episodes terminating spontaneously.

**Persistent AFib was defined as the occurrence, in the previous 12 moths, of two or more episodes of AFib, each lasting more than 7 days before being terminated pharmacologically or by electrical cardioversion, or lasting less than 7 days but necessitating early cardioversion owing to intolerable symptoms or hemodynamic compromise, with sinus rhythm maintained for 60 min or more, after termination.

***Permanent AFib was defined as AFib, the sole rhythm for the last 12 moths.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Stabile, 2006 Italy 16214831	Biosense-Webster, Italy	Circumferential PV ablation + AAD*	68	67	62	57	6.1	nd	4.6	58	B	Moderate
		AAD* only	69									

* Amiodarone. A class Ic anti-arrhythmic was used if patients had a history of side effects or intolerance to amiodarone. Dosing schedule not provided in detail but reported mean doses were amiodarone of 209 mg, flecainide of 191 mg, propafenone of 750mg, sotalol of 184 mg, and dysopyramide of 500mg.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Stabile, 2006 Italy 16214831	Yes	nd (100% implied) [Low peak-to-peak bipolar potentials (<0.1 mV) inside the lesion by local electrogram analysis and voltage maps]	Circumferential lines around each PV Mitral isthmus line Cavotricaspid isthmus line (if conduction in this region was detected)	No	8 mm* (nd)	100**	60	nd
					3.5 mm, cooled* (nd)	50**	45	

*8 mm tip catheter was used only in the first 17 patients, and was replaced with 3.5 mm cooled-tip catheter in the remaining patients.
**The half of the energy (50 W and 25 W) was used when ablation was performed in the posterior wall.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Stabile, 2006 Italy 16214831	Atrial arrhythmia-free survival	Atrial arrhythmia lasting > 30 s in the 1-year follow-up period after 1-moth blanking period	Circumferential PV ablation + AAD	12	38	68	nd	nd	<0.001 (Log-rank?)	HR=3.2	2.0-5.1	Nd
			AAD only	12	6	69						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
The number of arrhythmia was reported in the paper but converted.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes*		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 mo

*30 s ECG everyday and irregularly obtained ECG in the event of symptoms by transtelephonic ECG, and routine standard ECG, Holter, and echocardiography at 1, 4, 7, 10, 13 mo.

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
Stabile, 2006 Italy 16214831	Re-admission	Per-patient number of hospitalization (including that for ablation)	Time	Circumferential PV ablation + AAD	12	68	0	Median 1	nd	0.34 (unclear)
				AAD only	12	69	0	Median 2		

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Different tips in Circumferential PV ablation + AAD	Stabile, 2006 Italy 16214831	Atrial arrhythmia-free survival	Atrial arrhythmia lasting > 30 s in the 1-year follow-up period after 1-moth blanking period	8 mm	12	9	17	nd	nd	0.64 (Log-rank?)	nd	nd	nd
				3.5 mm, cooled	12	29	51						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
The number of arrhythmia was reported in the paper but converted.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Stabile, 2006 Italy 16214831	Circumferential PV ablation + AAD	12	0/68	1/68 (1%)	1/68 (1%)*			0	Transient phrenic paralysis	1/68 (1%)
									AAD-related***	2/68 (3%)
									Coronary artery disease****	1/68 (1%)
	AAD only	12	0	0	TIA, 1/69 (1%)**	0	0	0	Cancer*****	2/69 (3%)
									Sudden death******	1/69 (1%)

*This patient developed "stroke" during RFA procedure and died of brain hemorrhage 9 mo later.
**Timing not reported.
***These two patients developed some unclear side effects of anti-arrhythmics leading to "intolerance" at 4 and 6 mo after randomization necessitating change of drug.
****This patient underwent PTCA 3 moth after ablation. Unclear about the relation with ablation.
*****Unclear about the relation with intervention. One of the two died of cancer (timing not reported).
******Unclear about the relation with intervention. Timing also unclear.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Stabile, 2006 Italy 16214831	Yes	Yes	Nd	Yes, 2% (1% in ablation arm and 3% in drug alone arm)	Yes	Yes	Yes	Yes	Yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Nd**	Yes***	Yes****				
Explanation for Overall Quality Grade:				Was rated as A but changed to B; outcomes were assessed while the patients were on AADs (combined modality therapy)						

*observational study cannot be an A, retrospective study is always a C
**No clear description as to whether second procedure was performed, inferring that only single procedure was considered.
***30 s ECG everyday and irregularly obtained ECG in the event of symptoms by transtelephonic ECG, and routine standard ECG, Holter, and echocardiography at 1, 4, 7, 10, 13 mo.
****Only one patient in the drug only arm refused transtelephonic ECG.
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Stabile, 2006 Italy 16214831		X	
Explanation for Applicability Grade:		N<100, many exclusion criteria (not applicable especially to patients with underlying heart disease or moderate to severe CHF.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author **Year** **Country** **UI**	**Comments**
Stabile, 2006 Italy 16214831	• Overall excellent conduct and detailed reporting except for some minor omissions on statistical tests applied. • NOTE: Clinical outcomes were evaluated while patients were continuously taking an anti-arrhythmic (for good?).

Tamborero Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Tamborero 2005 Spain 16311935		x		x	PVI vs. CPVA; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Tamborero 2005 Spain 16311935	symptomatic AF, failed AADs; only included patients who had a MRA to evaluate PV stenosis (?)	did not have MRA (?)	nd	1 mo	Patients with suspected focal origin AF received PVI; others received CPVA; 78 consecutive patients, only results from 73 who received MRA to evaluate PV stenosis were included

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Tamborero 2005 Spain 16311935	government?	PVI	32	85	50	75	5.2		3.7	58	C	moderate
		CPVA	41	66	52	80	6		4.2	53		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Tamborero 2005 Spain 16311935	yes in group 1	? [eliminated or dissociated PV potentials]	group 1 – PVI (see Silva 2003, UI 12689570) group 2 – CPVA used CARTO; endpoint to reduce potential <0.15 mV	n	4 mm	40-50	50	
					8 mm	50-60	55	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Tamborero 2005 Spain 16311935		free from AF (?) recurrence	PVI	14.7 mo	23	32	72%					
			CPVA		31	41	76%		NS			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	nd		
Was a blanking period (time when AFib episodes were not recorded) used?	n	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Tamborero 2005 Spain 16311935	PVI	4 mo	stenosis >70%; 6/32 (19%)							
	CPVA	4 mo	stenosis >70%; 0/41							

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Tamborero 2005 Spain 16311935	n	NA	NA	NA	y	n	n	n	n	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	n	y	y				
Explanation for Overall Quality Grade:				incomplete reporting						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Tamborero 2005 Spain 16311935		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Tamborero 2005 Spain 16311935	indications for PVI were different from indications for CPVA; the two groups were therefore not comparable; better to assess this report as individual cohorts rather than a comparative study

Tang 2006 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Tang 2006 China 17235682		x	x		pts with DM vs. without DM; KQ 2, 4	SI/AG

Almost definite partial overlap with separately extracted Liu 2005 528, Ma 2006 458, Dong 2005 603.

