APPENDIXES

Appendix A: Search Strategy

Database: MEDLINE 1996-April Week 4 2007

#	Search History
1	exp Hypertension, Renal/
2	exp Renal Artery Obstruction/
3	renal arter$ stenosis.tw.
4	renal arter$ dis$.tw.
5	renovascular dis$.tw.
6	reno vascular dis$.tw.
7	renal vascular dis$.tw.
8	(arvd or "atherosclerotic renovascular dis$").tw.
9	renal steno$.tw.
10	steno$ kidney.tw.
11	renovascular steno$.tw.
12	or/1-11
13	limit 12 to humans
14	limit 13 to english language
15	limit 14 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index or "review of reported cases")
16	14 not 15
17	[limit to MEDLINE entry dates August 2005 to April 23, 2007]

Appendix B: Excluded Studies

Cianci R, Coen G, Manfredini P et al. Diagnosis and outcome of renal function in patients with renal artery stenosis: which role have color Doppler sonography and magnetic resonance angiography? Minerva Cardioangiologica. 2006;54:139-144.
Diagnosis of RAS only

Cooper CJ, Murphy TP, Matsumoto A et al. Stent revascularization for the prevention of cardiovascular and renal events among patients with renal artery stenosis and systolic hypertension: rationale and design of the CORAL trial. American Heart Journal. 2006;152:59-66.
Study design only

Edwards MS, Corriere MA, Craven TE et al. Atheroembolism during percutaneous renal artery revascularization. Journal of Vascular Surgery. 2007;46:55-61.
N<30 (PTRA study)

Hanzel G, Balon H, Wong O, Soffer D, Lee DT, Safian RD. Prospective evaluation of aggressive medical therapy for atherosclerotic renal artery stenosis, with renal artery stenting reserved for previously injured heart, brain, or kidney. American Journal of Cardiology. 2005;96:1322-1327.
Already included in original CER

Kalra PA, Guo H, Kausz AT et al. Atherosclerotic renovascular disease in United States patients aged 67 years or older: risk factors, revascularization, and prognosis. Kidney International. 2005;68:293-301.
Retrospective (PTRA study)

Kashyap VS, Sepulveda RN, Bena JF et al. The management of renal artery atherosclerosis for renal salvage: does stenting help? Journal of Vascular Surgery. 2007;45:101-108.
Retrospective (PTRA study)

Kennedy DJ, Burket MW, Khuder SA, Shapiro JI, Topp RV, Cooper CJ. Quality of life improves after renal artery stenting. Biological Research for Nursing. 2006;8:129-137.
Cross-sectional study

Mitchell JA, Subramanian R, White CJ et al. Predicting blood pressure improvement in hypertensive patients after renal artery stent placement: renal Fractional Flow Reserve. Catheterization & Cardiovascular Interventions. 2007;69:685-689.
N<30 (PTRA study)

Muller-Hulsbeck S, Frahm C, Behm C et al. Low-profile stent placement with the monorail technique for treatment of renal artery stenosis: midterm results of a prospective trial. Journal of Vascular & Interventional Radiology. 2005;16:963-971.
N<30 analyzed (PTRA study)

Murphy TP, Cooper CJ, Dworkin LD et al. The Cardiovascular Outcomes with Renal Atherosclerotic Lesions (CORAL) study: rationale and methods. Journal of Vascular & Interventional Radiology. 2005;16:1295-1300.
Study design only

Pearce JD, Craven BL, Craven TE et al. Progression of atherosclerotic renovascular disease: A prospective population-based study. Journal of Vascular Surgery. 2006;44:955-962.
No outcomes of interest

Rivolta R, Bazzi C, Stradiotti P, Paparella M. Stenting of renal artery stenosis: is it beneficial in chronic renal failure? Journal of Nephrology. 2005;18:749-754.
Already included in original CER

Rocha-Singh K, Jaff MR, Rosenfield K, Trial I. Evaluation of the safety and effectiveness of renal artery stenting after unsuccessful balloon angioplasty: the ASPIRE-2 study.[see comment]. Journal of the American College of Cardiology. 2005;46:776-783.
Already included in original CER

Rocha-Singh KJ, Ahuja RK, Sung CH, Rutherford J. Long-term renal function preservation after renal artery stenting in patients with progressive ischemic nephropathy. Catheterization & Cardiovascular Interventions. 2002;57:135-141.
Retrospective (PTRA study)

Scarpioni R, Michieletti E, Cristinelli L et al. Atherosclerotic renovascular disease: medical therapy versus medical therapy plus renal artery stenting in preventing renal failure progression: the rationale and study design of a prospective, multicenter and randomized trial (NITER). Journal of Nephrology. 2005;18:423-428.
Study design only

Appendix C: Peer Reviewers

We gratefully acknowledge the following individuals who reviewed the initial draft of this Report and provided us with constructive feedback. Acknowledgments are made with the explicit statement that this does not constitute endorsement of the report by the peer reviewers.

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Drs. Gilbert, Rundback, Textor and Tuttle were also members of the EPC's Technical Expert Panel for the original CER

Appendix D: Supplemental Tables and Figure

Table 2. Direct comparisons of angioplasty or surgery and medical treatment for renal artery stenosis *(new results in italics)*

