

Appendix A. Search Strategy

Table A-1. Search strategy

Set Number	Concept	Search Statement
1	Pancreatic Cancer/pancreas	exp pancreatic neoplasms/ or pancreas cancer/ or pancreatic cyst/
2		((exp pancreas/ or exp pancreas, exocrine/) and (neoplasm/ or adenocarcinoma/ or neoplasms/)) or pancreas tumor/ or Pancreatic neuroendocrine tumor/
3		(Pancrea\$ adj3 (mass\$ or cancer\$ or tumor?r\$ or sarcoma\$ or neoplasm\$ or carcinoma\$ or adenocarcinoma\$)).mp.
4		neuroendocrine tumors/ and pancrea\$.ti,ab.
5		Pancreatic neoplasms
6		4 not 5
7		1 or 2 or 3 or 6
8	Imaging	Endosonography/ or exp fluorodeoxyglucose F18/ or exp magnetic resonance imaging or exp positron-emission tomography/ or exp tomography, x-ray computed/ or exp ultrasonography/ or endoscopic echography/ or ultrasound/
9		Computer assisted emission tomography/ or computer assisted tomography/ or nuclear magnetic resonance imaging/ or positron emission tomography/
10		Exp Diagnostic imaging/ or exp magnetic resonance imaging/ or pancreas/ra or pancreas/us or pancreatic ducts/ra or pancreatic ducts/us
11		("computed tomography" or "positron emission" or "positron-emission" or "magnetic resonance" or "endoscopic ultraso\$" or "computer assisted emission tomography" or "computer assisted tomography" or computer-assisted tomography).ti,ab.
12		(SDCT or MDCT or FDG-PET or CT or PET or PET/CT or MRI or EUS).mp.
13		"Fludeoxyglucose positron emission tomography".mp.
14		((single?detector or multi?detector or multi?dimensional) adj (CT or "computed tomography")).mp.
15		(Endoscop\$ adj (ultrasound or ultrasonograph\$ or echograph\$)).ti,ab.
16		Or/8-15
17	Pancreatic cancer and imaging	7 and 16
18	Diagnosis	exp pancreatic neoplasms/di or pancreatic cyst/di
19		Diagnos\$.mp. or early diagnosis/ or diagnosis, differential/ or diagnosis/ or neuroendocrine tumor/di [Diagnosis]
20		pancreatic neoplasms/di, pa, us [Diagnosis, Pathology, Ultrasonography] or pancreas tumor/di [Diagnosis] or pancreas cancer/di
21		pancreatitis, chronic/di, pa, us [Diagnosis, Pathology, Ultrasonography] or chronic pancreatitis/di [Diagnosis]
22		17 and di.fs.
23		Or/18-22
24	Pancreatic cancer and imaging and diagnosis	17 and 23
25	Staging	Cancer staging/ or Neoplasm staging/
26		((mass\$ or cancer\$ or tumor?r\$ or sarcoma\$ or neoplasm\$ or carcinoma\$ or adenocarcinoma\$) and (biopsy or category or classification or classify or detect\$ or stage or diagnos\$ or staging)).ti,ab.
27		((mass\$ or cancer\$ or tumor?r\$ or sarcoma\$ or neoplasm\$ or carcinoma\$ or adenocarcinoma\$) and ("fine needle" or fine-needle or FNA or FNB or specimen or sample or sampling)).ti,ab.
28		Or/25-27

Table A-1. Search strategy (continued)

Set Number	Concept	Search Statement
29	Pancreatic cancer and imaging and staging	17 and 28
30	Diagnosis test – accuracy, specificity	17 and (exp diagnosis/ or di.fs.)
31		17 and (receiver operating characteristic/ or ROC curve/ or diagnostic accuracy/ or accuracy/)
32		17 and (precision or sensitivity or specificity or predict\$ or forecast\$ or likelihood or ((false or true) adj (positive or negative))).mp.
33		17 and (predictive value of tests/ or exp diagnostic errors/ or exp diagnostic error/)
34	Pancreatic cancer and imaging and diagnostic testing	Or/29-33
35	Screening	mass screening/ or early detection of cancer/ or population surveillance/
36		Cancer screening/ or cancer risk/ or risk factors/
37		(risk\$ or screen\$ or hereditary or inherit\$ or gene\$ or family history).ti,ab.
38		or/ 35-37
39	Pancreatic cancer and imaging and screening	17 and 38
40	Prognosis/survival	incidence/ or mortality/ or follow up studies/ or prognos\$.mp. or predict\$.mp. or course\$.mp. or (first and episode).ti,ab. Or cohort.ti,ab.
41		Exp "prediction and forecasting"/ or exp prognosis/ or exp survival rate/ or surviv\$.mp.
42		40 or 41
43	Pancreatic cancer and imaging and prognosis/survival	17 and 42
44	Combine sets to review	24 or 29 or 34 or 39 or 43
45	Limit by date	Limit 44 to yr="1990-2013"
46	Limit	Limit 45 to humans
47	Limit	Limit 46 to English language
48	Remove duplicates	Remove duplicates from 47

Appendix B. Full-Length Review of Excluded Studies

- Adamek HE, Albert J, Breer H, et al. Pancreatic cancer detection with magnetic resonance cholangiopancreatography and endoscopic retrograde cholangiopancreatography: a prospective controlled study. *Lancet*. 2000 Jul 15;356(9225):190-3. *No statement in the methods about plan to capture harms*
- Afify AM, al-Khafaji BM, Kim B, et al. Endoscopic ultrasound-guided fine needle aspiration of the pancreas. Diagnostic utility and accuracy. *Acta Cytol*. 2003 May-Jun;47(3):341-8. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Agarwal B, Krishna NB, Labundy JL, et al. EUS and/or EUS-guided FNA in patients with CT and/or magnetic resonance imaging findings of enlarged pancreatic head or dilated pancreatic duct with or without a dilated common bile duct. *Gastrointest Endosc*. 2008 Aug;68(2):237-42; quiz 334. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Ahmed SI, Bochkarev V, Oleynikov D, et al. Patients with pancreatic adenocarcinoma benefit from staging laparoscopy. *J Laparoendosc Adv Surg Tech A*. 2006 Oct;16(5):458-463. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Ahn SS, Kim M-J, Choi J-Y, et al. Indicative findings of pancreatic cancer in prediagnostic CT. *Eur Radiol*. 2009;19(10):2448-2455. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Ainsworth AP, Hansen T, Frstrup CW, et al. Indications for and clinical impact of repeat endoscopic ultrasound. *Scand J Gastroenterol*. 2010 Apr;45(4):477-82. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Aithal GP, Anagnostopoulos GK, Tam W, et al. EUS-guided tissue sampling: comparison of dual sampling" (Trucut biopsy plus FNA) with "sequential sampling" (Trucut biopsy and then FNA as required). *Endoscopy*. 2007 Aug;39(8):725-30. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Alle V, Gurusamy KS, Kali A, et al. Role of Positron Emission Tomography (PET) in pancreatic resection for suspected pancreatic and periampullary cancer. *Int J Surg*. 2011;9(5):366. *Just a meeting abstract*
- Al-Nahhas A, Win Z, Szyszko T, et al. What can gallium-68 PET add to receptor and molecular imaging? *Eur J Nucl Med Mol Imaging*. 2007 Dec;34(12):1897-1901. *Narrative review*
- Alsibai KD, Denis B, Bottlaender J, et al. Impact of cytopathologist expert on diagnosis and treatment of pancreatic lesions in current clinical practice. A series of 106 endoscopic ultrasound-guided fine needle aspirations. *Cytopathology*. 2006 Feb;17(1):18-26. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Alsohaibani F, Giris S, Sandha GS. Does onsite cytotechnology evaluation improve the accuracy of endoscopic ultrasound-guided fine-needle aspiration biopsy? *Can J Gastroenterol*. 2009 Jan;23(1):26-30. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Amin Z, Theis B, Russell RC, et al. Diagnosing pancreatic cancer: the role of percutaneous biopsy and CT. *Clin Radiol*. 2006 Dec;61(12):996-1002. *Unclear whether biopsies were ultrasound-guided*
- Anderson MA. Diagnostic and therapeutic applications of EUS in pancreatic disease. *Gastroenterol Hepatol*. 2007 Oct;3(10):768-771. *Narrative review*
- Anderson SW, Soto JA. Pancreatic duct evaluation: Accuracy of portal venous phase 64 MDCT. *Abdom Imaging*. 2009 Jan;34(1):55-63. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Andrawes SA, Hindy P, Taur Y, et al. Accuracy of endoscopic elastography for detection of malignant pancreatic mass lesions. Systematic review and meta-analysis. *Gastrointest Endosc*. 2012 Apr;75(4 Suppl 1):AB207. *No data specific to an imaging test of interest*