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Tang 2006 China 17235682	AF; ±DM	previous RFA; intra atrial thrombus	2004-2006	2 mo	two groups not totally comparable at baseline (pts with DM older, longer history of Af, larger Lad)

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Tang 2006 China 17235682	government	RFA in pts with type 2 DM	31	81	62	74	9.6		4.11	63		
		RFA in pts without type 2 DM	232	75	56	71	6.7		3.83	63.6		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Tang 2006 China 17235682	y	nd [electrical isolation of all PVs]	CPVA; isthmus was also ablated if there were preprocedural AFL, or macro-reentrant AT during procedure	n	3.5 mm irrigated (ThermoCool)	35	43	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Tang 2006 China 17235682	recurrence	any episode of AT ≥ 30 s	RFA in pts with type 2 DM	13.4			32.3%					
			RFA in pts without type 2 DM				22.4%		0.24			
	complication was an independent risk factor for AF recurrence (OR 2.888, 95%CI 1.056-7.900, P=0.039)											

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Tang 2006 China 17235682	RFA in pts with type 2 DM		0	1/31 (3.2%)	2/31 (6.5%)				pneumothorax	1/31 (3.2%)
									hematoma	5/31 (16%)
	RFA in pts without type 2 DM		50% stenosis: 2/232 (0.9%)	2/232 (0.9%)	1/232 (0.4%)				cardiac arrest (VF) (survived)	1/232 (0.4%)
									hematoma	6/232 (2.6%)
									*pericardial effusion	4/232 (1.7%)
									femoral pseudoaneurysm	1/232 (0.4%)
									femoral vein thrombosis	1/232 (0.4%)

*One pericardial effusion leading to pericardiocentesis in a patient with low BP

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Tang 2006 China 17235682	n	NA	n	nd	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	n	y	n				
Explanation for Overall Quality Grade:				two groups not totally comparable at baseline						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Tang 2006 China 17235682		X	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Tang 2008 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Tang 2008 China 18364135	x					MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Tang 2008 China 18364135	Drug refractory paroxysmal AF	nd	nd	nd	Complicated atrial flutter=33%

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Tang 2008 China 18364135	Non-profit	CartoMerge guided versus CartoXP guided circumferential PVI	81	100	59.8	67	3.1	nd	3.8	61	B	Narrow

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Tang 2008 China 18364135	yes	100% [abolishment or dissociation of PVPs confirmed by Lasso catheter]	Linear ablation of the cavotricuspid isthmus would be performed routinely until bidirectional block was achieved at the isthmus if patient had previous history of typical atrial flutter	no	Irrigated tip (Biosense Webster Inc, CA)	30-40	43	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Tang 2008 China 18364135	Success of ablation	No recurrence of atrial tachyarrhythmias according to the symptoms, ECG and Holter monitoring during the follow up periods from the 4th month of post ablation procedure	CartoMerge (3-D) guided circumferential PVI	11.9	33	42			>0.50			
			CartoXP (3-D) guided circumferential PVI	12.4	29	39						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: “OR=1.7” or “HR=0.9”

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	yes	**If yes, how long was it?**	4 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Tang 2008 China 18364135	CartoMerge guided versus CartoXP guided circumferential PVI		0 (severity not defined)	2/81 (2.5%)	0	0		0		

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Tang 2008 China 18364135	yes	nd	nd	yes	nd	yes	yes	no	yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	no	no	yes	No				
Explanation for Overall Quality Grade:				Unclear if repeated procedures were accounted for						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Tang 2008 China 18364135	x		
Explanation for Applicability Grade:		100% paroxysmal AF patients only	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Tao Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Tao 2008 China 18855350				x		EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Antiarrhythmics (Time)	Other Important Characteristics
Tao 2008 China 18855350	AF, first time RFA 20-80 y, symptomatic AF refractory to ≥2 AAD, NYHA I or II	EF<45%, contraindication to anticoagulation, LA thrombus, previous AF ablation <12 mo follow-up	<2007	Amiodarone (propafenone if amiodarone contraindicated) x 3 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Tao 2008 China 18855350	nd	Circumferential pulmonary vein ablation	259	Persistent: 30%	57	70	6.8	nd	3.85	63	C	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Tao 2008 China 18855350	Y	(additional ablation if necessary to achieve isolation)	Tricuspid annulus isthmus, if AFL	Y	External Irrigated, 3.5 mm (ThermoCool)	35 W	43°	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Tao 2008 China 18855350	Late recurrence	Between 1-12 mo ATachy >30 sec (Sxic) or >5 min (ASxic)	RFA	18.2	66	249	26.5%					
	Very late recurrence	>12 mo (not 0-12 mo)	RFA	18.2	14	249	5.6%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Y		
Was a blanking period (time when AFib episodes were not recorded) used?	Y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Tao 2008 China 18855350	RFA	18.2	0/249	0/249	[TIA 2/249 (0.8%)	0/249	Severe hematoma requiring transfusion 1/249 (0.4%)	0/249		

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Tao 2008 China 18855350	N	NA	NA	Y	NA	N	Y	Y	Y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Y	Y	Y	Y	N				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Themistoclakis Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Themistoclakis 2008 US & Italy 18325850			X			EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Antiarrhythmics (Time)	Other Important Characteristics
Themistoclakis 2008 US & Italy 18325850	PV antrum isolation (symptomatic, drug resistant, parox, persistent, or permanent AF) Single ablation (only)	nd	2001-2005	If persistent or permanent AF AAD for 2 mo. Usually sotalol or dofetilide.	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Themistoclakis 2008 US & Italy 18325850	nd	RFA	1298	54%	56	78%	6.6		4.4 cm >4 cm 69%	54% <40% 9%	B	

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Themistoclakis 2008 US & Italy 18325850	Yes	100%	SVC isolation (78%) if SVC potentials and no phrenic nerve capture during pacing Non-PV antrum/SVC foci ablation (7.5%) when identified	Yes	8 mm (Celsius DS)	nd	nd (microbubbles)	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Themistoclakis 2008 US & Italy 18325850	"Late" atrial tachyarrhythmia (vs no AAD)	post-3 mo	RFA	41 mo (21-63 mo)	292 (288 Sxic; 4 ASx)	1298	22%					
	AF recurrence	post-3 mo	RFA	41 mo (21-63 mo)	252	1298	19%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? Eg, Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	3 months

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Parox	Themistoclakis 2008 US & Italy 18325850	"Late" atrial tachyarrhythmia (vs no AAD)	post-3 mo	RFA	41 mo (21-63 mo)	107	699						
Persistent						65	230	2.21	1.55-3.16	<.001	2.17	1.33-3.53	.002
Permanent						120	369	2.68	1.98-3.61	<.001	2.28	1.51-3.46	<.001

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Themistoclakis 2008 US & Italy 18325850	nd on AE									

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Themistoclakis 2008 US & Italy 18325850	No	NA	NA	No	NA	Yes	Yes	Yes (multivariable)	Yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes (implied, 48 hr Holter)	Yes				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Themistoclakis 2008 US & Italy 18325850			
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Themistoclakis 2008 US & Italy 18325850	Very likely large overlap with multiple other articles from Cleveland Clinic and Umberto I hospital

Thomas Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Thomas 2004 Australia 15172657		x			open irrigated vs. non-irrigated tip PVI; KQ 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Thomas 2004 Australia 15172657	severely (interrupted normal activities) symptomatic AF who had PVI		ND		Last 48 compared to the first 31 patients; extracted adverse events data only, outcomes reported were less than 6 mo

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Thomas 2004 Australia 15172657	nd	open irrigated (ThermoCool, Cordis-Webster)	48	69	56	77	6.2		4.21			
		4 mm tip (Cordis-Webster or Boston Scientific, Blazer)	31	77	55	81	6.7		4.26			

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Thomas 2004 Australia 15172657	y	98% of veins (239/244) PVI		n	irrigated 4 mm	30-40	50	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Thomas 2004 Australia 15172657												