Author, Year / Study Design	Intervention	Mean BP / Mean GFR [SCr]	Mean % Stenosis / % Bilateral Stenosis	No. Evaluated RAS (ARAS)	RAS Location / Years Enrolled	Mean Duration / Range	Results: HTN (%) and BP Δ	Results: CKD (%) and GFR / SCr Δ	Results: CVD (%)	Qual / Appl
Angioplasty vs Medical Treatment, RCT										
Webster, 1998[12] SNRASCG RCT (bilateral disease, see other entries)	Angioplasty No stent	190/99 [2.1]	>50%	12 (12)	Ostial 46%	(3-54 mo)	6 mo BP Δ = -24/-9 Adj BP Δ = -34/-11 (adjusted for followup time)	6 mo SCr Δ = +0.01 Final SCr Δ = +0.11 "Renal failure":[A] 8%	Angio-plasty:[A] CHF 9% CVA 4% MI 4%	B
	Medicine 2-3 of atenolol, bedrofluazide, CCB[B]	190/101 [1.7]	100%	16 (16)	nd		6 mo BP Δ = -13/-10 NS (net) Adj BP Δ = -8/-1 P=0.02 (net)	6 mo SCr Δ = +0.10 NS (net) Final SCr Δ = +0.05 NS (net) "Renal failure":[A] 7%		
RCT (unilateral disease, see other entries)	Angioplasty No stent	189/105 [1.6]	>50%	13 (13)	Ostial 52%	(3-54 mo)	6 mo BP Δ =-19/-11 Adj BP Δ = -2/-2	6 mo SCr Δ = +0.07 Final SCr Δ = +0.09	Medical:[A] CHF 13% CVA 13% MI (unclear)	Mod
	Medicine 2-3 of atenolol, bedrofluazide, CCB[B]	182/99 [1.9]	0%	14 (14)	nd		6 mo BP Δ =-19/-15 NS Adj BP Δ = -10/-2 NS (net)	6 mo SCr Δ = +0.44 NS (net) Final SCr Δ = 0 NS (net)		
Plouin, 1998[15] EMMA RCT	Angioplasty +/-stent[C]	165/98 73	>60%	23 (23)	Ostial 39%	6 mo	BP Δ = -14/-8	0/23 CrCl Δ = +4		B
	Medicine[D] Multiple regimens[F]	165/96 73	0%	25 (25)	1992-1995		BP Δ = -7/-1 p=NS/0.04 (net)	1/19[E] CrCl Δ = 0 NS (net)		Low
Angioplasty vs Medical Treatment or Delayed Angioplasty, RCT										
van Jaarsveld, 2000[13,14,16,23] DRASTIC RCT	Angioplasty No stent[G]	179/104 67	76% 23%	56 (56)	nd	1 yr	BP Δ = -19/-12	4% CrCl Δ = +3		B
	Medicine[H] (n=28) Multiple regimens[I] Delayed angioplasty (n=22)	180/103 60	72% 22%	50 (50)	1993-1998		BP Δ = -17/-7 NS (net)	12% CrCl Δ = +2 NS (net)		
						Quality of Life:	*Physical complaints: Number of complaints decreased more after angioplasty than medicine, NS* *EuroQol and MOS: Overall NS* *MOS social functioning:* *3 mo: angioplasty better than medicine (+11 v 0, p=.06)* *12 mo: medicine better than angioplasty (+20 v -2, p=0.04)*			High

Continued.

Table 2. Direct comparisons of angioplasty or surgery and medical treatment for renal artery stenosis (continued)

Author, Year Study Design	Intervention	Mean BP Mean GFR [SCr]	Mean % Stenosis % Bilateral Stenosis	No. Evaluated RAS (ARAS)	RAS Location Years Enrolled	Mean Duration Range	Results HTN (%) and BP Δ Cured	Imp	UnΔ	Worse	CKD (%) and GFR / SCr Δ Imp	UnΔ	Worse	CVD (%)	Qual Appl
Angioplasty vs Medical Treatment, Nonrandomized, Controlled Trial															
Losito, 2005[24]	*Angioplasty* *Few with stent*	*166/92* *[1.8]*	*74%*	*136* *(136)*	*Proximal 79%, Ostial 6%, Distal 15%*	*54.4 mo*	*BP Δ = -22/-10*				*SCr Δ = +0.48* *ESRD = 9.4%*				*B*
Prosp	*Medicine* *nd*	*160/89* *[1.7]*	*26%*	*54* *(54)*	*1992-2000*	*nd*	*BP Δ = -11/-8 P<0.05 (net)*				*SCr Δ = +1.29 P=0.04 (net)* *ESRD = 13.0% NS (net)*				*Mod*
Webster, 1998[12]	Angioplasty No stent	196/109 [1.9]	>50%	28 (28)	Ostial 63%	nd	Adj BP Δ = -13/-11				Final SCr Δ = +0.15				B
NRCT (see other entries)	Medicine 2-3 of atenolol, bedrofluazide, CCB[B]	197/103 [1.6]	nd	51 (51)	nd	(3-54 mo)	Adj BP Δ = -12/-6 NS (net)				Final SCr Δ = 0.05 NS (net)				Low
Taylor, 1989[22]	Angioplasty No stent	160/96 nd	>60%	5 (nd)	nd	6.5 mo 1-21 mo			nd BP Δ = -23/-6			SCr Δ = -0.5 (including 7 receiving surgery)			C
Prosp	No revascularization nd (0-3 drugs)	174/100 nd	nd	15 (nd)	nd	13 mo 7-20 mo			20% BP Δ = -24/-20			SCr Δ = +1.0 P=0.08 (base); P<0.01 (net)			Low
Englund, 1991[21]	Angioplasty No stent	165/96 [3.9]	nd	21 (?19-21)	nd	17 mo nd	0		BP Δ = -9/-5			SCr Δ = +1.05			C
Retro	Medicine nd	185/101 [3.8]	nd	17 (17)	1981-1988	16 mo nd	0 BP Δ = -24/-12 NS (net)				SCr Δ = 0.+69 NS (net)				Low
Pizzolo, 2004[17 J]	Angioplasty +/-stent[K]	168/95 [1.5]	~88% 30%	63 (63)	nd	28 mo	0	57%	43%		82%		18%		C
Retro	Medicine Multiple regimens[L]	159/91 [1.4]	~79% 27%	37 (37)	1996-2002	1-60 mo	0 P<0.05	29%	71%		52%		48%		Low

Continued.

Table 2. Direct comparisons of angioplasty or surgery and medical treatment for renal artery stenosis (continued)

Author, Year / Study Design	Intervention	Mean BP / Mean GFR [SCr]	Mean % Stenosis / % Bilateral Stenosis	No. Evaluated RAS (ARAS) / Years Enrolled	RAS Location / Range	Mean Duration	Results: HTN (%) and BP Δ				Results: CKD (%) and GFR / SCr Δ			Results: CVD (%)	Qual / Appl
							Cured	Imp	UnΔ	Worse	Imp	UnΔ	Worse		
Angioplasty or Surgery vs Medical Treatment, Nonrandomized, Controlled Trial															
Pillay, 2002[18]	Procedure Various[M]	nd	>50%	12 (nd)	nd	2.5 yr	DBP Δ = -15				SCr Δ = +0.6 P=0.01 (base) Dialysis: 1/12				C
Prosp	Medicine nd		100%	21 (nd)	1994-1998	>2 yr	DBP Δ = -6 NS (net)				SCr Δ = 0 NS (base) Dialysis 0/12				Low
Johansson, 1999[20]	Procedure Various[N]	179/91	≥ 50%	105 (~91)	nd	7.1 yr	53% (1 yr)								C
Prosp	Medicine nd	61	nd	64 (~56)	1983-1984 & 1988-1994		nd								Low
Surgery vs Medical Treatment, RCT															
Uzzo, 2002[19]	Surgery Multiple	nd	≥ 75%	25 (25)	nd	6.2 yr	No difference in "blood pressure control" (NS)				No difference in dialysis-free survival or change in GFR (NS)			Stop point:[O] 68%	C
RCT	Medicine nd	nd	nd	27 (27)	nd	up to 7 yr								67% NS[P]	Low

Δ, change; Adj, adjusted; Appl, applicability rating; ARAS , atherosclerotic renal artery stenosis; BP, blood pressure; CHF, congestive heart failure; CKD, chronic kidney disease; CVA, cerebrovascular event (stroke); CVD, cardiovascular disease; DBP, diastolic blood pressure; GFR, glomerular filtration rate (or creatinine clearance, mL/min or mL/min/1.73 m^2); HTN, hypertension; Imp, improved; MI, myocardial infarction; mo, months; nd, no data; NS, nonsignificant; Qual, quality rating; RAS, renal artery stenosis; Rx, prescriptions; SCr, serum creatinine (mg/dL); UnΔ, unchanged (or stable); yr, years.