Ang TL, Teo EK, Ang D, et al. A pilot study of contrast harmonic endosonography using DEFINITY in the evaluation of suspected pancreatic and peri-ampullary malignancies. *J Interv Gastroenterol*. 2011 Oct;1(4):160-165. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Arabul M, Karakus F, Alper E, et al. Comparison of multidetector CT and endoscopic ultrasonography in malignant pancreatic mass lesions. *Hepatogastroenterology*. 2012 Jul-Aug;59(117):1599-603. *No data specific to an imaging test of interest*

Arcidiacono PG, Carrara S. Endoscopic ultrasonography: Impact in diagnosis, staging and management of pancreatic tumors. An overview. *JOP*. 2004 Jul;5(4):247-252. *Narrative review*

Ardengh JC, De Paulo GA, Ferrari Jr AP. Pancreatic carcinomas smaller than 3.0 cm: Endosonography (EUS) in diagnosis, staging and prediction of resectability. *HPB*. 2003;5(4):226-230. *No comparative specificity data*

Ardengh JC, Lopes CV, Campos AD, et al. Endoscopic ultrasound and fine needle aspiration in chronic pancreatitis: differential diagnosis between pseudotumoral masses and pancreatic cancer. *JOP*. 2007;8(4):413-21. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Ardengh JC, Lopes CV, de Lima LF, et al. Diagnosis of pancreatic tumors by endoscopic ultrasound-guided fine-needle aspiration. *World J Gastroenterol*. 2007 Jun 14;13(22):3112-6. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Ardengh JC, Lopes CV, De Lima LFP, et al. Cell block technique and cytological smears for the differential diagnosis of pancreatic neoplasms after endosonography-guided fine-needle aspiration. *Acta Gastroenterol Latinoam*. 2008 Dec;38(4):246-251. *Non-English*

Ardengh JC, Malheiros CA, Pereira V, et al. Endoscopic ultrasound-guided fine-needle aspiration using helical computerized tomography for TN staging and vascular injury in operable pancreatic carcinoma. *JOP*. 2009;10(3):310-7. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Arslan A, Buanes T, Geitung JT. Pancreatic carcinoma: MR, MR angiography and dynamic helical CT in the evaluation of vascular invasion. *Eur J Radiol*. 2001;38(2):151-159. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Arvold ND, Niemierko A, Mamon HJ, et al. Pancreatic cancer tumor size on CT scan versus pathologic specimen: implications for radiation treatment planning. *Int J Radiat Oncol Biol Phys*. 2011 Aug 1;80(5):1383-90. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Arya M, Mathur S, Sonpal N, et al. Maintaining yield while minimizing eus guided fna passes in a community hospital setting. *Am J Gastroenterol*. 2010;105:S411. *Just a meeting abstract*

Asagi A, Ohta K, Nasu J, et al. Utility of contrast-enhanced FDG-PET/CT in the clinical management of pancreatic cancer: impact on diagnosis, staging, evaluation of treatment response, and detection of recurrence. *Pancreas*. 2013 Jan;42(1):11-9. *No comparative specificity data*

Ashida R, Ioka T, Ishida N, et al. For early detection of pancreatic cancer. *J Gastroenterol Hepatol*. 2012 Dec;27:370. *Just a meeting abstract*

Aslanian H, Salem R, Lee J, et al. EUS diagnosis of vascular invasion in pancreatic cancer: surgical and histologic correlates. *Am J Gastroenterol*. 2005 Jun;100(6):1381-5. *No data specific to an imaging test of interest*

Azabdaftari G, Goldberg SN, Wang HH. Efficacy of on-site specimen adequacy evaluation of image-guided fine and core needle biopsies. *Acta Cytol*. 2010 Mar-Apr;54(2):132-137. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Aziz AM, Said T, Poovathumkadavil A, et al. Using Multidetector CT in Predicting Resectability of Pancreatic Head Tumors: Surgical and Pathologic Correlation. *J Egypt Natl Canc Inst*. 2010 Dec;22(4):233-9. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Baghbanian M, Shabazkhani B, Ghofrani H, et al. Efficacy of endoscopic ultrasound guided fine needle aspiration in patients with solid pancreatic neoplasms. *Saudi J Gastroenterol*. 2012 Nov-Dec;18(6):358-63. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Balthazar EJ. CT contrast enhancement of the pancreas: Patterns of enhancement, pitfalls and clinical implications. *Pancreatology*. 2012 Feb;11(6):585-7. *Narrative review*

Bang JY, Trevino J, Ramesh J, et al. Randomized trial comparing the fanning and standard techniques for EUS-guided FNA of solid pancreatic mass lesions. *Gastrointest Endosc*. 2012 Apr;75(4 Suppl 1):AB445-AB446. *Just a meeting abstract*

Bang JY, Hebert-Magee S, Trevino J, et al. Randomized trial comparing the 22-gauge aspiration and 22-gauge biopsy needles for EUS-guided sampling of solid pancreatic mass lesions. *Gastrointest Endosc*. 2012 Aug;76(2):321-7. *N <50*

Bao PQ, Johnson JC, Lindsey EH, et al. Endoscopic ultrasound and computed tomography predictors of pancreatic cancer resectability. *J Gastrointest Surg* 2008 Jan; 12(1): 10-6, discussion 16. *Correlated vessel involvement via imaging to actual resectability, thus not direct*

Barber TW, Kalff V, Cherk MH, et al. 18 F-FDG PET/CT influences management in patients with known or suspected pancreatic cancer. *Intern Med J*. 2011 Nov;41(11):776-83. *No data specific to an imaging test of interest*

Barreiro CJ, Lillemoie KD, Koniaris LG, et al. Diagnostic laparoscopy for periampullary and pancreatic cancer: what is the true benefit? *J Gastrointest Surg*. 2002 Jan-Feb;6(1):75-81. *No data specific to an imaging test of interest*

Bartsch DK. Familial pancreatic cancer. *Br J Surg*. 2003 Apr 1;90(4):386-387. *Narrative review*

Basir Z, Pello N, Dayer AM, et al. Accuracy of cytologic interpretation of pancreatic neoplasms by fine needle aspiration and pancreatic duct brushings. *Acta Cytol*. 2003 Sep-Oct;47(5):733-8. *Only a single imaging test of interest, and N <50*

Basnayake C, Moore G, Croagh D, et al. Analysis of factors that influence accuracy of endoscopic ultrasound-guided fine needle aspiration for solid pancreatic masses. *J Gastroenterol Hepatol*. 2012 Oct;27:51. *Just a meeting abstract*