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Thomas 2004 Australia 15172657	irrigated tip		moderate stenosis (50-70%) 2/158 veins (1.3%); symptomatic : 0		1/48					
	4 mm		moderate stenosis (50-70%) 4/81 (5%) veins; symptomatic : 0	1/31						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
		Was RFA Procedure Adequately Described?	Were the Recurrence Outcomes Fully Defined?	Was Success Rate After a Single Procedure (not including redo) Reported?	Was Asymptomatic AFib Screened For?	Was Compliance with Screening Reported?				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Tondo 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Tondo, 2005 Italy 15683472	x				RCT of guidance systems (EnSite NavX vs fluoroscopic).	EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Tondo, 2005 Italy 15683472	Symptomatic paroxysmal or persistent, drug refractory AFib	nd	nd	Pre-RFA anti-arrhythmic (implied) continued x 3 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Tondo, 2005 Italy 15683472	nd	Irrigated, 4 mm (ThermoCool) Group 1: PVI guided by EnSite NavX Group 2: PVI guided by fluoroscopic	60	63%	56	52%	nd	nd	4.0	57%	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Tondo, 2005 Italy 15683472	Yes	100% ["keeping the loop-shaped multipolar catheter at the PV ostium to ascertain complete electrical isolation"]	Left isthmus line between the mitral annulus and the inferior left PV (if AFib at time of procedure). Linear lesion at the roof of the LA (in 5 patients). Inferior VC-tricuspid annulus lesion (in all).	No	Irrigated 4 mm	nd	nd	7.5 min (5 min with 3D mapping; 10 min with fluoroscopy)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Tondo, 2005 Italy 15683472	Recurrence	Including 1st 3 months	4 mm	7	9*	60						
Tondo, 2005 Italy 15683472	2nd ablation		4 mm	7	2	60						
Tondo, 2005 Italy 15683472	AF recurrence		PVI guided by EnSite NavX	7	3	30	10%		nd			
			PVI guided by fluoroscopic	7	6	30	20%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
* In group 1: 3/30 with recurrence prior to 3 months requiring increased medication dosages. In group 2: 6/30 (timing not reported), 4 of which self-terminated. Probably ignore this outcome.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Implied. Used 24 hr ECGs		
Was a blanking period (time when AFib episodes were not recorded) used?	No (see highlight above)	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Tondo, 2005 Italy 15683472	Irrigated, 4 mm									

"No procedure-related complications occurred."

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Tondo, 2005 Italy 15683472	Yes (but not for our purposes)	nd	nd	0%	nd	NA	NA	No	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No (see comments)	No. Implied. And included early events	Yes	Yes	No				
Explanation for Overall Quality Grade:				No data on RCT design methods. Included events during blanking period. Incomplete reporting of recurrence. Eligibility criteria unclear.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Tondo, 2005 Italy 15683472		Moderate	
Explanation for Applicability Grade:		N=60. Eligibility criteria unclear.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Tondo, 2005 Italy 15683472	RCT of two guidance systems: EnSite NavX nonfluoroscopic mapping system that creates a 3-D reconstruction of the LA and PV structure vs. conventional fluoroscopy. Incomplete reporting of recurrence outcome (timing) without use of blanking period. Cannot assess for our purposes. Incomplete data on procedure (energy, temperature). Unclear why ablation time differed by guidance system. Other items vaguely reported. Study population (esp eligibility criteria) unclear.

Tondo 2006 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Tondo, 2006 Italy 16981920			X? (per report)			TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Tondo, 2006 Italy 16981920	paroxysmal or persistent AF refractory to AAD	nd	nd	3 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Tondo, 2006 Italy 16981920	nd	PV vestibular circumferential ablation and additional lines	105	10%	56	82%	3.6	38*	4.6	52%	C	Moderate

*symptomatic CHF (mean NYHA 2.8)

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Tondo, 2006 Italy 16981920	Yes	100% [complete elimination of PV potentials]	Left mitral isthmus line (between the mitral annulus and the inferior left PV) IVC-tricuspid annulus blocking line	No	Irrigated 3.5 mm (Cordis ThermoCool)	30-35*	42-45*	

*40W (mitral-isthmus line) and 15-25W (CS)

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Nd/No	**If yes, how long was it?**	NA

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
With CHF	Tondo, 2006 Italy 16981920	Sinus rhythm	No explicit definition on recurrence or blanking period	PV vestibular circumferential ablation and additional lines	14	35	40	87%		NS (exact test)			
Without CHF						60	65	92%					
With CHF	Tondo, 2006 Italy 16981920	Re-procedure for AF	No explicit definition	PV vestibular circumferential ablation and additional lines	14	3	40	8%		NS (exact test)			
Without CHF						7	65	11%					
With CHF	Tondo, 2006 Italy 16981920	Re-procedure for atrial flutter	No explicit definition	PV vestibular circumferential ablation and additional lines	14	10	40	13%		NS (exact test)			
Without CHF						7	65	11%					
With CHF	Tondo, 2006 Italy 16981920	Free from anticoagulation	No explicit definition	PV vestibular circumferential ablation and additional lines	14	40	40	100%		<0.001 (exact test)			
Without CHF						15	65	23%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between
With CHF	Tondo, 2006 Italy 16981920	QOL	Time (tolerable) for exercise	min	PV vestibular circumferential ablation and additional lines	14	40?	9	14	5	<0.001 (t-test)
Without CHF							65?	15	17	2	NS
With CHF	Tondo, 2006 Italy 16981920	LVEF	Improvement of LVEF evaluated for patients in sinus rhythm	%	PV vestibular circumferential ablation and additional lines	14	?	33	47	14	<0.01 (t-test)
Without CHF							nd	nd	nd	nd	Nd
With CHF	Tondo, 2006 Italy 16981920	QOL	SF-35, physical functioning	score	PV vestibular circumferential ablation and additional lines	6	40?	27.6	86.4		<0.05 (t-test)
Without CHF							65?	26.4	59.6		<0.05 (t-test)
With CHF	Tondo, 2006 Italy 16981920	QOL	SF-35, social functioning	score	PV vestibular circumferential ablation and additional lines	6	40?	42.3	83.2		<0.05 (t-test)
Without CHF							65?	45.4	85.3		<0.05 (t-test)
With CHF	Tondo, 2006 Italy 16981920	QOL	SF-35, emotional well-being	score	PV vestibular circumferential ablation and additional lines	6	40?	37.8	75.0		<0.05 (t-test)
Without CHF							65?	38.7	76.0		<0.05 (t-test)
With CHF	Tondo, 2006 Italy 16981920	QOL	SF-35, energy/fatigue	score	PV vestibular circumferential ablation and additional lines	6	40?	23.4	63.2		<0.05 (t-test)
Without CHF							65?	25.5	64.3		<0.05 (t-test)
With CHF	Tondo, 2006 Italy 16981920	QOL	SF-35, limitation due to physical health	score	PV vestibular circumferential ablation and additional lines	6	40?	7.6	64.6		<0.05 (t-test)
Without CHF							65?	8.2	66.7		<0.05 (t-test)
With CHF	Tondo, 2006 Italy 16981920	QOL	SF-35, general functioning	score	PV vestibular circumferential ablation and additional lines	6	40?	46.4	74.8		<0.05 (t-test)
Without CHF							65?	47.4	76.7		<0.05 (t-test)

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
NOTE: all analyses were before-after comparisons within each subgroup, not net difference between subgroups.

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Tondo, 2006 Italy 16981920	PV vestibular circumferential ablation and additional lines	14	nd	1/105 (1%)	0/105	nd	5/105 (5%)	nd		

Complication rates in patients with CHF were statistically significantly higher than those without CHF (P<0.01).