[A] Combined unilateral and bilateral RAS.
[B] Or, frusemide, methyldopa, or prazosin. Angiotensin converting enzyme inhibitors were not allowed.
[C] 21 angioplasty alone, 2 angioplasty with stent.
[D] Intention to treat. 7 of 26 patients randomized to medical therapy received angioplasty within 6 months.
[E] ≥50% increase in plasma creatinine.
[F] Goal diastolic blood pressure (DBP)<95 mm Hg, using, if necessary, atenolol 50 mg, furosemide 40 mg, and/or enalapril 10 mg.
[G] Protocol called for no stent, but stents were placed in 2 patients.
[H] Intention to treat. 22 of 50 patients randomized to medical therapy at 3 months received angioplasty because of persistent hypertension or deterioration of kidney function.
[I] Randomized to amlodipine 10 mg (+ atenolol 50 mg if age >40 yr) or enalapril 20 mg (+ hydrochlorothiazide 25 mg if age >40 yr), or if could not tolerate either regimen, atenolol 100 mg (+ hydrochlorothiazide 25 mg if age >40 yr).
[J] Entry criteria for those receiving angioplasty and those receiving medical therapy were markedly different. Those receiving angioplasty had primary evaluation for resistant hypertension or unexplained azotemia. Those receiving conservative therapy had angiographic evaluation for other causes, primarily lower extremity arteriopathy. Endovascular therapy not considered for this latter group.
[K] 21 angioplasty alone; 42 angioplasty with stent.
[L] Goal BP≤140/90. Most frequent used classes of drugs were ACE inhibitors (62%), diuretics (62%), calcium antagonists (49%), and beta-blockers (30%).

[M] Among 12 patients, “9 angioplasties (1 failure) and 1 bilateral stent. 4 kidneys had... surgery.”
[N] 88 angioplasty, 17 reconstructive surgery or nephrectomy.
[O] DBP>100 on treatment, or kidney function worsening (by GFR, SCr, or dialysis), or atherosclerotic cardiovascular event, or death.
[P] By Cox proportional hazard survival analysis.

Table 3. Adverse events associated with medical and angioplasty treatments of renal artery stenosis in direct comparison studies (no new data)

Author Year	N RAS (ARAS)	Intervention	Kidney-related	CVD-related	Thrombosis/ occlusion	Bleeding	30 d mortality	Other
Pizzolo 2004[17]	122 (122)	Angioplasty (+/- stent) vs Medical (multiple regimens)	Partial kidney infarction 3% (Angioplasty) Periprocedure acute worsening kidney insufficiency 3% (Angioplasty)	Periprocedure MI 1.6% (Angioplasty)	Cholesterol embolism 1.6% (Angioplasty)			3 of the 4 adverse events occurred in the same person. No data on adverse events in medicine arm
Webster 1998[12]	55 (55)	Angioplasty (no stent) vs. Medical (atenolol, bedrofluazide, and/or calcium antagonist, or others)		In hospital stroke 5% (Angioplasty) Symptomatic hypotension 2% (Angioplasty)	No dissections, perforation, or renal artery thrombosis	Bleeding at arterial site 20% (Angioplasty)	No deaths	Pain requiring narcotic analgesic 10% (Angioplasty) No data on adverse events in medicine arm
Plouin 1998[15]	49 (49)	Angioplasty (+/- stent) vs. Medical (multiple regimens)	Renal artery dissection 4% (Angioplasty) 0% (Medical)		No occlusions	Hematoma at puncture site 22% (Angioplasty) 4% (Medical)		
Englund 1991[21]	38 (36)	Angioplasty (no stent) vs. Medical (nd)	Rupture of dilated renal artery & nephrectomy 3% (Angioplasty)				3% (Angioplasty) 5% (Medical)	
Van Jaarsveld 2000[13,14,16]	106 (106)	Angioplasty (no stent) vs. Medical (multiple regimens) or delayed angioplasty		Periprocedural angina 0% (Angioplasty) 2% (Medical / Delayed angioplasty) Periprocedural MI 0% (Angioplasty) 2% (Medical / Delayed angioplasty)	Occlusion of affected artery 0% (Angioplasty) 16% (Medical / Delayed angioplasty) Rupture of affected artery 0% (All)	Groin hematoma necessitating transfusion or intervention 4% (Angioplasty) 8% (Medical / Delayed angioplasty)		Embolization of cholesterol crystals 0% (Angioplasty) 14% (Medical / Delayed angioplasty) Symptomatic hypotension at angioplasty 1.8% (Angioplasty) 0% (Medical / Delayed angioplasty)

ARAS, atherosclerotic renal artery stenosis; CVD, cardiovascular disease; d, day; MI, myocardial infarction; N, number evaluated; nd, no data; RAS, renal artery stenosis

Table 4. Medical treatments for blood pressure maintenance of atherosclerotic renal artery stenosis (no new data)

Author, Year Study Design	Mean BP Mean GFR [SCr]	Mean % Stenosis % Bilateral Stenosis	No. Evaluated RAS (ARAS)	Intervention Study Years	Mean Followup Duration (Range)	Results BP Control	Results Kidney Function	Results Cardio-vascular Disease	Qual Appl
Hanzel, 2005[27]	154/77	≥70%	40	Aspirin, statin, and antihypertensive therapy[A]	21 mo		SCr Δ +0.1 (+7%) *P=0.02*		B
Prosp	61 [1.3]	18%	(40)	nd	(nd)	BP Δ –11/-5 *P=0.03/0.01*	GFR Δ –4 (–6%) *P=0.03*	Stroke 1/40 MI 1/40	Mod
Franklin, 1985[28,29]	180/106	>50%	13	Triple-drug regimen cross to enalapril 5-20 mg	7.5[D] mo	BP Δ –50/-29			C
RCT & Prosp[B]	[1.3][C]	49%[C]	(nd)	nd	(nd)	*P≤0.01*			Low
Ogihara, 1991[30]	172/103	nd	10	Delapril 7.5-120 mg	Mostly 12 wk >1 yr in some	8/10 BP Δ ≥ -20/-10			C
Prosp	nd	nd	(nd)	nd		5/10 BP Δ ≥ -30/-15			Low
Tillman, 1984[31]	180/104[E]	nd	20	Enalapril 10-40 mg	19 mo	BP Δ -40/-19[D]	SCr Δ +0.3		C
Prosp	[1.3]	25%	(≤19)	nd	(8-32 mo)	*P<0.05*	*P<0.05*		Low

Δ, change; Appl, applicability rating; ARAS , atherosclerotic renal artery stenosis; BP, blood pressure; GFR, glomerular filtration rate (mL/min or mL/min/1.73 m^2); HTN, hypertension; mo, months; nd, no data; Mod, moderate; Prosp, prospective nonrandomized study; Qual, quality rating; RAS, renal artery stenosis; RCT, randomized controlled trial; SCr, serum creatinine (mg/dL); wk, weeks; yr, year.