Bhutani MS. Endoscopic ultrasonography. *Endoscopy*. 2007 Nov;39(11):1005-1009. *Narrative review*

Bipat S, Saffire SKS, Van Delden OM, et al. Ultrasonography, computed tomography and magnetic resonance imaging for diagnosis and determining resectability of pancreatic adenocarcinoma: A meta-analysis. *J Comput Assist Tomogr*. 2005 Jul-Aug;29(4):438-445. *Duplicate*

Birchard KR, Semelka RC, Hyslop WB, et al. Suspected pancreatic cancer: Evaluation by dynamic gadolinium-enhanced 3D gradient-echo MRI. *AJR Am J Roentgenol*. 2005;185(3):700-703. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Bluen BE, Lachter J, Khamaysi I, et al. Accuracy and quality assessment of EUS-FNA: A single-center large cohort of biopsies. *Diagn Ther Endosc*. 2012;139563. Epub 2012 Oct 31. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Bolog N, Constantinescu G, Oancea I, et al. Magnetic resonance imaging of bile and pancreatic ducts: a retrospective study. *Rom J Gastroenterol*. 2004 Jun;13(2):91-7. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Boraschi P, Donati F, Gigoni R, et al. Mangafodipir trisodium-enhanced MR imaging of pancreatic disease. *Eur Radiol*. 2006 May;16(5):988-997. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Boraschi P, Donati F, Gigoni R, et al. Secretin-stimulated multi-detector CT versus mangafodipir trisodium-enhanced MR imaging plus MRCP in characterization of non-metastatic solid pancreatic lesions. *Dig Liver Dis*. 2009 Nov;41(11):829-37. *No data specific to an imaging test of interest*

Borbath I, Van Beers BE, Lonneux M, et al. Preoperative assessment of pancreatic tumors using magnetic resonance imaging, endoscopic ultrasonography, positron emission tomography and laparoscopy. *Pancreatology*. 2005;5(6):553-61. *EUS accuracy directly influenced reference standard*

Brais RJ, Davies SE, O'Donovan M, et al. Direct histological processing of EUS biopsies enables rapid molecular biomarker analysis for interventional pancreatic cancer trials. *Pancreatology*. 2012 Jan-Feb;12(1):8-15. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Brandwein SL, Farrell JJ, Centeno BA, et al. Detection and tumor staging of malignancy in cystic, intraductal, and solid tumors of the pancreas by EUS. *Gastrointest Endosc.* 2001 Jun;53(7):722-7. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Breitkopf CR, Sinicrope PS, Rabe KG, et al. Factors influencing receptivity to future screening options for pancreatic cancer in those with and without pancreatic cancer family history. *Hered Cancer Clin Pract.* 2012 Jun 27;10(1). *Hypothetical imaging test*

Brimiène V, Brimas G, Strupas K. Differential diagnosis between chronic pancreatitis and pancreatic cancer: a prospective study of 156 patients. *Medicina (Kaunas).* 2011;47(3):154-62. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Brix G, Nissen-Meyer S, Lechel U, et al. Radiation exposures of cancer patients from medical X-rays: How relevant are they for individual patients and population exposure? *Eur J Radiol.* 2009 Nov;72(2):342-347. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Brugel M, Rummeny EJ, Dobritz M. Vascular invasion in pancreatic cancer: Value of multislice helical CT. *Abdom Imaging.* 2004 May-Apr;29(2):239-245. *Just a meeting abstract*

Bruno MJ. Endoscopic ultrasonography. *Endoscopy.* 2006 Nov;38(11):1098-1105. *Narrative review*

Buchs NC, Frossard JL, Rosset A, et al. Vascular invasion in pancreatic cancer: evaluation of endoscopic ultrasonography, computed tomography, ultrasonography, and angiography. *Schweiz Med Wochenschr.* 2007 May 19;137(19-20):286-91. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Buchs NC, Frossard JL, Rosset A, et al. Vascular invasion in pancreatic cancer. *Swiss Med Wkly.* 2007 May 19;137(19-20):286-291. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Burski CM, Varadarajulu S, Trevino J. Diagnosing cancer in chronic pancreatitis: The struggle persists. *Gastrointest Endosc.* 2012 Apr;75(4 Suppl 1):AB193. *Just a meeting abstract*

Caglar E, Senturk H, Atasoy D, et al. The Role of EUS and EUS-FNA in the Management of Pancreatic Masses: Five-Year Experience. *Hepatogastroenterology.* 2013 Jan 24;60(126). *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Calculli L, Casadei R, Amore B, et al. Correlazione tra la tomografia computerizzata spirale e l'eco color-Doppler nella definizione dell'interessamento del tronco mesenterico-portale nel carcinoma pancreatico. *Radiol Med.* 2002 Oct 1;104(4):307-315. *Non-English*

Camp ER, Vogel SB. Blind Whipple resections for periampullary and pancreatic lesions. *Am Surg.* 2004 Jan;70(1):6-10; discussion 11-2. *No data specific to an imaging test of interest*

Campisi A, Brancatelli G, Vullierme M-P, et al. Are pancreatic calcifications specific for the diagnosis of chronic pancreatitis? A multidetector-row CT analysis. *Clin Radiol.* 2009 Sep;64(9):903-911. *Not pancreatic adenocarcinoma*

Camus M, Trouilloud I, Villacis AL, et al. Effectiveness of combined endoscopic ultrasound-guided fine-needle aspiration biopsy and stenting in patients with suspected pancreatic cancer. *Eur J Gastroenterol Hepatol.* 2012 Nov;24(11):1281-7. *Used treatment prior to (or during) the imaging test(s)*

Canto MI, Goggins M, Yeo CJ, et al. Screening for pancreatic neoplasia in high-risk individuals: an EUS-based approach. *Clin Gastroenterol Hepatol.* 2004 Jul;2(7):606-21. *Only a single imaging test of interest, and N <50*

Canto MI, Hruban RH, Fishman EK, et al. Frequent detection of pancreatic lesions in asymptomatic high-risk individuals. *Gastroenterology.* 2012 Apr;142(4):796-804; quiz e14-5. *Duplicate*

Carneiro MP, Lopes FCR, Domingues RC, et al. Whole-body MRI and FDG PET fused images for evaluation of patients with cancer. *AJR Am J Roentgenol.* 2009 Apr;192(4):1012-1020. *Not pancreatic adenocarcinoma*

Cassinotto C, Cortade J, Belleannee G, et al. An evaluation of the accuracy of CT when determining resectability of pancreatic head adenocarcinoma after neoadjuvant treatment. *Eur J Radiol.* 2013 Apr;82(4):589-93. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Cermak TS, Wang B, DeBrito P, et al. Does on-site adequacy evaluation reduce the nondiagnostic rate in endoscopic ultrasound-guided fine-needle aspiration of pancreatic lesions? *Cancer Cytopathol.* 2012 Oct 25;120(5):319-25. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Chandarana H, Babb J, Macari M. Signal characteristic and enhancement patterns of pancreatic adenocarcinoma: evaluation with dynamic gadolinium enhanced MRI. *Clin Radiol.* 2007 Sep;62(9):876-83. *No outcomes of interest*

Chang KJ. EUS-guided FNA: The training is moving. *Gastrointest Endosc.* 2004 Jan;59(1):69-73. *News/opinion/editorial*

Chang L, Stefanidis D, Richardson WS, et al. The role of staging laparoscopy for intraabdominal cancers: An evidence-based review. *Surg Endosc.* 2009 Feb;23(2):231-41. *Narrative review*