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Tondo, 2006 Italy 16981920	No	NA	NA	?nd	Yes (all patients followed at least 12 mo per report)	NA	NA	No	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Yes	Yes	No				
Explanation for Overall Quality Grade:				No data on clear inclusion/exclusion criteria (really a prospective study?). Probably Included events during blanking period. Incomplete reporting of recurrence.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Tondo, 2005 Italy 15683472		Moderate	
Explanation for Applicability Grade:		Eligibility criteria unclear.	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Turco Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Turco 2007 Italy 17302684			X		adverse events only; RCT of RFA vs. RFA+AAD does not address KQs; the two arms of the RCTs are treated as one cohort	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Turco 2007 Italy 17302684	PAF or persistent AF; intolerant or failed AADs	<18 or >75 y; permanent AF; persistent AF triggered by AFL or atrial tachycardia; WPW; NYHA III or IV; EF≤35%; pacemaker or ICD; LAD > 6 cm	2004-2005	50% received AAD	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Turco 2007 Italy 17302684	nd	Circumferentia PVII+ cavo-tricuspid + MIL	107	60	57	65	4.5 y	nd	4.8	57		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Turco 2007 Italy 17302684	y	Nd (Endpoint was <0.1mv potentials inside the lesions as determined by local electrogram analysis and voltage maps.)	circumferential lines around each PV + cavo-tricuspid + MIL	n	3.5 mm cooled tip	42 25 W posterior wall	45	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Turco 2007 Italy 17302684	circumferential PVI + cavo-tricuspid + MIL			1/107 (0.9%)						

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
		Was RFA Procedure Adequately Described?	Were the Recurrence Outcomes Fully Defined?	Was Success Rate After a Single Procedure (not including redo) Reported?	Was Asymptomatic AFib Screened For?	Was Compliance with Screening Reported?				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Verma 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Verma, 2005 USA 15653029				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Verma, 2005 USA 15653029	• Symptomatic any type of AF refractory to at least two AADs • First-time PVAI	• Previous PVAI • Any previous catheter ablation • Previous cardiac surgery	01/2002-08/2003	2 mo	Patients with LA scar (defined as a complete absence of electrogram by the Lasso or an absence of voltage or of bipolar voltage amplitude of ≤ 0.05 mV indistinguishable from noise) had statistically significantly larger LA size and lower LVEF than those without scar.

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Verma, 2005 USA 15653029	Heart and Stroke Foundation of Canada	PVAI	700	39	53	nd	6.1	nd	4.0	54	C	Wide

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Verma, 2005 USA 15653029	Yes	[complete electrical disconnection of the PV antrum from the LA (=no PV potentials by the Lasso)]	PVAI with the assessment of PVI SVC isolation	No	8 mm	70	55	45

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Verma, 2005 USA 15653029	Freedom from AF	AF or atypical atrial flutter occurring beyond 2-moth post-PVAI based on patient reporting, rhythm-transmitter, Holter, and/or ECG	PVAI	15.8	553	658						
Verma, 2005 USA 15653029	Repeat procedure	Not clearly defined**	PVAI	15.8	134	700						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**18 patients did not undergo a repeat procedure although they developed relapse.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Patients with LAS	Verma, 2005 USA 15653029	Freedom from AF	AF or atypical atrial flutter occurring beyond 2-moth post-PVAI based on patient reporting, rhythm-transmitter, Holter, and/or ECG (only the first procedure was taken into account)	PVAI	15.8	18	42	43%		0.003 (Log-rank)			
Patients without LAS						535	658	81%					
Patients with LAS	Verma, 2005 USA 15653029	Freedom from AF	AF or atypical atrial flutter occurring beyond 2-moth post-PVAI based on patient reporting, rhythm-transmitter, Holter, and/or ECG (second procedure was also taken into account)*	PVAI	15.8	nd	42	52%		nd			
Patients without LAS						nd	658	90%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*All patients with recurrence were assumed to undergo a second procedure although 18 of them did not in reality.
Multivariate analyses by the Cox regression showed only LA scar was a statistically significant independent predictor of late AF recurrence (HR=3.4, 95% CI, 1.3-9.4; P=0.01). Other factors taken into account in the analyses were age, non-paroxysmal AF, gender, duration of AF, the number of previous AADs, structural heart disease, LA size, LVEF, C-reactive protein, and brain natriuretic peptide. Univariate analyses showed age and non-paroxysmal AF were also statistically significant factors.

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	

No AEs reported.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Verma, 2005 USA 15653029	No	NA	NA	Unclear	Nd/NA	Nd/NA	Yes	Yes	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Verma, 2005 USA 15653029			Wide
Explanation for Applicability Grade:		Provided exclusion criteria would be considered minor	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Verma 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Verma, 2007 USA 17338763				X?		TTe/AG

"randomly selected"???

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Verma, 2007 USA 17338763	Symptomatic AF refractory to at least one AAD • PVAI + ablation of CFAEs (randomly consecutively selected cases) • PVAI alone (randomly selected matched controls)	nd	nd	2 mo	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Verma, 2007 USA 17338763	Hear and Stroke Foundation of Canada (fellowship)	PVAI + CFAEs	100	40	57	63	5.2	nd	4.3	53	C	Wide
		PVAI alone	100									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Verma, 2007 USA 17338763	Yes	100% [All PV potentials surrounding the vein were abolished (by the Lasso) during sinus rhythm or coronary sinus pacing]	• PVAI followed by assessment of PVI (for all 200 patients) • SVC (except for patients at risk of phrenic nerve injury) • Ablation of CFAEs in the septum and anterior LA wall (for 100 patients as adjuvant therapy)	Yes*	8 mm	70	50	57 (PVAI + CFAEs) 44 (PVAI alone)

*90% of adjuvant CFAEs group
Inducibility – Isuprel and CS pacing

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Verma, 2007 USA 17338763	Freedom from AF	AF or atypical atrial flutter occurring beyond 2-moth post-PVAI based on patient reporting, rhythm-transmitter, Holter, and/or ECG	PVAI + CFAEs	12	85	100	80%		0.054 (log-rank)			
			PVAI alone		80	100	85%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**Originally reported as recurrence rates

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal AF	Verma, 2007 USA 17338763	Freedom from AF	AF or atypical atrial flutter occurring beyond 2-moth post-PVAI based on patient reporting, rhythm-transmitter, Holter, and/or ECG	PVAI + CFAEs	12	52	60	87%		0.39 (log-rank)			
				PVAI alone		51	60	85%					
Persistent/Permanent AF	Verma, 2007 USA 17338763	Freedom from AF	AF or atypical atrial flutter occurring beyond 2-moth post-PVAI based on patient reporting, rhythm-transmitter, Holter, and/or ECG	PVAI + CFAEs	12	33	40	82%		0.047 (log-rank)			
				PVAI alone		29	40	72%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Originally reported as recurrence rates

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Verma, 2007 USA 17338763	PVAI +/- ablation of CFAEs	12	0/200	0/200	0/200	nd	nd	nd	Peripheral vein hematoma (no transfusion)*	3/200 (2%)

*Two at the femoral venous site and one at the internal jugular vein site.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Verma, 2007 USA 17338763	No	NA	NA	Yes (0%)	nd	NA/nd	Yes	nd	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	No	Yes	Yes (83%)				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Verma, 2007 USA 17338763			Wide
Explanation for Applicability Grade:		The reported patient spectrum sounds (no exclusion criteria).	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Walczak Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Walczak 2006 Poland 16444625				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Walczak, 2006 Poland 16444625	Highly symptomatic drug-refractory AF	nd	nd		

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Walczak, 2006 Poland 16444625	nd	Selective PVI (0-3 PVs)*	60	70	48	64	Nd	nd	3.8	64	C	
		All PVI (4 or 5 PVs)**	20									

*Three PVIs were performed in 19 patients, two PVIs in 23 patients, and only one PVI in 7 patients.
*The fifth vein was either middle vein or accessory vein.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Walczak, 2006 Poland 16444625	Yes	Nd [Assessed by pacing but not explicitly defined]	• Cavo-tricuspid isthmus line* • LA roof line** • Focal isolation or single ablation in another vein (CS, SVC, or ligament of Marshall) or in the LA or RA (crista terminalis, septum, or isthmus)***	Yes****	nd	30-35	50-55	

*18 patients (18 in Group 1 but also 6 in Group II – reference Table II)
**5 patients (5 patients in Group II and 1 patient I Group I)
***Eight patients in "selective PVI" group did not undergo any PVI. 5-focal isolation or ablation in another single vein (CS…etc) and in the remaining 3 – single focal isolation in the atrium.
****Only 30 patients

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Walczak, 2006 Poland 16444625	Effective Rhythm Control	No or only single transient palpitation episode or atrial tachyarrhythmia lasting > 30 s	Selective PVI (0-3 PVs)*	17	54	60	90%	Nd	nd			
			All PVI (4 or 5 PVs)**		16	20	80%	Nd				

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Nd		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	NA

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Walczak, 2006 Poland 16444625	PVI (in 0-5 PVs) + additional ablation	17	5/183 (3%)*							