[A] All patients received aspirin 325 mg/day and a statin to achieve LDL cholesterol <100 mg/dl. Antihypertensive therapy was initiated with an ACE inhibitor or ARB, and other agents were added as necessary. Six patients (15%) developed progressive decreases in single-kidney GFR underwent late renal artery stenting. After stenting, patients received ticlopidine 250 mg twice daily or clopidogrel 75 mg/day for more than 30 days.
[B] Initially an RCT, then an open-label trial during a "maintenance period."
[C] Data was based on the total of 39 patients who were randomized to standard triple therapy group. Of these, in 13 patients therapy was switched from the triple-drug regimen to enalapril during the extension period, and the outcomes were based on these 13 patients.
[D] Median
[E] Value was estimated from graph.

Table 5. Adverse events associated with the medical treatment of renal artery stenosis (no new data)

Author Year	N RAS (ARAS)	Intervention	Kidney-related	CVD-related	Thrombosis/ occlusion	Bleeding	30 d mortality	Other
Franklin 1985[28,29]	75 (57)	Medical (Enalapril vs STT)		Orthostatic hypotension 11% (enalapril) CNS symptoms 18% (STT)				No leucopenia, dysgeusia, rash, or proteinuria
Takabatake 1987[32]	21	Medical (Captopril)		Hypotension comparable in bilateral and unilateral stenosis (nd on %)				
Tillman 1984[31]	20 (≤19)	Medical (Enalapril)		Symptomatic tachycardia 20% Angina 5%				
Jackson 1986[33,34]	16 (16)	Medical (Enalapril)	Increased SCr 25%					No rash, taste disturbance, or neutropenia
Hricik 1983[35]	11 (nd)	Medical (Captopril)	Transient kidney insufficiency 100%					

ARAS, atherosclerotic renal artery stenosis; CNS, central nervous system; CVD, cardiovascular disease; d, day; GFR, glomerular filtration rate; MI, myocardial infarction; N, number evaluated; nd, no data; RAS, renal artery stenosis; STT, "standard triple therapy"; SCr, serum creatinine.

[A] All patients received aspirin 325 mg/day and a statin to achieve LDL cholesterol <100 mg/dl. Antihypertensive therapy was initiated with an ACE inhibitor or ARB, and other agents were added as necessary. Six patients (15%) developed progressive decreases in single-kidney GFR underwent late renal artery stenting. After stenting, patients received ticlopidine 250 mg twice daily or clopidogrel 75 mg/day for more than 30 days.

Table 6. Natural history or nonspecified medical treatments of atherosclerotic renal artery stenosis (no new data)

Author, Year Study Design	Mean BP Mean GFR [SCr]	Mean % Stenosis % Bilateral Stenosis	No. Evaluated RAS (ARAS)	Intervention Study Years	Mean Followup Duration (Range)	Results BP Control	Kidney Function	Cardiovascular Disease	Qual Appl
Caps, 1998[36]	163/84[A]	≥60%	100[B]	Medical Rx	nd		Kidney atrophy: 21% [C]		B
Prosp	[1.6] [A]	nd	(100)	1990-1993	(2-24 mo)				Mod
Cheung, 2002[42]	167/87	≥50%	26 or 11[D]	Mostly medical Rx[E]	35 mo		ΔGFR: -4.9/yr (n=11) GFR Δ >20%: 6/11		C
Prosp & Retro	35.5	100%	(nd)	nd	(1-82 mo)				Low
Conlon 2001[37]	nd	≥50%	362	Various	3.2 y		Only mortality data reported		B
Prosp	[1.2]	17%	(nd)	nd	(6-90 mo)				Low
Fergany, 1994[38]	179/102	nd	20	Medical Rx	43 mo	BP Δ -39/-17 *P=0.03*	SCr Δ +0.2 *NS*		C
Prosp	[1.2]	65%	(nd)	1970-1990	(4-120 mo)				Low
Houston, 2004[39]	nd	>60%	45	nd	9 yr		SCr Δ +0.3[F] *P=0.004*		C
Prosp	[~1.8][F]	nd	(nd)	nd					Mod
Iglesias, 2000[41]	143/84	>20%	96 or 78[G]	nd	55 mo		ΔSCr: +0.06 / yr (n=78)		C
Retro	[1.2]	20%	(nd)	nd	(nd)				Mod
Pillay, 2002[18]	nd/88[F]	>50%	52 or 35[H]	Medical Rx	2 yr	DBP Δ -8[F] *P=NS*	SCr Δ +0.2[F] (n=35) *P=0.002* Dialysis: 2/52		C
Prosp	[1.2][F]	0%	(nd)	1994-1998	(2 yr)				Low
Uzu, 2002[40]	170/77	≥ 75%	20	Medical Rx	nd		Dialysis: 8/20	CVD deaths: 8/20	B
Prosp	[3.2]	59%	(nd)	1996-1998	(3-36 mo)				Low

Δ, change; Appl, applicability rating; ARAS , atherosclerotic renal artery stenosis; BP, blood pressure; CVD, cardiovascular disease; DBP, diastolic blood pressure; GFR, glomerular filtration rate (or creatinine clearance, mL/min or mL/min/1.73 m^2); mo, months; Mod, moderate; nd, no data; NS, nonsignificant; Qual, quality rating; RAS, renal artery stenosis; Rx, prescription; SCr, serum creatinine (mg/dL); yr, years.

[A] Data were based on all 204 kidneys, including 43 (21 percent) kidneys with normal baseline arteries at baseline.
[B] Number of kidneys
[C] Cumulative incidence of kidney atrophy (a reduction in kidney length >1 cm during followup compared to the length at baseline examination) over a period of 2 year
[D] Only nondialysis and survived patients with baseline renal functional data were analyzed for followup renal function analyses.
[E] Very few patients received angioplasty; of which only one received stent.
[F] Value was estimated from graph.
[G] Patients who died within 180 days excluded from analyses of annual changes SCr. These patients had better survival rate than the whole cohort.
[H] Survivors only.