Chang WI, Kim BJ, Lee JK, et al. The clinical and radiological characteristics of focal mass-forming autoimmune pancreatitis: comparison with chronic pancreatitis and pancreatic cancer. *Pancreas.* 2009 May;38(4):401-8. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Chari ST, Takahashi N, Levy MJ, et al. A diagnostic strategy to distinguish autoimmune pancreatitis from pancreatic cancer. *Clin Gastroenterol Hepatol.* 2009 Oct;7(10):1097-103. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Chatterjee S, Wadehra V, Cunningham J, et al. Impact of on-site adequacy assessment for eus fna of solid pancreatic lesions. *Gut.* 2011 Apr;60:A51-A52. *Just a meeting abstract*

Cherian PT, Mohan P, Douiri A, et al. Role of endoscopic ultrasound-guided fine-needle aspiration in the diagnosis of solid pancreatic and peripancreatic lesions: is onsite cytopathology necessary? *HPB.* 2010 Aug;12(6):389-95. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Chhieng DC, Benson E, Eltoun I, et al. MUC1 and MUC2 expression in pancreatic ductal carcinoma obtained by fine-needle aspiration. *Cancer.* 2003 Dec 25;99(6):365-71. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Chung O. *Pancreas.* *Curr Opin Gastroenterol.* 2008 Sep;24(5):569-572. *News/opinion/editorial*

Chun-Ye Q, Xun S, Ming G. Correlation between spiral CT preoperative staging of pancreatic cancer and PTEN and COX-2 expression. *Hepatogastroenterology.* 2012 Sep;59(118):2000-2. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Cipolletta L, Bianco MA, Rotondano G, et al. Pancreatic head mass: What can be done? Diagnosis: ERCP and EUS. *JOP.* 2000 Sep;1(3):108-110. *News/opinion/editorial*

Cipollone I, Kelly M, Corbally C, et al. Is there still a utility for selected laparoscopic staging in pancreas cancer with contemporary multi detector CT scanning? *Pancreatology.* 2012 May-Jun;12(3):e12. *Just a meeting abstract*

Cleveland P, Gill KR, Coe SG, et al. An evaluation of risk factors for inadequate cytology in EUS-guided FNA of pancreatic tumors and lymph nodes. *Gastrointest Endosc.* 2010 Jun;71(7):1194-9. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Codreanu I, Dasanu CA, Weinstein GS, et al. Fluorodeoxyglucose-induced allergic reaction: a case report. *J Oncol Pharm Pract.* 2013 Mar;19(1):86-8. *Other (such as case report)*

Croome KP, Jayaraman S, Schlachta CM. Preoperative staging of cancer of the pancreatic head: is there room for improvement? *Can J Surg.* 2010 Jun;53(3):171-4. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

Das A, Nguyen CC, Li F, et al. Digital image analysis of EUS images accurately differentiates pancreatic cancer from chronic pancreatitis and normal tissue. *Gastrointest Endosc.* 2008 May;67(6):861-7. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*

de Bree E, Tziftsis DD, Santos RM, et al. Objective assessment of the contribution of each diagnostic test and of the ordering sequence in jaundice caused by pancreatobiliary carcinoma. *Scand J Gastroenterol.* 2000 Apr;35(4):438-45. *No data specific to an imaging test of interest*

- De Icaza E, Lopez-Cervantes M, Arredondo A, et al. Likelihood ratios of clinical, laboratory and image data of pancreatic cancer: Bayesian approach. *J Eval Clin Pract.* 2009 Feb;15(1):62-68. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- de la Fuente SG, Ceppa EP, Reddy SK, et al. Incidence of benign disease in patients that underwent resection for presumed pancreatic cancer diagnosed by endoscopic ultrasonography (EUS) and fine-needle aspiration (FNA). *J Gastrointest Surg.* 2010 Jul;14(7):1139-42. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- de Luna R, Eloubeidi MA, Sheffield MV, et al. Comparison of ThinPrep and conventional preparations in pancreatic fine-needle aspiration biopsy. *Diagn Cytopathol.* 2004 Feb;30(2):71-6. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Delrue L, Blanckaert P, Mertens D, et al. Assessment of tumor vascularization in pancreatic adenocarcinoma using 128-slice perfusion computed tomography imaging. *J Comput Assist Tomogr.* 2011 Jul-Aug;35(4):434-8. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- Deshmukh S, Roberts K, Smith AM. Obstructive jaundice and pancreatic disease. *BMJ.* 2013 Jan 5;346(7889):e6701. *Just a meeting abstract*
- Deshpande V, Mino-Kenudson M, Brugge WR, et al. Endoscopic ultrasound guided fine needle aspiration biopsy of autoimmune pancreatitis: diagnostic criteria and pitfalls. *Am J Surg Pathol.* 2005 Nov;29(11):1464-71. *Only a single imaging test of interest, and did not meet criteria for harms/screening/patient perspectives*
- DeWitt J, Devereaux B, Chriswell M, et al. Is endoscopic ultrasound really better than multidetector CT for pancreatic cancer? *Evid Based Gastroenterol.* 2005 May;6(2):50. *Just a meeting abstract*
- DeWitt J, Devereaux B, Chriswell M, et al. Comparison of endoscopic ultrasonography and multidetector computed tomography for detecting and staging pancreatic cancer.[Summary for patients in *Ann Intern Med.* 2004 Nov 16;141(10):I46; PMID: 15545671. *Ann Intern Med.* 2004 Nov 16;141(10):753-63. *Duplicate*
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Appendix C. Evidence Tables

Systematic Reviews

Table C-1. Key Question 1a systematic reviews: study characteristics

Study	Databases Searched	Search Start	Search End	Modalities	Inclusion Criteria	Exclusion Criteria	N articles Included	N Patients	Conclusions on Quality	Analysis Methods
Madhoun et al. 2013 ²⁶	MEDLINE, PubMed, other unnamed databases	Jan-94	Oct-11	EUS-FNA	Compared two <u>needle gauges</u> , pathologic confirmation and/or 6 month clinical follow-up, sufficient data for 2x2	None reported	8	1,292	Good, but risk of review bias	Pooled sensitivity and specificity, bivariate SROC using SAS
Puli et al. 2013 ¹⁶⁷	MEDLINE, EMBASE, CINAHL, Cochrane Central Reg., DARE, others	Jan-66	Jan-12	EUS-FNA	Published in English, pathologic confirmation and/or clinical follow-up, sufficient data for 2x2	None reported	41	4,766	Good: all studies met 4 to 5 of the 14 QUADAS criteria	Pooled sensitivity, specificity, and DOR; summary ROC
Chen et al. 2012 ²⁷	MEDLINE, PubMed	Jan-02	Jan-12	EUS-FNA	Published in English, pathologic confirmation and/or 6 month clinical follow-up, sufficient data for 2x2	Cystic lesions and other specific types of malignancies	15	1,717	Results of high-quality studies were more consistent	Pooled sensitivity, specificity, and DOR; summary ROC using Meta-Disc
Hewitt et al. 2012 ²⁸	MEDLINE	1997	2009	EUS-FNA	Published in English, pathologic confirmation and/or 6 month clinical follow-up, sufficient data for 2x2, N >10	STARD <13, included ampullary lesions	33	4,984	Results of high-quality studies were more consistent	Pooled sensitivity, specificity, and DOR; summary ROC using Meta-Disc

Table C-1. Key Question 1a systematic reviews: study characteristics (continued)