*The unit of analysis is each PV as explicitly reported descriptions may not necessarily be patient-based analysis. Only 4 out of 5 were symptomatic (possibly four PVs in only one patient?). Significant stenosis was defined as 70% or greater.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Walczak, 2006 Poland 16444625	No	NA	NA	nd	nd	nd	?	No	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
Explanation for Overall Quality Grade:				Retrospective						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Walczak, 2006 Poland 16444625	X		
Explanation for Applicability Grade:		Some patients did not undergo PVI	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Wang 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Wang, 2007 China 17522081	X					EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Wang, 2007 China 17522081	Paroxysmal AFib	LA thrombi	2006	Amiodarone or class IC AAD x 1 mo	HTN 39%; CAD 4%

POPULATION

Author Year Country UI	Funding source	Intervention(s)*	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Wang, 2007 China 17522081	nd ("No conflict of interest")	PVI (no observation time)	28	100%	56	57%	4.2 yr	nd	3.8 cm	nd		
		PVI (30 min observation)	32									
		PVI (60 min observation)	30									

* In groups B&C, catheter left in for observation and re-testing for isolation. All recovered PV potentials were "re-isolated by closing the gaps along the initial circular ablation lines."

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, °C	Total Ablation Time, min
Wang, 2007 China 17522081	Yes	100% implied	Circumferential PV antrum ablation encircling PVs	No	Irrigated 3.5 mm (ThermoCool Navistar)	40 W (anterior wall) 30 W (posterior wall)	45° max (anterior wall) 43° max (posterior wall)	50 min 84 min 94 min

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Wang, 2007 China 17522081	Recurrence	Any atrial tachyarrhythmia (symptomatic or asymptomatic) lasting >30 secs (documented)	PVI, no observation	6 (actual)	7	18			.03			
			PVI, 30 min		3	21						
			PVI, 60 min		1	21						
	Recurrence		PVI, no observation	6.7 mo (mean)	11	28			.04			
			PVI, 30 min		5	32						
			PVI, 60 min		4	30						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
Complete data (all patients) at 4 mo. Also data each month to mo 8 (n≥10/arm) and mo 9 (but only 14 total).

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	1 month

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Wang, 2007 China 17522081	Circumferential PVI			0/90	0/90				Pseudoaneurysm (treated conservatively)	2/90

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Wang, 2007 China 17522081	Yes	nd	nd	Yes (0%)	nd	Essentially	OK. But survival curve analysis would have been more meaningful	NA	Yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	No				
Explanation for Overall Quality Grade:		Reported data too early (incomplete data at 6 mo). ND on RCT methods.								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Wang, 2007 China 17522081		Moderate	
Explanation for Applicability Grade:		N~30 per arm (although less at exactly 6 mo)	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Wang 2008 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Wang 2008 China 18256124				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Wang 2008 China 18256124	Symptomatic drug refractory AF	nd	2005-2006		43 (10%) had previous procedure (ostial PVI or CPVI)

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Applicability
Wang 2008 China 18256124	none	CPVI (WACA)	452	72	63	60	5.2	nd	3.7	nd	

WACA at 35W 0.5 cm away (30W 1 cm away if posterior wall was concerned) from the ostia by 3.5 mm cooled tip (Navi-Star ThermoCool) with PV isolation as the endpoint of the procedure. No addition lines or targeted ablation by induction. Isolation was achieved at 96% (RPVs) and 93.6% (LPVs).

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Wang 2008 China 18256124	CPVI (WACA)	Nd (just after the procedure, inferred)	nd	4/452 (0.9%)	2/452 (0.4%)	nd	2/452 (0.4%) AVF 2/452 (0.4%) PA	nd		

AVF=AV fistula, PA=pseudo-aneurysm

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Wang 2008 China 18256124			X
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Wazni 2003 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Wazni 2003 US Germany Italy 14610012	x				PVI-left atrial isthmus ablation with or without cavotricuspid isthmus (CTI) ablation in patients with AF and AFL; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Wazni 2003 US Germany Italy 14610012	1 documented episode of typical AFL while not on AAD; AF and AFL, failed or could not tolerate AADs	intracardiac thrombi	2000-2002	nd	all patients have AFL and AF

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Wazni 2003 US Germany Italy 14610012	nd	PV-LAJ disconnection + CTI	49	59	55	81	5.5	nd	4.2	53	B	moderate
		PV-LAJ disconnection	59									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Wazni 2003 US Germany Italy 14610012	y	100% (?) [not defined] In Marrouche 2003: PV isolation: abolition of all ostial PV potentials recorded on the circular mapping catheter during SR or CS and RA pacing	PV-LAJ disconnection (described in Marrouche 2003); For CTI: protocol to assess bidirectional block (prove the existence of double potentials along the ablation line separated by ≥100 ms during sinus rhythm; also assessed during pacing from both sides of the ablation line)	n	cool-tipped 4mm (EP Technologies)	nd	35	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Wazni 2003 US Germany Italy 14610012	AF recurrence	nd	PV-LAJ disconnection + CTI	>8 Wk	7	49	14%					
			PV-LAJ disconnection		6	59	10%		NS			
	AF recurrence	KM analysis	PV-LAJ disconnection + CTI	12 mo	0	42	0					
			PV-LAJ disconnection		0	53	0		NS			
	AFL recurrence only	nd	PV-LAJ disconnection + CTI	>8 Wk	0	49	0					
					3	59	5%		NS			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y (not defined)		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Wazni 2003 US Germany Italy 14610012	PV-LAJ disconnection + CTI		moderate (50-70%) asymptomatic, 1/49 (2%)		0/49					
	PV-LAJ disconnection		moderate (50-70%) asymptomatic, 1/59 (1.7%)		0/59					

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Wazni 2003 US Germany Italy 14610012	y	nd	n	y	n	nd	y	nd	y	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	n	y	y	nd				
Explanation for Overall Quality Grade:				randomization technique not reported; recurrence not fully defined						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Wazni 2003 US Germany Italy 14610012		X	
Explanation for Applicability Grade:		N <100 per arm	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

Wazni 2005 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Wazni 2005 Germany Italy 15928285	x				PVI (first line therapy) vs. AAD (first line therapy); KQ 1, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Wazni 2005 Germany Italy 15928285	monthly symptomatic AF ≥ 3 mo	<18 y or > 75 y, hx of AF ablation, open heart surgery, AAD, contraindication to long-term anticoagulants, atrial flutter	2001-2002	nd	warfarin initiated in all pts in ADD and maintained throughout the study; warfarin in PVI group for ≥ 3 mo (continued if AF recurrence, or ≥ 50% PV narrowing); target INR 2-3

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Wazni 2005 Germany Italy 15928285	Industry	PVI (First line therapy)	33	96	54	nd	0.4	nd	nd	54	B (from A)	Moderate
		AAD (First line therapy) (max tolerable dose; flecainide 100-150 mg or sotalol 120-160 mg bid, or propafenone 225-300 mg tid)	37									

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Wazni 2005 Germany Italy 15928285	Yes	100% [no PV potential or electrical dissociation]	none	No	8 mm	nd	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Mean Follow-up, mo	Intervention	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Wazni 2005 Germany Italy 15928285	symptomatic AF recurrence	>15 s during Holter or event monitoring	12 mo	PVI	4	32						
				AAD	22	35			<0.001			
	hospitalization		12 mo	PVI	3	32						
				AAD	19	35			<0.001			
	thromboembolic events	TIA, stroke, DVT, or PE		PVI	0	32						
				AAD	0	35			N/A			
	PV stenosis	mild <50%; moderate 50-70%; severe >70%	12 mo	PVI	1 mild; 1 moderate	32						
				AAD	0	35			0.50			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	2 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference btw groups	P between
Wazni 2005 Germany Italy 15928285	QOL	SF-36 physical functioning subscale	score (1-100)	PVI	6 mo	32	71	97	20 (95%CI 13.2 to 24.2)	0.001
				AAD		35	69	75		
		SF-36 mental health subscale	score (1-100)	PVI	6 mo	32	65	65	-4 (95%CI -3.5 to -7.5)	0.62
				AAD		35	64	68		