Table 7. Angioplasty with stent placement for treatment of renal artery stenosis *(new studies in italics)*

Author, Year / Study Design	Mean BP / Mean GFR [SCr]	Mean % Stenosis / % Bilateral Stenosis	No. Evaluated RAS (ARAS)	RAS Location / Years Enrolled	Mean Duration / Range	Results: HTN (%) and BP Δ				Results: CKD (%) and GFR / SCr Δ			Results: % Restenosis	Qual / Appl
						Cured	Imp	UnΔ	Worse	Imp	UnΔ	Worse		
Kennedy, 2003[60,61 A]	168/82	>60[B]	261	nd	21 mo								48	B
Prosp	51	38	(253)	1993-2001	1-85	BP Δ = -19/-6 P=0.0001				CrCl Δ = -2 P <0.05			17 mo	High
Ruchin, 2007[79]	*162/78*	*84*	*89*	*nd*	*28 mo*								*6.2*	*B*
Prosp	*50*	*nd*	*(87)*	*1997-2003*	*6-84*	*BP Δ = -23/-1.7 P<0.0001/NS*				*eGFR Δ = +2.0 NS*			*nd*	*High*
van de Ven, 1999[76]	186/103	>50	40	Ostial 100%	6 mo	15	43	43		13	65	20	14	B
Prosp	[1.8]	18	(40)	1993-1997	nd									High
Zeller, 2004[69-73]	102	>70	354[K]	Ostial 95%	34 mo		46	43	11	10	39	27		B
Prosp	[1.5]	nd	(340)	1996-2002	2-79	MAP Δ = -8 P<0.0001				GFR Δ = +3.0 NS			nd	Mod
Rocha-Singh, 2005[65]	168/82	>70	208	Ostial 100%	nd								17[C]	B
Prosp	[1.4]	21	(208)	1997-1999	9-24 mo	BP Δ = -19/-5 P=0.001				SCr Δ = +0.10 P<0.04			9 mo	Mod
Dangas, 2001[45 D]	170/84	74	131	Ostial 75%	15 mo		47	40	13	18	61	21		B
Prosp	[1.9]	17	(nd)	nd	nd	BP Δ = -25/-10 P<0.001				SCr Δ = +0.1 NS			nd	Mod
White, 1997[68]	173/88	>50	100	Ostial 81%	6 mo								19[C]	B
Prosp	[2.4]	33	(100)	1992-1994	nd	BP Δ = -27/-11 P<0.01							6 mo	Mod
Gill, 2003[51]	191/98[E]	>50[F]	100[G]	Ostial 78%	25 mo	4	79	17		31	42	31	66[H]	B
Prosp	[2.7][I]	26	(100)	1993-1999	1-66	BP Δ = -27/-12 P<0.01				SCr Δ = -0.6 mg/dL[J] NS			11 mo	Mod
Iannone, 1996[59]	160/80	67	63	Ostial 78%	10 mo	4	35	54	7	36	46	18	14[c]	B
Prosp	[1.8]	22	(63)	1992-1993	1-22	BP Δ = -12 / -1 P=0.01/NS				SCr Δ = -0.1 NS			11 mo	Mod
Sapoval, 2005[80]	*172/92*	*68*	*52*	*Ostial 62%*	*6 mo*	*5*	*61*	*34*				*3.8*	*14.3*	*B*
Prosp	*[1.2]*	*nd*	*(52)*	*2001-2002*	*nd*	*BP Δ = -20 / -7 NS*				*SCr Δ = -0.07 NS*			*6 mo*	*Mod*
Harden, 1997[56]	169/95	>50	32	Ostial 75%	17 mo					34	34	28	12.5	B
Prosp	nd	34	(32)	1992-1995	nd	BP Δ = -6 / -8 NS/ <0.01							6 mo	Mod

Continued.

Table 7. Angioplasty with stent placement for treatment of renal artery stenosis (continued)

Author, Year / Study Design	Mean BP / Mean GFR [SCr]	Mean % Stenosis / % Bilateral Stenosis	No. Evaluated RAS (ARAS)	RAS Location / Years Enrolled	Mean Duration / Range	Results: HTN (%) and BP Δ — Cured	Imp	UnΔ	Worse	CKD (%) and GFR / SCr Δ — Imp	UnΔ	Worse	% Restenosis	Qual / Appl
Tsao, 2005[81]	*146/78*	*86*	*54*	*Ostial 95%*	*6 mo*					*15*	*79*	*6*	*3*	*B*
Prosp	*36*	*22*	*(53)*	*2001-2004*	*nd*		*BP Δ =-15/-7 P<0.05*				*SCr Δ= ~ -0.1 NS*		*6 mo*	*Low*
Blum, 1997[43]	MAP 133	>50	68	Ostial 100%	27 mo	11	42	15					12	B
Prosp	[1.2]	9	(68)	1989-1996	3-84		MAP Δ = -20 P<0.0001				SCr Δ= 0 NS		3-24 mo	Low
Gross, 1998[55]	163/93	75	30	Ostial 100%	6 mo		69	31					12.5	B
Prosp	[1.4]	23	(30)	nd	nd		BP Δ =-18/-10 P=0.004/0.007						6 mo	Low
Dorros, 2002[46-50]	168/84	nd	1058	nd	nd								nd	C
Prosp	[1.7]	36	(1058)	1990-1997	1-4 yr		BP Δ = -21/-6 P<0.05				SCr Δ = -0.4 P<0.05			Mod
Lederman, 2001[62]	164/84	62	300	Ostial: 95%	16 mo		70			8	78	14	21	C
Prosp and Retro	[1.5]	41	(293)	1993-1998	6-24		BP Δ = -22/ -8				SCr Δ = +0.1 P=0.05		17 mo	Mod
Rocha-Singh, 1999[66]	110 MAP[L]	>75	150	Ostial 43%	13 mo	6	50		44	23	69	8	12[C]	C
Prosp	[1.5][M]	20[N]	(150)	1993-1995	nd						SCr Δ = +0.04 NS		13 mo	Mod
Tuttle, 1998[67]	160/84	>70	129	Ostial 100%	nd		55			15	81		14[C]	C
Prosp & Retro	40	15	(129)	1991-1996	6-24		BP Δ = -8/-4[O] P<0.05				CrCl Δ= 0 NS		8 mo	Mod
Ramos, 2003[63]	160/91	>70	105	Ostial 32%	12.2 mo	18	47						14	C
Prosp	54	43	(105)	nd	3.3-23		BP Δ = -15/-8 P<0.0001				GFR Δ = +8 P=0.007		12 mo	Mod
Harjai, 1997[57]	178/91	>70	66	Ostial 73%	19 mo		66						25	C
Prosp	[1.6]	27	(66)	1992-1995	nd		BP Δ = -32/-17 nd						9 mo	High

Continued.