Study	Databases Searched	Search Start	Search End	Modalities	Inclusion Criteria	Exclusion Criteria	N articles Included	N Patients	Conclusions on Quality	Analysis Methods
Wu et al. 2012 ³⁰	MEDLINE, EMBASE, Cochrane Library, Scopus, others	Jan-95	Aug-11	MR (diffusion-weighted), PET/CT	Published in English, pathologic confirmation, sufficient data for 2x2, N >10, QUADAS >9/14	None reported	MR: 7, PET/CT: 9, total: 16	MR: 390, PET/CT: 414	Selected only high-quality articles	Hierarchical SROC using Stata
Wu et al. 2012 ³¹	MEDLINE, EMBASE, CANCELIT, Cochrane	Jan-01	Aug-11	MR (diffusion-weighted)	Published in English, pathologic confirmation and/or 6 month clinical follow-up, sufficient data for 2x2, N >10, QUADAS >9/14	None reported	11	586	Reference diagnosis frequently included MR results	Pooled sensitivity, specificity, and DOR; summary ROC using Meta-Disc and Stata
Tang et al. 2009 ³²	MEDLINE, EMBASE, Scopus, others	Jan-66	Apr-09	PET/CT, EUS (not FNA), PET	Published in English or Chinese, pathologic confirmation and/or 6 month clinical follow-up, sufficient data for 2x2, N >10, QUADAS >9/14	Cystic or neuroendocrine tumors, could not isolate data for individual modalities, co-existing disease	PET/CT: 7, EUS: 21, standalone PET: 27, total: 51	Not reported	Good (since QUADAS was used as inclusion criterion)	Pooled sensitivity, specificity, and DOR; summary ROC using Meta-Disc
Zhao et al. 2009 ¹⁶⁸	MEDLINE, PubMed	Not reported	Not reported	CT (includes single slice)	Published in English, pathologic confirmation, sufficient data for 2x2	Incomplete reporting	18	1,201	None	Pooled sensitivity, specificity, and DOR; summary ROC
Hartwig et al. 2008 ¹⁶⁹	PubMed	Jan-66	Jul-08	EUS-FNA	No language restriction, N ≥40	None reported	EUS-FNA: 28, total 53	4,225	None	Median across studies

Table C-1. Key Question 1a systematic reviews: study characteristics (continued)

Study	Databases Searched	Search Start	Search End	Modalities	Inclusion Criteria	Exclusion Criteria	N articles Included	N Patients	Conclusions on Quality	Analysis Methods
Bipat et al. 2005 ²⁹	MEDLINE, EMBASE, CANCERLIT, Cochrane	Jan-90	Dec-03	CT, MR, ultrasound	Published in English or German, some reference test, sufficient data for 2x2, N ≥20	None reported	MR: 14, CT: 27, total: 68	MR: 1,099; CT: 2,782	None	Bivariate sensitivity, specificity and covariate analysis using SAS

Table C-2. Key question 1a systematic reviews: published results

Study	Modality	Method	Patient Subgroup	Diagnostic Decision	N Studies	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy	Significant Heterog.	Comment
Bipat et al. 2005 ²⁹	CT	All	All	Initial diagnosis	23	91% (86%-94%)	85% (76%-91%)		Not reported	
Madhoun et al. 2013 ²⁶	EUS-FNA	22-gauge	All	Initial diagnosis	8	85% (82%-88%)	100% (98%-100%)		No	
Madhoun et al. 2013 ²⁶	EUS-FNA	25-gauge	All	Initial diagnosis	8	93% (91%-96%)	97% (93%-99%)		No	
Puli et al. 2013 ¹⁶⁷	EUS-FNA	All	All	Initial diagnosis	41	87% (86%-88%)	96% (95%-99%)		No	
Chen et al. 2012 ²⁷	EUS-FNA	All	All	Initial diagnosis	15	92% (91%-93%)	95% (93%-98%)		Yes	Heterogeneity driven by a single outlier with lower sensitivity and specificity than other studies
Hewitt et al. 2012 ²⁸	EUS-FNA	All	All (Note 1)	Initial diagnosis	33	85% (84%-86%)	98% (97%-99%)		Yes	
Hewitt et al. 2012 ²⁸	EUS-FNA	All	All (Note 2)	Initial diagnosis	32	91% (90%-92%)	94% (93%-96%)		Yes	
Hartwig et al. 2008 ¹⁶⁹	EUS-FNA	All	All	Initial diagnosis	28	median 83%	median 100%	median 88%	Not reported	
Wu et al. 2012 ³⁰	MR	Diffusion-weighted	All	Initial diagnosis	7	85% (74%-92%)	91% (71%-98%)		Yes	All studies also included in previous review
Wu et al. 2012 ³¹	MR	Diffusion-weighted	All	Initial diagnosis	11	86% (79%-91%)	91% (81%-96%)		Yes	
Bipat et al. 2005 ²⁹	MR	All	All	Initial diagnosis	11	84% (78%-89%)	82% (67%-92%)		Not reported	
Wu et al. 2012 ³⁰	PET/CT	All	All	Initial diagnosis	9	87% (see comment)	83% (71%-91%)		Yes	Typographical error in published confidence interval
Tang et al. 2009 ³²	PET/CT	All	All	Initial diagnosis	7	90.1% (85.5%-93.6%)	80.1% (73.1%-86.0%)		Yes	Subgroup of retrospective studies also reported

Table C-2. Key question 1a systematic reviews: published results (continued)

Study	Modality	Method	Patient Subgroup	Diagnostic Decision	N Studies	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy	Significant Heterog.	Comment
Bipat et al. 2005 ²⁹	CT	All	All	Resectability	32	81% (76%-85%)	82% (77%-97%)		Not reported	
Bipat et al. 2005 ²⁹	MR	All	All	Resectability	7	82% (69%-91%)	78% (63%-87%)		Not reported	

Notes: 1– only malignant cytology defined as positive, 2– malignant, suspicious, or atypical cytology defined as positive

Table C-3. Key Question 2a systematic reviews: study characteristics

Study	Databases Searched	Search Start	Search End	Modalities	Inclusion Criteria	Exclusion Criteria	N Articles Included	N Patients	Conclusions on Quality	Analysis Methods
Zhao et al. 2009 ¹⁶⁸	MEDLINE, PubMed	Not reported	Not reported	CT (includes single slice)	Published in English, pathologic confirmation, sufficient data for 2x2	Incomplete reporting	18	1,201	None	Pooled sensitivity, specificity, and DOR; summary ROC

Table C-4. Key Question 2a systematic reviews: published results

Study	Modality	Method	Patient Subgroup	Diagnostic Decision	N Studies	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy	Significant Heterog.	Comment
Zhao et al. 2009 ¹⁶⁸	CT	Includes single-slice	All	Vascular invasion	19	77% (72%-81%)	81% (78%-85%)		Yes	
Zhao et al. 2009 ¹⁶⁸	CT	2004–2008 studies	All	Vascular invasion	5	85% (78%-91%)	82% (74%-88%)		Yes	

Comparative Accuracy Studies

Table C-5. General study information of comparative accuracy studies

Study	Country	Name of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Fang et al. 2012 ⁴³	China	Southwest Hospital of the Third Military Medical University, and Zhujiang Hospital of Southern Medical University	November 2008 to August 2010	Prospective	The National High Technology Research and Development Program of China, the Natural Science Foundation of Guangdong Province, the Science and Technology Project of Guangzhou City, Guangdong Province and the Ministry of Education of P. R. China, Guangdong Province and the Chinese Academy of Sciences, the Science and Technology Project of Guangdong Province, and National Natural Science Foundation of China. No declared conflicted of interest, however the authors had developed and patented one of technologies being assessed (Medical Image Three-Dimensional Visualization System MI-3DVS). "There has been no industry or pharmaceutical support."
Herrmann et al. 2012 ⁶⁴	Germany	Universität München,	September 2008 and April 2009	prospective	NR
Tellez-Avila et al. 2012 ⁶⁸	Mexico	Instituto Nacional de Ciencias Medicas y Nutrition Salvador Zubiran, Mexico City, Mexico	March 2005– March 2010	Prospective	No funding source reported. Authors declare no conflict of interest
Holzapfel et al. 2011 ⁷⁰	Germany	Technische Universitaet Muenchen	NR	Prospective	NR
Koelblinger et al. 2011 ⁵⁸	Austria	Medical University of Vienna	September 2006 to November 2007	Prospective	All nine authors stated explicitly that they had no financial activities to disclose related to the article, and no financial activities to disclose not related to the article, and no other relationships to disclose
Motosugi et al. 2011 ⁵⁷	Japan	University of Yamanashi	March 2008 to June 2010	Retrospective	NR