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	PV Stenosis, n/N	Cardiac Tamponade, n/N	Stroke, n/N	Esophageal Perforation, n/N	Peripheral Vascular Complications, n/N	30-Day Mortality, n/N	Other Major AE, n/N	
Wazni 2005 Germany Italy 15928285	PVI	moderate 1/32		0/32				bleeding (not defined)	2/32
	AAD	0/35		0/35				bleeding	1/35

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Wazni 2005 Germany Italy 15928285	Yes	Yes	No	Yes	nd	Yes	Yes	NA	Yes	B (from A)
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	Yes	Yes	Yes	Yes				
Explanation for Overall Quality Grade:				Discrepant descriptions on rhythm control on the text and the presented K-M curves						

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Wazni 2005 Germany Italy 15928285		X	
Explanation for applicability grade	relatively small sample size in each arm		

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Wazni 2005 Germany Italy 15928285	only 2/8 SF-36 subscales presented here; 5/8 subscales significantly better in the PVI group

Wazni 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Wazni 2007 US 17998456		x			after RFA: Enoxaparin 1 mg/kg bid vs. 0.5 mg/kg bid vs. usual warfarin dose; KQ 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Wazni 2007 US 17998456	consecutive patients with persistent AF undergoing PV antrum isolation	nd	nd		all pts have persistent AF; adverse events only

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Wazni 2007 US 17998456	nd	post RFA Enoxaparin 1 mg/kg bid vs. 0.5 mg/kg bid vs. warfarin (to keep INR 2 -3.5)	105	0	55	78	nd	nd	4.4	54	not rated	moderate
			100	0								
			150	0								

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Wazni 2007 US 17998456	nd	Nd [abolition of all ostial PV potentials recorded on the circular mapping catheter during sinus rhythm or coronary sinus and right atrial pacing(see Marrouche 2003]	see Marrouche 2003 and Wazni 2005	n	8 mm	nd	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?			
Was a blanking period (time when AFib episodes were not recorded) used?		**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Wazni 2007 US 17998456	post RFA Enoxaparin 1 mg/kg bid				1/105 (1%)				mild pericardial effusion	1/105 (1%)
									bleeding requiring hospitalization	10/105 (10%)
									bleeding requiring transfusion	9/105 (9%)
									pseudo aneurysms requiring thrombin	see footnote*
	post RFA Enoxaparin 0.5 mg/kg bid				2/100 (2%)				symptomatic pericardial effusion requiring pericardiocentesis	2/100 (2%)
									bleeding requiring hospitalization	10/105 (10%0
									bleeding requiring transfusion	
									pseudo aneurysms requiring thrombin	see footnote*
	post RFA usual warfarin (to keep INR 2 - 3.5)				0/150 (0%)				mild pericardial effusion	1/150 (0.6%)
									bleeding requiring hospitalization	2/150 (1.3%)
									bleeding requiring transfusion	
									pseudo aneurysms requiring thrombin	2/150 (1.3%)

*post RFA Enoxaparin 1 mg/kg bid group and post RFA Enoxaparin 0.5 mg/kg bid combined had 3/205 patients with pseudo aneurysms requiring thrombin

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Wazni 2007 US 17998456	no	NA	NA		n	n	nd	n	y	
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		nd	nd	nd	nd	nd				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Wazni 2007 US 17998456		x	
Explanation for Applicability Grade:		**all with persistent AF**	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Willems Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Willems, 2006 Germany 16782716	X				RCT of PVI vs. PVI+ Substrate modification (additional lines)	MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Willems 2006 Germany 16782716	>2 failed attempts of an anti-arrhythmic drug therapy for symptomatic AF episodes; persistent AF lasting for >1 month	Patients with concomitant severe heart disease and impaired systolic left ventricular function (LVEF<40%) and/or LA enlargement >55 mm	nd	Flecainide (n=6), propafenone (n=1), sotalol (n=3) for up to 8 weeks	8 patients (4 in each group) had CAD

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Willems, 2006 Germany 16782716	nd	PVI: circumferential (Lasso) PVI plus cavotricuspid isthmus ablation (right atrial isthmus ablation). PVI+SM (substrate modification): same as PVI group following additional left linear ablation connecting the posterior ablation line of the left and right superior PV at the posterior part of the superior LA.	62	0	59	nd	6 (range 1.5-10)	nd	4.8	≥40	A	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Willems, 2006 Germany 16782716	yes	(1) PVI group: 100% [Completely PV block indicated by elimination or dissociation of all PV potentials during sinus rhythm. This was validated by pacing at coronary sinus or LA appendage.]	Cavotricuspid isthmus RFA	no	Open irrigated tip (Celsius ThermoCool, Biosense Webster Inc.)	30	nd	32.3
	yes	(2) PVI+SM group: 100% PVI, 72% linear ablation in the LA, 44% block for the roof-line [Same as group 1 in addition to complete conduction block for linear ablation in the LA. Evaluation of the roof-line was performed by mapping a corridor of double potentials along the line during LA appendage pacing]	Cavotricuspid isthmus RFA Roof line: line connecting the posterior ablation line of the left and right superior PV at the posterior part of the superior LA Mitral line: LIPV to MA Validation of lines via activation sequence	no	Open irrigated tip (Celsius ThermoCool, Biosense Webster Inc.)	PVI: 30 SM: 50; 40*	50	PVI: 35.7 SM: 23.7

*The maximum power level was adjusted from 50 W to 40 W after 4 patients following the reports of cases with cardiac tamponade during linear LA ablation.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Willems, 2006 Germany 16782716	Sinus rhythm	Lack of any symptomatic or asymptomatic AF episode (>30 s) documented by conventional or Tele-ECG recording. Suspected LA flutter was also considered as recurrence due to the fact that the differentiation using Tele-ECG criteria can be impossible	PVI	Median 16 (range 14-18)	6	30			0.0001 (log-rank test)			
			PVI+SM	Median 17 (range 15-19)	22	32						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes (each patient received a Tele-ECG recorder that could record an ECG for a 1-min duration. Patients were advised to record and transmit at least one ECG per day irrespective of the symptoms. ECGs were transmitted to a central lab using a regular telephone)		
Was a blanking period (time when AFib episodes were not recorded) used?	no	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Willems, 2006 Germany 16782716	PVI+SM	nd		1/32 (3%)*	1/32 (3%)**					

*During LA isthmus ablation with 50 W, which was immediately drained without further complication. After limiting the maximum power level to 40 W for LA isthmus ablation, neither cardiac tamponade nor pericardial effusion occurred.

**minor ischemic stroke accompanied by dizziness occurring the day after ablation.

Note: The two patients who had procedure-related complications recovered subsequently without sequelae. No procedure-related complications in PVI group.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Willems, 2006 Germany 16782716	Yes (not for our report purpose)	yes	nd	0%	nd	yes (0% dropout)	yes	yes	yes	B
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	yes	yes	yes	no				
Explanation for Overall Quality Grade:				unclear what proportion of patients remained on AADs at followup						

*observational study cannot be an A, retrospective study is always a C

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Willems, 2006 Germany 16782716		X	
Explanation for Applicability Grade:		N<100; persistent AF only	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Willems, 2006 Germany 16782716	In 9/10 patients with recurrences in the PVI+SM group, ablation of .1 line was incomplete including 4 patients with 2 incomplete lines (mitral isthmus: n=5, roof-line: n=8). Only 1 patient with 2 incomplete lines was in sinus rhythm during follow-up (mean 17 months). Repeat MRI and transesophageal echo did not reveal narrowing or enhanced flow velocity in any of the investigated patients.