Table 7. Angioplasty with stent placement for treatment of renal artery stenosis (continued)

Author, Year / Study Design	Mean BP / Mean GFR [SCr]	Mean % Stenosis / % Bilateral Stenosis	No. Evaluated RAS (ARAS)	RAS Location / Years Enrolled	Mean Duration / Range	Results: HTN (%) and BP Δ — Cured	Imp	UnΔ	Worse	CKD (%) and GFR / SCr Δ — Imp	UnΔ	Worse	% Restenosis	Qual / Appl
Holden, 2006[78]		*153/101*	*nd*	*63*	*nd*	*nd*	*0*	*55*			*CKD 3A:[1] 52*	*48*	*0*		*C*
											CKD 3B:[2] 32	*60*	*8*		
											CKD 4:[3] 33	*67*	*0*	*8*	
Prosp		*76% Stage 3 24% Stage 4*	*nd*	*(63)*	*nd*	*nd*	*BP Δ (44 with HTN) = -32/-10*				*SCr Δ =~ -0.1*				*High*
Goncalves, 2007[77]		*177/98*	*nd*	*46*	*nd*	*nd*									*C*
Prosp		*[2.3]*	*nd*	*(46)*	*1999-2003*	*7-52 mo*	*BP Δ = -42/-15 P<0.0001*				*SCr Δ = -0.4 mg/dL P<0.001*			*nd*	*High*
Henry, 2003[58]		169/104	85	56	Ostial 100%	23 mo	18	59	23		18	82	0		C
Prosp [P]		[1.3]	14	(56)	1999-2002	2-47	BP Δ = -19/-11 P<0.01				SCr Δ = -0.1 mg/dL NS			nd	Low
Rivolta, 2005[64]		161/86	>70	52	nd	24					15	60	25	10	C
Prosp		[2.9]	37	(52)		9-54	BP Δ = -18/-7 P<0.01[Q]							6 mo	Mod
Gill-Leertouwer, 2002[52,53]		177/96[R]	>50	40	nd	1 yr								14	C
Prosp		[1.3][S] [2.4][T]	nd	(40)	1996-1998	nd	Clinical success 85%				Clinical success 25%			12 mo	Low
Bucek, 2003[44]		nd	>80	40	Ostial 100%	3.3 yr[U]		38	43				25	13-15	C
Prosp & Retro		nd	nd	(40)	1997-2002	0.8-6.3								40 mo	Low
Gray, 2002[54 V]		174/85	>70	39	nd	21 mo		72	15		51	26	23	10	C
Prosp		[3.2]	46	(39)	1991-1997	1-61								21 mo	Mod

Δ, change; Appl, applicability rating; ARAS, atherosclerotic renal artery stenosis; BP, blood pressure; CrCl, creatinine clearance; CKD, chronic kidney disease; CVD, cardiovascular disease; eGFR, estimated GFR; GFR, glomerular filtration rate (or creatinine clearance, mL/min or mL/min/1.73 m^2); HTN, hypertension; Imp, improved;, mo, months; MAP, mean arterial pressure; Mod, moderate; nd, no data; NS, nonsignificant; ,Prosp, prospective nonrandomized study; Qual, quality rating; RAS, renal artery stenosis; Retro, retrospective study; SCr, serum creatinine (mg/dL); UnΔ, unchanged (or stable); yr, years.

[1] Chronic kidney disease stage 3A, baseline GFR 41-59 mL/min
[2] Chronic kidney disease stage 3A, baseline GFR 30-40 mL/min
[3] Chronic kidney disease stage 3A, baseline GFR 15-29 mL/min

[A] CVD outcomes: myocardial infarction 11%; CHF 20%; stroke 7%.
[B] Diagnosed by digital caliper technique.
[C] % restenosis reported according to the arteries evaluated.
[D] Myocardial infarction 5%.
[E] Among 48/50 with resistant HTN.
[F] N=102/126 > 85% stenosis.
[G] N analyzed at baseline for BP=48 and CKD=65.
[H] Of the arteries evaluated: Neointimal hyperplasia 61%; stent migration 22%, and true stent restenosis 17%.
[I] Among 65/75 with CKD at baseline.
[J] N analyzed = 18.
[K] Evaluated at follow-up n=113.
[L] Outcomes evaluated n=127.
[M] Outcomes evaluated n=132.
[N] Among those with follow-up (n=127).
[O] Analyzed at 12 mo (n=41).
[P] Utilized distal protection device and follow-up data available for maximum numbers at 6 month.
[Q] Significant only for systolic blood pressure.
[R] 60% less than 2 yr duration of HTN.
[S] Baseline value among those with clinical success (n=27).
[T] Baseline value among those with clinical failure (n=13).
[U] Median.
[V] New York Heart Association class Δ=-1.4 P<0.001.

Table 8. Adverse events associated with angioplasty with stent placement treatment of renal artery stenosis *(new studies in italics)*

Author Year	N RAS (ARAS)	Intervention	Kidney-related	CVD-related	Thrombosis/ occlusion	Bleeding	30 d mortality	Other
Dorros 2002[46-50]	1058	Angioplasty stent placement	Contrast induced acute kidney failure 13%			Retroperitoneal hemorrhage 1 %	Deaths 0.3%	
Zeller 2004[69-73]	340 268 (268)	Angioplasty stent placement	Severe deterioration of kidney function 1.5% Local dissection or perforation 4%		False aneurysm 1% Access site occlusion 0.3%	Severe access site bleeding 2%	30 d mortality 0.6% Death after 3 d due to embolic stroke 0.3%	Stent displacement 1%
Lederman 2001[62]	300 (293)	Angioplasty stent placement	Guidewire induced dissection of renal artery branch 0.3%		Intraprocedural thrombosis of the target renal artery 0.3%		Death from MI 0.3%	Acute/flash pulmonary edema 0.3% Stent migration into aorta 0.3% Aspirin hypersensitivity 0.3%
Kennedy 2003[60,61]	261 (253) 127 (127)	Angioplasty stent placement			Total occlusion of stented artery 0.8%	Hematuria due to vessel perforation 0.8%		Access site complications with brachial approach 3% Access site complications with femoral approach 3% Dislodged stent 1.0% Dislodged unexpanded stent 0.8%
Rocha-Singh 2005[65]	208 (208)	Angioplasty stent placement		Major vascular event In-hospital 2.4% Out of hospital up to 2 yr 2.9% Cerebrovascular accident 0%	Major embolic event In-hospital 1.4% Out of hospital up to 2 yr 4.8%		Major hemorrhage In-hospital 1% Out of hospital up to 2 yr 0.5%	Access site complications 5%
Rocha-Singh 1999[66]	150 (150)	Angioplasty stent placement	Contrast induced nephropathy 5% Kidney parenchymal guidewire perforations 1.3%				Death from tubular necrosis and multiorgan failure 0.7% Death from GI hemorrhage after stent implant while on warfarin 0.7%	Overall major complication rate 3%

Continued.