Table C-5. General study information of comparative accuracy studies (continued)

Study	Country	Name of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Rao et al. 2011 ⁵⁵	China	Zhongshan Hospital, Fudan University and Shanghai Medical Imaging Institute	NR	Retrospective	NR
Shami et al. 2011 ⁷³	USA	University of Virginia Health System	NR	Prospective	NR
Takakura et al. 2011 ⁵⁶	Japan	Jikei University School of Medicine	October 2007 to September 2009	NR	NR
Imai et al. 2010 ⁷¹	Japan	Kyoto University	August 2005 to July 2008	Retrospective	"No author has any conflict of interest"
Lee et al. 2010 ⁶²	South Korea	Ewha Women's University	January 2003 to June 2005	Retrospective	"There is no actual or potential conflict of interest for all authors in this manuscript"
Kauhanen et al. 2009 ⁵⁹	Finland	Turku University Hospital	September 2006 to October 2007	Prospective	Supported by National Graduate School of Clinical Investigation of Final, and a hospital grant. No statements about conflicts of interest.
Farma et al. 2008 ⁷²	USA	H. Lee Moffitt Cancer Center and Research Institute	January 2006 to December 2007	Retrospective	NR
Saif et al. 2008 ⁶⁵	USA	Yale University School of Medicine	May 2003 to March 2004	Prospective	"Conflicts of interest: None to declare"
Schick et al. 2008 ⁵¹	Germany	Muenster University Hospital	July 2005 to February 2007	Prospective	NR
Casneuf et al. 2007 ⁶³	Belgium	Gent	October 2004 to April 2006	Prospective	NR
Tamm et al. 2007 ⁵³	USA	University of Texas MD Anderson Cancer Center	NR	Retrospective	NR
Mehmet Ertuk et al. 2006 ⁶⁰	Japan	University of Yamanashi	January 2003 to October 2004	Retrospective	NR
Heinrich et al. 2005 ⁶⁶	Switzerland & Austria	University Hospital of Zurich & Internal Medicine Landeskrankenhaus Feldkirch, Austria	June 2001 to April 2004	Prospective	NR

Table C-6. Patient characteristics of comparative accuracy studies

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Fang et al. 2012 ⁴³	Confirmed pancreatic or periampullary neoplasms and had received both imaging tests being compared, did not have distant organ metastases, and had undergone surgery	57	81% (46/57)	57.9	43 pancreatic ductal adenocarcinoma of the head, 14 pancreatic ductal adenocarcinoma of the body/tail	The study also included some patients with periampullary cancer, but data were provided specifically for pancreatic cancer. Patient characteristics are based on all enrolled.
Herrmann et al. 2012 ⁶⁴	Pancreatic tumours suspicious for malignancy and scheduled for resective surgery	44	36% (16/44)	median age 65±12 years, range 34–86 years		
Tellez-Avila et al. 2012 ⁶⁸	Referred because of pancreatic lesion	50	54% (27/50)	61±11.5 years	17/19 patients with adequate tissue samples by EUS. Tissue sampling not attempted in 31 patients. After surgery, histological vascular invasion was demonstrated in 18 patients, vein invasion in 11, and arterial invasion in 9.	
Holzapfel et al. 2011 ⁷⁰	Potentially resectable as seen by MDCT, received diffusion weighted MRI	31	48% (15/31)	61.4 (range 32–84)	23 pancreatic ductal adenocarcinoma, 1 acinar cell carcinoma, 1 neuroendocrine carcinoma, 1 benign IPMN, 1 malignant IPMN, 1 cholangiocarcinoma, 1 papillary carcinoma, 2 focal chronic pancreatitis	

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Koelblinger et al. 2011 ⁵⁸	Informed consent, suspected of having pancreatic cancer, referred to the group of surgeons at the institution, no contraindications to CT/MRI, no time constraints, accepted enrollment, contacted sufficiently soon	89	54% (48/89)	65.5	43 pancreatic adenocarcinoma, 4 ampullary carcinoma, 7 metastases, 1 neuroendocrine tumor, 1 cystadenoma, 9 cystic tumor, 4 inflammatory pseudotumor, 1 focal steatosis, 26 normal pancreas	
Motosugi et al. 2011 ⁵⁷	Patients underwent both dynamic CT and MR cholangio-pancreatography with gadoxetic acid enhancement performed within 1 month, underwent follow-up CT or MR imaging more than 6 months after initial examination	100	47% (47/100)	Men: 67.5 (SD 10.6); Women: 68.2 (SD 10.6)	54 pancreatic carcinoma, 14 biliary stone and/or adenomyomatosis of the gallbladder, 10 biliary carcinoma, 4 gallbladder carcinoma, 3 liver metastasis from colon carcinoma, 6 intraductal papillary mucinous neoplasm of the pancreas, 9 no evidence of disease in the abdomen	
Rao et al. 2011 ⁵⁵	Evidence of small (≤ 2 cm) pancreatic solid tumor	46	54% (25/46)	57 (range 22–81)	18 pancreatic ductal adenocarcinoma, 13 neuroendocrine tumor, 8 metastases (primary cancer not reported but probably pancreatic cancer), 5 solid pseudopapillary tumor, 2 intrapancreatic accessory spleen	
Shami et al. 2011 ⁷³	Underwent both MRI and EUS-FNA for the workup of pancreatic cancer	127	44% (56/127)	66	All had pancreatic cancer; specific diagnoses not reported	

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Takakura et al. 2011 ⁵⁶	Patients with pancreatic duct dilatations over 3 mm as visualized by MRCP, who underwent both DWI and MDCT	83	27% (22/83)	37–91 years	Pancreatic cancer (presumably adenocarcinoma), IPMN, cholangio (bile duct), adeno of duodenum (papilla of Vater)	
Imai et al. 2010 ⁷¹	Diagnosed with invasive ductal adenocarcinoma of pancreas during a time range, no other pancreatic malignancies, underwent preoperative CT and MRI and PET	119	51% (61/119)	65 (range 32–85)	79 pancreatic adenocarcinoma head only, 23 pancreatic adenocarcinoma body only, 5 pancreatic adenocarcinoma tail only, 1 pancreatic adenocarcinoma head + body, 10 pancreatic adenocarcinoma body + tail, 1 pancreatic adenocarcinoma head+body+tail	Comparative accuracy data only reported for the 69/119 who received all three imaging tests CT MRI PET
Lee et al. 2010 ⁶²	Underwent surgery for pancreatic adenocarcinoma, surgical and pathological findings were available for correlation with imaging tests	56	46% (26/56)	60.9 (range 37–76)	56 pancreatic adenocarcinoma	
Kauhanen et al. 2009 ⁵⁹	Suspicion of pancreatic malignancy based on ultrasound and/or CT, or suspicion of malignant biliary stricture based on ERCP, no hepatocellular carcinoma, underwent PET/CT and MRI and 64-slice MDCT	38	50% (19/38)	62.6	17 pancreatic adenocarcinoma, 3 neuroendocrine tumor, 4 chronic pancreatitis, 5 benign cystic lesion, 1 malignant cystic lesion, 2 fibrosis, 6 normal pancreas	