Yamada Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Yamada, 2006 Japan 16607049				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Yamada, 2006 Japan 16607049	Symptomatic paroxysmal AF refractory to AADs	nd	nd	No (all AADs were discontinued)	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Yamada, 2006 Japan 16607049	Ministry of Health, Labour, and Welfare, Japan	Segmental ostial PVI	108	100	57	90	4	nd	3.5	66	C	Moderate

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Yamada, 2006 Japan 16607049	Yes	Nd [the abolition or dissociation of the distal PV potentials]	(SOCA) Additional RF to the gaps between periostial ablation sites in the PVs to prevent the recovery of electrical connections (only for patients to whom RF was delivered by a 8 mm catheter)	No	4 mm (nd)	30	55	
					8 mm (Blazer II)	40	55	

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Yamada, 2006 Japan 16607049	Re-procedure	Unclear definition	Segmental ostial PVI	6	27	108						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	NA

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Segmental ostial PVI (4 mm)	Yamada, 2006 Japan 16607049	Freedom from recurrence at 6 mo	No explicit definition of recurrence and post-procedure blanking period (after first procedure)	Segmental ostial PVI	6	25	47	53%		nd			
Segmental ostial PVI (8 mm)						41	61	68%					
Segmental ostial PVI (4 mm)	Yamada, 2006 Japan 16607049	Re-procedure	Unclear definition	Segmental ostial PVI	6	8	47			nd			
Segmental ostial PVI (8 mm)						10	61						
Segmental ostial PVI (4 mm)	Yamada, 2006 Japan 16607049	Freedom from recurrence at 6 mo	No explicit definition of recurrence and post-procedure blanking period (after multiple procedure)	Segmental ostial PVI	6	25	47	66%		<0.05 (log-rank)			
Segmental ostial PVI (8 mm)						41	61	84%					

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Yamada, 2006 Japan 16607049	Segmental ostial PVI	6	0/108	0/108	0/108	nd	nd	nd		

"No critical complications occurred in any cases."

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Yamada, 2006 Japan 16607049	No	NA	NA	Yes (100%)	NA	NA	Yes	nd	Yes	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	Yes	Yes	No				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Yamada, 2006 Japan 16607049		moderate	
Explanation for Applicability Grade:		**Only patients with paroxysmal AF**	

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Yamane 2002 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Yamane, 2002 France 11955852				X		TTe/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Yamane, 2002 France 11955852	Multidrug-resistant paroxysmal daily AF	nd	Nd		

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Yamane, 2002 France 11955852	nd	Ostial PVI*	157	100	54	60	4.7	nd	3.7	nd	C	Wide

*Earliest activation site(s) in the first 113 patients and electrogram polarity reversal site(s) in addition to earliest activation site(s) in the second 44 patients.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Yamane, 2002 France 11955852	Yes	99%* [elimination of PV muscle conduction distal to the ablation site(s) by abolition or dissociation of distal potentials]	nd	Yes	Irrigated and non-irrigated (nd)	20-30	50	Nd**

*only (each) PV-based analysis available (patient-based not available).
**8 min(/PV?) per report.

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Yamane, 2002 France 11955852	Free from AF	Free from AF without AAD. Recurrent AF and blanking period not explicitly defined**.	Ostial PVI	9	106	157	74%					
Yamane, 2002 France 11955852	Re-procedure	No reasons to undergo a re-procedure reported	Ostial PVI	9	60	157						
Yamane, 2002 France 11955852	Free from AF	Free from AF. Recurrent AF and blanking period not explicitly defined***.	Ostial PVI	9	93	157	59%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"
**Inferring re-procedures were also included in the analysis.
***Inferring only first procedure was taken into account.
All results were crude estimates.

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Nd		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
1 mapping approach*	Yamane, 2002 France 11955852	Free from AF	Free from AF. Recurrent AF and blanking period not explicitly defined**.	Ostial PVI	9	Nd	113	42%		NS (chi-squared)			
2 mapping approaches*						nd	44	39%					
With cardiovascular disease	Yamane, 2002 France 11955852	Free from AF	Free from AF. Recurrent AF and blanking period not explicitly defined**.	Ostial PVI	9	Nd	23	39%		NS (chi-squared)			
Without cardiovascular disease						Nd	134	52%					

Duplicate one row per outcome and per RFA intervention.
Eg, Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others
*Earliest activation site(s) in the first 113 patients and electrogram polarity reversal site(s) in addition to earliest activation site(s) in the second 44 patients were targeted.
**inferring only first procedure was taken into account.
NOTE: all results were crude estimates

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Yamane, 2002 France 11955852	Ostial PVI	9	0/157*	Nd*	nd	nd	nd	nd		

*Two moderate acute stenosis (55% narrowing) and two non-severe pericardial effusions (not requiring drainage) were reported.
**********no drainage, thus not hemodynamically unstable, thus NOT tamponade.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Yamane, 2002 France 11955852	No	NA	NA	nd	NA/nd	NA/nd	No?	No	No	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		Yes	No	unclear	Unclear/no	NA				
Explanation for Overall Quality Grade:				Retrospective. Details on statistical analyses were not provided.						

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Yamane, 2002 France 11955852			WIDE
Explanation for Applicability Grade:		No exclusion criteria infer that patient spectrum should be similar to general patients with parox AF in clinical practice.	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Yamane 2007 Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Yamane 2007 Japan 17457004		x			ostial vs. antrum PVI; KQ 3, 4	SI/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Yamane 2007 Japan 17457004	AF resistant to AADs, observed for ≥12 mo	persistent AF >12 mo	nd	not on AADs	non-concurrent comparison; ostial followed up for 2.8 y; antrum followed up for 1.8 y; esophagus monitored during procedure in 50% of patients in the antral group

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Yamane 2007 Japan 17457004	nd	ostial PVI	70	63	52	74			3.85			
		antral PVI	117	68	53	79			3.95			

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Yamane 2007 Japan 17457004	y (exclude PV <12mm and no arrhythmogenicity)	99% in each group [bidirectional block between LA and PV]	ostial PVI – 15 or 20 mm Lasso for mapping antral PVI – 25 or 30 mm Lasso for mapping	y	8 mm	30-35	50	22 36

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Yamane 2007 Japan 17457004	success	freedom from AF after 3 mo in patients with paroxysmal AF	after initial procedure: ostial PVI	2.8 y			58.7%					
			after initial procedure: antral PVI	1.8 y			61.4%		NS			
		freedom from AF after 3 mo in patients with persistent AF	after initial procedure: ostial PVI				32.4%					
			after initial procedure: antral PVI				36.2%		NS			
	success	freedom from AF after 3 mo in patients with paroxysmal AF	after final procedure: ostial PVI				76%					
			after final procedure: antral PVI				93%		0.015			
		freedom from AF after 3 mo in patients with persistent AF	after initial procedure: ostial PVI				48%					
			after initial procedure: antral PVI				78%		0.032			

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	y		
Was a blanking period (time when AFib episodes were not recorded) used?	y	**If yes, how long was it?**	1 mo

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Yamane 2007 Japan 17457004	ostial PVI		(single vein) 3/70 (4.3%)						left atrial flutter	1/70 (1.4%)
	antral PVI		0						left atrial flutter	4/117 (3.4%)

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Yamane 2007 Japan 17457004	n	NA	NA	NA (?retrospective)	n	n	y	n	y	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		y	y	y	y	y				
Explanation for Overall Quality Grade:		two groups not totally comparable; non-concurrent and different durations of followup								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Yamane 2007 Japan 17457004		x	
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Zado Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Zado 2008 US 18462325				X		EB/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Zado 2008 US 18462325	Drug refractory AF	nd	2000-2007	Some amiodarone, mostly class IC Parox 6-12 weeks Persistent 6 mo But allowed to continue based on patient/MD preferences	1st and repeat procedures

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Zado 2008 US 18462325	nd (1 author reports grant money from industry)	High risk* : All 4 PV Remaining: arrhythmogenic PVs only	1165 (1506 procedures)	64%	55	77	nd	nd	4.4	<50% 11%	C	

* Persistent AF, no provocable triggers, HTN, LAE, >50 y.