Table 8. Adverse events associated with angioplasty with stent placement treatment of renal artery stenosis (continued)

Author Year	N RAS (ARAS)	Intervention	Kidney-related	CVD-related	Thrombosis/ occlusion	Bleeding	30 d mortality	Other
Dangas 2001[45]	131 (nd)	Angioplasty stent placement	Kidney failure 6%		Femoral artery pseudoaneurysms 1.5%		Death 0.8%	
Tuttle 1998[67]	129 (129)	Angioplasty stent placement	Contrast induced acute kidney failure 12%		Atheroembolic disease 0.7% Arterial thrombosis 0.4%	Groin hematoma 7% Perirenal hematoma 0.4%	Death 3%	Stent migration 0.7%
Zeller 2005[82]	*143 (125)*	*Angioplasty stent placement*	*Transient SCr rise 1%*		*False aneurysm 5%*	*Large hematoma 2%*	*PE death 1%*	
Gill 2003[51]	100 (100)	Angioplasty stent placement	Transient SCr rise 1%		Transient lobar branch renal artery occlusion 2% Femoral artery false aneurysm 2% Femoral artery trauma 2% Non flow limiting intimal dissection 1%	Groin hematoma 6%	Death after lower limb cholesterol embolization 1% Death after thrombosis of aortofemoral prosthetic graft 1%	Migrating stent 1%
White 1997[68]	100 (100)	Angioplasty stent placement	Transient contrast nephropathy 2% No perforations		Femoral artery pseudoaneurysm 1% Brachial artery occlusion 1% Subacute stent thrombosis after 3 d 1%	Groin hematoma 5%	Ischemic cardiac death after 2 d 1%	
Ruchin, 2007[79]	*89 (87)*	*Angioplasty stent placement*			*Renal and peripheral thromboemboli 1%*	*Major bleeding 2%*		*Puncture site infection 1%*
Blum 1997[43]	68 (68)	Angioplasty stent placement				Local hematomas at puncture site 4%		No major complications
Harjai 1997[57]	66 (nd)	Angioplasty stent placement	Temporary rise in SCr 5%			Minor bleeding from vascular access site 5%		
Holden, 2006[78]]	*63 (63)*	*Angioplasty stent placement*	*Acute kidney injury 2%*					
Iannone 1996[59]	63 (61)	Angioplasty stent placement	Acute kidney failure 13% Renal artery perforation 5%		Psuedoaneurysm at insertion site 1.6%	Minor groin hematoma 10% Bleeding requiring transfusion including peripheral embolus requiring thrombolysis 16%	Death after perirenal bleeding 1.6%	
Henry 2003[58]	56 (56)	Angioplasty stent placement			Arterial spasm at site of protection device 4%		Death on d 3 from MI 1.8%	No device related complications

Continued.

Table 8. Adverse events associated with angioplasty with stent placement treatment of renal artery stenosis (continued)

Author Year	N RAS (ARAS)	Intervention	Kidney-related	CVD-related	Thrombosis/ occlusion	Bleeding	30 d mortality	Other
Sapoval, 2005[80]	*52 (52)*	*Angioplasty stent placement*	*Renal artery dissection 8%*			*Hematoma at puncture site 2%*		
Goncalves, 2007 [77]	*46 (44)*	*Angioplasty stent placement*	*Renal artery dissection 2%*					
van de Ven 1999[76]	40 (40)	Angioplasty stent placement	Transient decrease in kidney function due to radiography contrast agent 21% Kidney failure induced by cholesterol embolism 10% Renal artery injury 7%		Renal artery occlusion 2% Acute thrombosis 2% Femoral artery aneurysm or arteriovenous fistula 7%	Bleeding 19%		Technical failure 7%
Harden 1997[56]	32 (32)	Angioplasty stent placement			Femoral artery pseudoaneurysm 9%	Hemorrhage 9%	Death from circulatory collapse after stent placement 3%	
Gross 1998[55]	30 (30)	Angioplasty stent placement	Dissection after predilatation 10%		No vessel had early or subacute thrombotic occlusion			No guidewire perforation detected.

ARAS, atherosclerotic renal artery stenosis; CKD, chronic kidney disease; CVD, cardiovascular disease; d, days; GI, gastrointestinal; MI, myocardial infarction; N, number of subjects; nd, no data; PTRA, percutaneous renal angioplasty; RAS, renal artery stenosis; SCr, serum creatinine.

[Tables 9 and 10 of original report not included here]

Table 11. Surgical renal artery revascularization for the treatment of renal artery stenosis (no new data)

Author, Year / Study Design	Mean BP / Mean GFR [SCr]	Mean % Stenosis / % Bilateral Stenosis	No. Evaluated RAS (ARAS)	RAS Location / Years Enrolled	Mean Duration / Range	Results: HTN (%) and BP Δ — Cured	Imp	UnΔ	Worse	CKD (%) and GFR / SCr Δ — Imp	UnΔ	Worse	CVD (%)	Qual / Appl
Cherr, 2002[85-89]	200/104	≥ 80%	500	Ostial: nd	4.7 yr	12%	73%		15%	43%	47%	10%	74% of late deaths 2°to CVD; nonfatal events 28% (angina, MI, PTCA, CABG)	C
Retro	41	59%	(500)	1987-1999	1-159 mo	BP Δ = -53/-23 P<0.0001 (base)				GFR Δ = 7.1 P<0.0001 (base) 17% became dialysis dependent				Low
Galaria, 2005[84]	171/82	≥ 50%	100	Ostial: nd	3.5 yr	68% (3 yr) 59% (5 yr)								C
Retro	51	44%	(100)	1984-2004	0-17 yr					CKD event[A] = 20% (3 yr), 26% (5 yr)				Low
Alhadad, 2004[83]	180/100	nd	106	Ostial: nd%	nd									C
Retro	nd	nd	(86)	1987-1996	0-12 yr	Only mortality data reported (after 6 mo). See mortality figure								Low
Marone, 2004[90]	nd	Both cohorts ≥ 75%	Cohort 1: 139 (139)	Ostial: nd	48 mo	Cohort 1: kidney function improved or unchanged in 76% Cohort 2: kidney function improved or unchanged in 72% Dialysis free survival at 5 years was 55% (both cohorts?)								C
Retro	Cohort 1: [>2]Cohort 2: [≥1.5]	nd	Cohort 2: 96 (96)	Cohort 1: 1980-1990 Cohort 2: 1990-2001	6 wk to 12.6 yr									Low

Δ, change; Appl, applicability rating; ARAS , atherosclerotic renal artery stenosis; BP, blood pressure; CABG, coronary artery bypass graft; CKD, chronic kidney disease; CVD, cardiovascular disease; GFR, glomerular filtration rate (or creatinine clearance, mL/min or mL/min/1.73 m^2); HTN, hypertension; Imp, improved; MI, myocardial infarction; mo, months; nd, no data; PTCA, percutaneous transluminal coronary angioplasty; Qual, quality rating; RAS, renal artery stenosis; SCr, serum creatinine (mg/dL); UnΔ, unchanged (or stable); wk, weeks; yr, years.