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Farma et al. 2008 ⁷²	Patients referred to center with a presumed pancreatic neoplasm and who had preoperative PET/CT scans, only patients with pancreatic lesions	82	48% (39/82)	Median: 69 (24 to 88)	65 pancreatic cancer, 17 IPMNs	
Saif et al. 2008 ⁶⁵	Suspected pancreatic cancer or focal lesion in the pancreas, and had both CT and PET/CT	12	25% (3/12)	61 (range 43–74)	11 malignant pancreatic adenocarcinoma, 1 benign	
Schick et al. 2008 ⁵¹	Solid pancreatic masses of unknown etiology, did not have known pancreatic cancer or known metastases, able to complete the exam, no mental retardation, informed consent	46	30% (14/46)	61.7 (range 31 to 87)	22 ductal adenocarcinoma, 1 adenocarcinoma of the ampulla of Vater, 1 neuroendocrine carcinoma, 1 cholangiocellular carcinoma, 1 metastasis from breast cancer, 1 GIST in duodenum, 14 chronic pancreatitis, 2 pseudocyst with blood/necrotic tissue, 2 bile duct stenosis, 1 focal tuberculosis	
Casneuf et al. 2007 ⁶³	Referred for PET/CT for suspected pancreatic disease	34	47% (16/34)	61	18 adenocarcinoma, 4 neuroendocrine tumor, 3 unknown pancreatic tumor, 6 pancreatitis, 3 cystadenoma.	Age was estimated by the EPC based on separately-reported medians of 63 for the 25 positives and 58 for the 9 negatives. The study reported another 12 patients who were included for assessment of recurrence; these patients' data were not extracted.

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Tamm et al. 2007 ⁵³	1) Clinical suspicion of pancreatic cancer, 2) had undergone both dual-phase MDCT and EUS, 3) MDCT had shown either definite or questionable tumor, or MDCT resulted in a high clinical suspicion of a pancreatic mass, 4) MDCT did NOT show a cystic mass or hypervascular mass suggestive of a neuroendocrine tumor, 5) either clear histopathological proof of true status OR at least 9 months clinical followup after negative MDCT or negative EUS-FNA	117	46% (54/117)	69	95 adenocarcinoma, 2 extrahepatic cholangiocarcinoma, 1 intraductal papillary mucinous neoplasm without a cystic component, 1 ampullary carcinoma, 10 chronic pancreatitis, 1 benign pancreatic duct stricture, 3 benign common bile duct stricture, 1 choledochal cyst	
Mehmet Ertuk et al. 2006 ⁶⁰	Either 1) underwent surgery for pancreatic adenocarcinoma and had had both multiphase MDCT and MRI prior to surgery, or 2) did not have pancreatic carcinoma and underwent CT and MRI during the same period of time	45	56% (25/45)	67.4 (range 42 to 85)	14 head adenocarcinoma, 6 body adenocarcinoma, 4 tail adenocarcinoma, 3 elevated CA 19-9 but no adenocarcinoma, 5 acute pancreatitis, 7 chronic pancreatitis, 6 IPMN.	Age calculated based on weighted average of reported mean ages of positives and negatives

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Heinrich et al. 2005 ⁶⁶	Patients with a focal lesion in the pancreas or with clinical suspicion of pancreatic cancer was eligible for this analysis	59	49% (29/59)	Median: 61 (40 to 80)	43 ductal adenocarcinoma, 1 acinuscell carcinoma, 1 Neuroendocrine cancer, 1 Metastasis from colon cancer, 1 serous microcystic adenoma, 1 high-grade epithelial dysplasia, 1 focal tuberculosis, 3 chronic pancreatitis (pseudotumor); 7 no definitive histologic diagnosis was available	
Agarwal et al. 2004 ⁵⁴	If clinical suspicion of pancreatic cancer was based on: obstructive jaundice with biliary stricture seen on ERCP (n=47), suspected pancreatic mass on CT (n=19), and two or more episodes of acute pancreatitis in 6 months without predisposing factors (n=15)	81	51% (41/81)	66.4 (SD 10.5)	71 malignant and 10 benign. Of the 71 malignant tumors: 58 were located in the pancreatic head, five in the uncinate process, and eight in the neck, body or tail of the pancreas)	

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
DeWitt et al. 2004 ⁵⁰	1) Clinically suspected or recently diagnosed solid or cystic pancreatic cancer with the past 8 weeks, 2) agreed to undergo EUS and CT and surgery (if necessary), 3) had not already undergone ERCP or EUS for suspected pancreatic cancer; 4) did not decline or remain undecided about surgical intervention; 5) were not referred by surgeons outside their hospital system; 6) were not pregnant; 7) were not incarcerated; 8) could independently provide informed consent; 9) were not considered high surgical risk (not ASA class III IV or V); 10) had known or suspected periampullary masses; 11) had cholangiocarcinoma; 12) had cancer with suspected locally advanced arterial involvement or metastatic disease detected by previous imaging studies.	104	43% (45/104)	64	28 unresectable pancreatic cancer determined after surgery, 25 resectable pancreatic cancer, 5 chronic pancreatitis, 1 benign intraductal papillary mucinous tumor, 1 macrocystic serious [sic] cystadenoma, 1 benign neuroendocrine tumor, 1 accessory spleen, 1 ampullary cancer, 9 benign resectable focal pancreatic masses without vascular invasion, 26 pancreatic adenocarcinoma determined without surgery, 1 neuroendocrine carcinoma determined without surgery, 2 suspected unresectable gall bladder carcinoma or hepatoma, 3 no mass, 1 suspected liver abscess, 8 benign disease	-

Table C-6. Patient characteristics of comparative accuracy studies (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Lemke et al. 2004 ⁶⁷	Suspected pancreatic lesion	104	51% (53/104)	Median 64 (Range 23–84)	(See comments) 57 adenocarcinoma, 5 carcinoma of papilla of Vater, 1 bile duct carcinoma, 1 neuroendocrine tumor, 28 chronic pancreatitis, 5 papillary adenoma, 3 other benign lesions	Final diagnoses: 53 surgical resection, 25 exploratory surgery, 16 percutaneous needle aspiration biopsy, 10 clinical follow-up
Soriano et al. 2004 ⁶⁹	Had pancreatic or ampullary carcinoma, fit for surgery, confirmed neoplasm, gave consent, no massive metastasis precluding surgery, at least 3 imaging techniques could be performed	62	47% (29/62)	65	42 Pancreas head cancer, 6 pancreas body cancer, 4 pancreas tail cancer, 10 ampullary cancer	
Rieber et al. 2000 ⁶¹	known or suspected pancreatic malignancy, Minimum age of 18 years, patient consciousness and cooperation, written informed consent, free withdrawal from the study, no participation in drug administration phase of another trial	20	30% (6/20)	Avg. 62 (range 34–88)	8 pancreatic adenocarcinoma, 10 chronic pancreatitis, 2 stenosing papillitis	

Table C-7. General test details of comparative accuracy studies

Study	Imaging Tests of Interest	Order of Tests Performed	Elapsed Time Between Imaging Tests	Number of Test Readers per Scan	Prior Experience of These Readers With This Imaging Test	Other Reported Details About the Readers	Reference Standard Determination Based on:
Fang et al. 2012 ⁴³	CT angiography with 3D reconstruction vs. without 3D reconstruction	CTA was always first	None; the same images were used. 3D reconstruction was performed by software	2 (not the same as those who read the other test)	NR	NR	Intraoperative exam
Herrmann et al. 2012 ⁶⁴	MDCT vs. PET/CT	Not clear. FDG PET CT, FLT PET and diagnostic CT were performed in different subgroups of patients. Some patients came with diagnostic CTs prior to treatment at this institution and others had it afterwards.	One day between FLT and FDG. No specified time between FDG and diagnostic CT	3	"board certified"	board certified nuclear medicine physicians and "board certified" radiologist	Cytology/histology
Tellez-Avila et al. 2012 ⁶⁸	MDCT vs. EUS-FNA	MDCT was always first	NR	2	"Certified Radiologists"	NR	Pathologic specimen required to confirm imaging results. Accuracy of study to determine presence of vascular invasion preoperatively was the outcome measure. Reviewed presence of histologic vascular invasion (artery/vein). Vascular invasion is considered good predictor for poor prognosis after local resection