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Zado 2008 US 18462325	Yes	100% (endpoint) Defined as loss of PV potentials (entrance block) and failure to capture LA when pacing each electrode pair of circular mapping catheter (exit block)	selected non-PV triggers (13%) CTI (h/o or induced typical atrial flutter) Macro reentrant AT if identified	Yes	nd	nd	nd	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Zado 2008 US 18462325	AF control	on or off AAD (per pt/MD preference or for previous recurrence), some with rare (≤6 episodes, 1 cardioversion max, >95% improvement)	RFA	~28	~688	781 (67% f/up)	88%					
	No AF off AAD	(underestimates because excludes those who chose to remain on AAD despite no AF)	RFA	~28	~496	781 (67% f/up)	63%					

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	Yes, but minimal attempt to capture ASx		
Was a blanking period (time when AFib episodes were not recorded) used?	Yes	**If yes, how long was it?**	8 wk

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Data reported by age group (<65, 65-74, ≥75) though no differences by age.	Zado 2008 US 18462325												

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Zado 2008 US 18462325	RFA		1/1506* (0.07%)	12/1506* (0.8%)	CVA/TIA 6/1506* (0.4%)	1/1506* (0.07%) Fistula	0 major	nd	Phrenic nerve injury (resolved)	2/1506* (0.13%)
									Anaphylaxis	2/1506* (0.13%)
									Retroperitoneal bleed	1/1506* (0.07%)

* in 1165 patients

25 major complications in 1506 procedures in 1165 patients.

**********Six patients had PV stenosis >70% detected on CT or MRI but only one required intervention because of symptoms.

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Zado 2008 US 18462325	No	NA	NA	No	No	No	No	No	+/-	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		No	Yes	No	Marginally	No				
Explanation for Overall Quality Grade:										

*observational study cannot be an A, retrospective study is always a C

N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Zado 2008 US 18462325			
Explanation for Applicability Grade:			

* If N<30 per intervention, then applicability is narrow

** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments
Zado 2008 US 18462325	Very likely large overlap with multiple other articles from UPenn

Zhou Evidence Tables

STUDY DESIGN

Author Year Country UI	RCT	Non-randomized comparative	Prospective cohort	Retrospective cohort	Others (Explain)	Extractor
Zhou, 2007 China 17624261			x			MC/AG

ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Author Year Country UI	Inclusion	Exclusion	Enrollment Years	Post RFA Anti-Arrhythmics (Time)	Other Important Characteristics
Zhou, 2007 China 17624261	Patients with persistent or paroxysmal AF who received PVI who had >1 risk factor for atrial thrombus formation received routine anticoagulation therapy prior and post ablation. The risk factors for atrial thrombus formation were as follows: (1) ≥65 years of age; (2) hypertension; (3) diabetes; (4) history of transient ischemic attack or stroke; (5) history of congestive heart failure or left ventricular end-diastolic diameter (LVED) >56 mm	None reported	July 2004 to January 2006	nd	

POPULATION

Author Year Country UI	Funding source	Intervention(s)	N enrolled	% Paroxysmal AF	Mean Age, yr	Male, %	Mean Symptom Duration, yr	CHF, %	Mean LAD, cm	Mean LVEF, %	Quality	Applicability
Zhou, 2007 China 17624261	National natural Science Foundation of China	Circumferential PVI	148	56.8	61	64	Paroxysmal AF=2.3 Persistent AF=3.6* (p<.05 compared to paroxysmal AF)	nd	Paroxysmal AF=4.4 Persistent AF=4.8* (p<.002 compared to paroxysmal AF)	nd		

RADIOFREQUENCY ABLATION CHARACTERISTICS

Author Year Country UI	PVI (y/n)	Isolation % Success (percent of patients) [Defn of Isolation]	Others (WACA, CFAE, Other Lines, Ganglionic Plexi)	Checked Inducibility (y/n)	Catheter Tip	Energy		
						Watts	Max Temp, ºC	Total Ablation Time, min
Zhou, 2007 China 17624261	yes	100% [disappearance of potential of all PVs on the pulmonary circling electrode (Lasso), or disassociation of the PV potential and atrial electrical activity]	none	no	8-mm or irrigated tip (Navistar, Biosense Webster)	50	8-mm: 55 Irrigated: 40	nd

RESULTS (dichotomized or categorical outcomes)

Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
							Result*	95% CI	P btw	Result*	95% CI	P btw
Zhou, 2007 China 17624261	AF recurrence	nd	Circumferential PVI	7.4	11	148						

Duplicate one row per outcome and per RFA intervention.
* Type in metric. For example: "OR=1.7" or "HR=0.9"

Did the (recurrence) outcome include asymptomatic AFib? e.g., Was 24 hour or greater ECG screening performed?	nd		
Was a blanking period (time when AFib episodes were not recorded) used?	nd	**If yes, how long was it?**	

RESULTS (continuous measures)

Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.

SUBGROUP ANALYSIS (dichotomized or categorical outcomes)

Subgroup	Author Year Country UI	Outcome	Definition	Intervention	Mean Follow-up, mo	n Event	N Total	Unadjusted			Adjusted		
								Result*	95% CI	P btw	Result*	95% CI	P btw
Paroxysmal AF	Zhou, 2007 China 17624261	AF recurrence	nd	Circumferential PVI	7.4	4	84			0.21			
Persistent AF						7	64						

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

SUBGROUP ANALYSIS (continuous measures)

Subgroup	Author Year Country UI	Outcome	Definition	Unit	Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Final	Net difference	P between

Duplicate one row per outcome and per RFA intervention.
e.g., Subgroups = male/female; age group (<50, 50-70, >70); CHF (+/-); chronic/persistent/paroxysmal; others

ADVERSE EVENTS

Author Year Country UI	Intervention	Mean Follow-up, mo	PV Stenosis (Severity), n/N (%)	Cardiac Tamponade, n/N (%)	Stroke, n/N (%)	Esophageal Perforation, n/N (%)	Peripheral Vascular Complications, n/N (%)	30-Day Mortality, n/N (%)	Other Major AE, n/N (%)	
Zhou, 2007 China 17624261	Circumferential PVI							1/148 (0.7%)**	Thrombus formation	Persistent AF: 4/64 (6.3%) Paroxysmal AF: 0/84 (0%)* (p=.033 compared to persistent AF)

**72-year-old male paroxysmal AF patient with hypertension, CHD and history of PCI, died of pulmonary infection 3 weeks post PVI

The following information will not be in the summary tables.

QUALITY

Author Year Country UI	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade*
Zhou, 2007 China 17624261	no	NA	NA	0 (assumed)	nd	Yes (0% dropout)	yes	yes	no	C
		Was RFA Procedure Adequately Described?	**Were the Recurrence Outcomes Fully Defined?**	**Was Success Rate After a Single Procedure (not including redo) Reported?**	**Was Asymptomatic AFib Screened For?**	**Was Compliance with Screening Reported?**				
		yes	no	no	no	no				
Explanation for Overall Quality Grade:		No data on AAD use, no data on ablation time, poor outcome reporting								

*observational study cannot be an A, retrospective study is always a C
N must be ≥100 per intervention for quality to be an A

APPLICABILITY ASSESSMENT

Author Year Country UI	Applicable to study population only (Narrow)*	Applicable to study population and others with some difficulty (Moderate)	Applicable to study population and others with ease (Wide)**
Zhou, 2007 China 17624261		x	
Explanation for Applicability Grade:		Targeting a specific group of patients (see inclusion criteria)	

* If N<30 per intervention, then applicability is narrow
** N must be ≥100 per intervention for applicability to be wide

SPECIFIC COMMENTS CONCERNING THE STUDY

Author Year Country UI	Comments

Appendix D: Panel of Expert Reviewers

Peer Reviewers

Peer reviewer comments on a preliminary draft of this report were considered by the EPC in preparation of this final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives are sought. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design and/or methodologic approaches do not necessarily represent the views of individual technical and content experts.

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