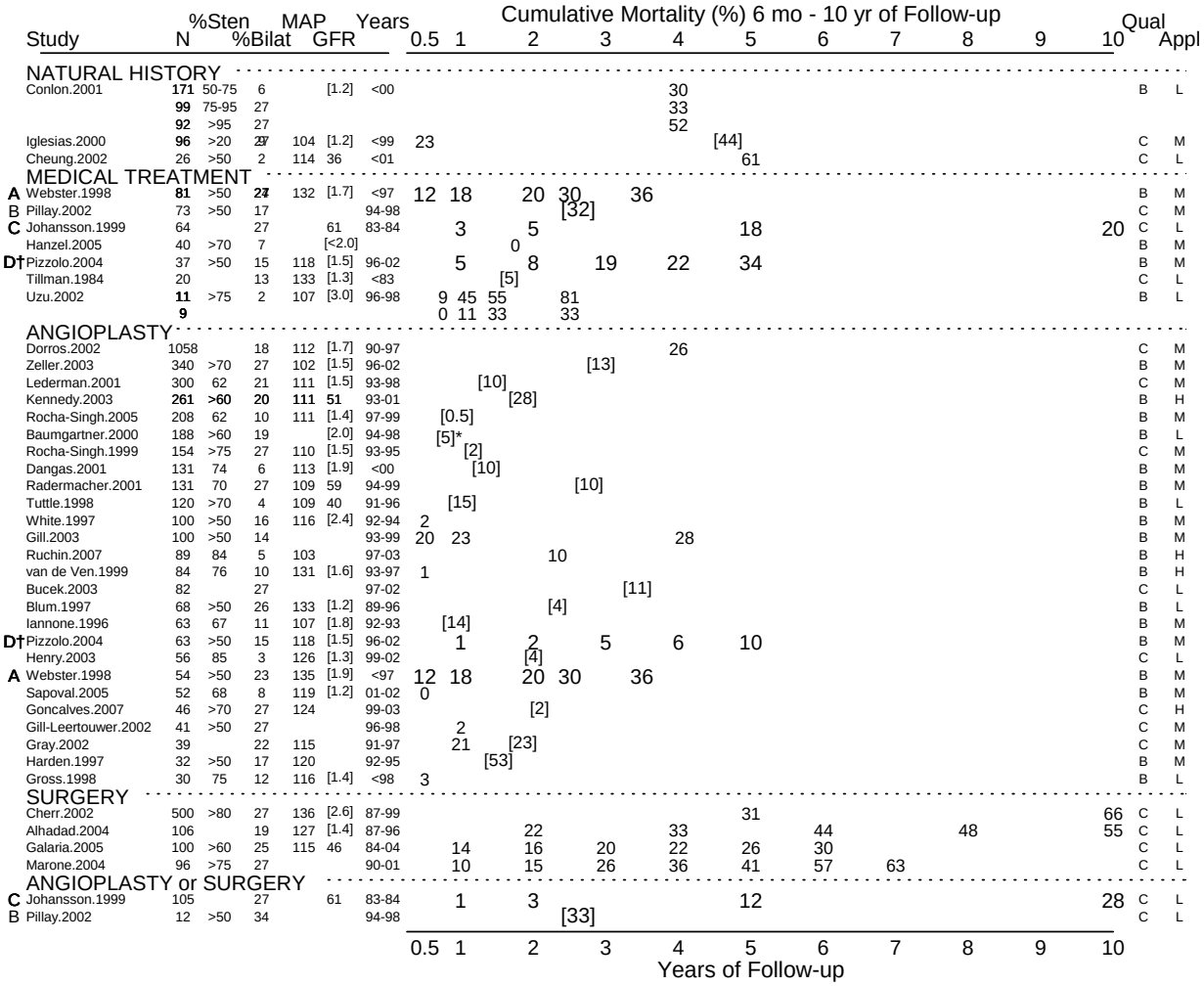
[A] Dialysis, CKD-related mortality, or SCr>1.5 mg/dL.

Table 12. Adverse events associated with the surgical treatment of renal artery stenosis (no new data)

Author Year	N RAS (ARAS)	Intervention	Kidney-related	CVD-related	Thrombosis/ occlusion	Bleeding	30 d mortality	Other
Cherr 2002[85-89]	500 (500)	Surgery		Perioperative: MI 3% Stroke 1% Significant arrhythmia 5% Nonfatal CVD 28%			Death: 5%	Perioperative morbidity 17% Including pneumonia 8%
Marone 2004[90]	325 (325)	Surgery					Perioperative mortality 6%, mostly secondary to coronary and cerebrovascular events	
Galaria 2005[84]	247 (247)	Angioplasty-Surgery	Perioperative kidney morbidity: 0% (Angioplasty) 6% (Surgery)	Perioperative minor cardiac morbidity <1% (Angioplasty) 14% (Surgery)			Deaths <0.1% (Angioplasty) (all due to cardiac events) Deaths 0.1% (Surgery) 6/10 due to cardiac complications, 3/10 pulmonary, 1/10 sepsis Major morbidity: 4% (Angioplasty) 4% (Surgery)	Technical complication rate: 18% (Angioplasty) 0% (Surgery) Pulmonary adverse events: 0% (Angioplasty) 9% (Surgery) Systemic infection: 0% (Angioplasty) 8% (Surgery) Other wound related events: 0% (Angioplasty) 6%(Surgery)
Alhadad 2004[83]	106 (86)	Angioplasty-Surgery					2% (Angioplasty) 9% (Surgical)	Multiorgan failure 0% (Angioplasty) 2% (Surgery) Sepsis 0% (Angioplasty) 1% (Surgery)

ARAS, atherosclerotic renal artery stenosis; CVD, cardiovascular disease; d, day; MI, myocardial infarction; mo, months; N, number evaluated; RAS, renal artery stenosis; SCr, serum creatinine.

Appendix Figure. Mortality study details



* Excluded patients who died within first 6 months

† Markedly different eligibility criteria for angioplasty and medicine treatment cohorts. See summary table.