Table C-7. General test details of comparative accuracy studies (continued)

Study	Imaging Tests of Interest	Order of Tests Performed	Elapsed Time Between Imaging Tests	Number of Test Readers per Scan	Prior Experience of These Readers With This Imaging Test	Other Reported Details About the Readers	Reference Standard Determination Based on:
Holzapfel et al. 2011 ⁷⁰	MDCT vs. MRI	MDCT was always first	Mean 7.5 days, range 1–16 days	2	NR	2 radiologists	Intraoperative surgical and ultrasound findings in all 31 patients, as well as histopathology in 11 of 31
Koelblinger et al. 2011 ⁵⁸	MDCT vs. MRI	NR	At most one week	2	At least 10 years' experience in both abdominal CT and MRI	2 gastrointestinal radiologists	Diagnosis: Histology in 59/89 (66%) overall (the 59 were comprised of 33 surgical histology and 26 who had either CT-guided or EUS-guided biopsy), and clinical followup of at least 6 months in the remaining 30 patients. Other clinical decisions: Surgical histology

Table C-7. General test details of comparative accuracy studies (continued)

Study	Imaging Tests of Interest	Order of Tests Performed	Elapsed Time Between Imaging Tests	Number of Test Readers per Scan	Prior Experience of These Readers With This Imaging Test	Other Reported Details About the Readers	Reference Standard Determination Based on:
Motosugi et al. 2011 ⁵⁷	MDCT vs. MRI	MDCT was always first	NR	3	Reader had only a small amount of experience in abdominal MRI while readers 2 and 3 had been in the abdominal subgroup for more than 5 years. Reader 1 interpreted far fewer abdominal MIRs in daily work compared with the other two readers.	CT and MIRs in patients with and without pancreatic carcinoma were interpreted independently and in random order by the three readers. More than 1 week of time interval was set between the reading sessions of images to reduce recall bias. Each reader graded the presence (or absence of pancreatic carcinoma on a 5 point confidence scale. Readers were blinded to the clinical histories and final diagnoses. Images were also interpreted for the presence of liver metastases in patients with pancreatic carcinoma. Each reader graded the presence (or absence) of liver mets on a 5 point scale. If any false-positive or false-negative results were observed in any reader's interpretation, the study coordinators assessed the reason for the misinterpretation by reviewing the images.	For diagnosis: 54 patients with pancreatic cancer confirmed at surgery (23), transendoscopic biopsy (24), or brush cytology of pancreatic duct (7). 46 patients without pancreatic cancer were confirmed at follow-up CT or MRI performed more than 6 months after initial examination. For metastases: 15 of 56 patients with pancreatic cancer were found to have 62 liver metastases: 6 lesions found by pathologic results, 49 lesions showing hypoattenuation on post contrast CT or MIR that had increased in size at follow-up exam, 7 lesions that had disappeared or decreased in size after chemotherapy at the follow-up exam
Rao et al. 2011 ⁵⁵	MDCT vs. MRI	MDCT was "usually the first choice"	NR	2	At least 5 years' experience	2 gastrointestinal radiologists	Histopathology
Shami et al. 2011 ⁷³	EUS-FNA vs. MRI	NR	NR	1	a "qualified" radiologist	NR	Surgical histology

Table C-7. General test details of comparative accuracy studies (continued)

Study	Imaging Tests of Interest	Order of Tests Performed	Elapsed Time Between Imaging Tests	Number of Test Readers per Scan	Prior Experience of These Readers With This Imaging Test	Other Reported Details About the Readers	Reference Standard Determination Based on:
Takakura et al. 2011 ⁵⁶	MDCT vs. MRI	Not specified.	No more than 90 days between tests	4	"Experienced"	2 gastroenterology fellows, 2 radiologists	cytology for some and clinical follow up for others
Imai et al. 2010 ⁷¹	MDCT vs. MRI	NR	NR	2 or more	"Experienced"	Radiologists	Surgery in 102, probe laparotomy in 17. Did not report this delineation specifically for the 69 patients in whom imaging accuracy were reported
Lee et al. 2010 ⁶²	MDCT vs. MRI	Random order	Mean 3.8 days (range 0–14)	2	Both readers had completed a subspecialty fellowship in gastrointestinal radiology	Two radiologists	Surgical findings in all
Kauhanen et al. 2009 ⁵⁹	MDCT vs. MRI vs. PET/CT	NR	MRI was within two weeks of MDCT and PET/CT; MDCT and PET/CT were same-day	1 for MDCT and MRI, 2 for PET/CT	NR	Abdominal radiologist. Used one reader from a different institution to prevent recall bias.	Diagnosis: Surgery in 23, biopsy in 3, autopsy in 3, and clinical followup in 9 (minimum followup 12 months). Metastases: Surgical findings in 7/14, and histopathology in the other 7
Farma et al. 2008 ⁷²	MDCT vs. PET/CT	MDCT was always first	NR	NR	NR	all patients were discussed in the multidisciplinary gastrointestinal tumor board mtg prior to definitive treatment planning	All patients had either a percutaneous or endoscopic core needle, or fine needle aspiration biopsy confirming histologic diagnosis.
Saif et al. 2008 ⁶⁵	MDCT vs. PET/CT	MDCT was always first	No time elapsed	NR	NR	Nuclear medicine physicians and radiologists	Pathology in 6, clinical followup in the other 6

Table C-7. General test details of comparative accuracy studies (continued)

Study	Imaging Tests of Interest	Order of Tests Performed	Elapsed Time Between Imaging Tests	Number of Test Readers per Scan	Prior Experience of These Readers With This Imaging Test	Other Reported Details About the Readers	Reference Standard Determination Based on:
Schick et al. 2008 ⁵¹	EUS-FNA vs. PET/CT	PET/CT was always first	Within 3 weeks	2	EUS-FNA: NA. PET/CT: Fused data were read by 2 readers in consensus. 1 was a board-certified nuclear medicine physician experienced in PET interpretation, and the other was a board-certified radiologist experienced in CT analysis.	EUS-FNA: NA. PET/CT: 1 nuclear medicine physician and 1 radiologist	Histology in 43/46 patients and clinical followup of at least 12 months in 3/46
Casneuf et al. 2007 ⁶³	MDCT vs. PET/CT	MDCT was always first	NR	1 for MDCT, 2 for PET/CT	NR	Identified by name	31/34 histological findings, 3/34 clinical course
Tamm et al. 2007 ⁵³	MDCT vs. EUS-FNA	MDCT was always first	NR	1	NR	3 radiologists	Histopathology from either surgical findings or biopsy, or if negative biopsy, then clinical followup of at least 9 months
Mehmet Ertuk et al. 2006 ⁶⁰	MDCT vs. MRI	Order not reported for patients who did not have pancreatic adenocarcinoma. For those who did, MDCT was performed first for 13/24 and MRI was performed first for 11/24	Time difference not reported for those without pancreatic adenocarcinoma. For those with it, at most one week	3	"Experienced"	3 abdominal radiologists	Surgery in the 24 known adenocarcinomas, and for the 21 negatives it was surgery in 3 and clinical followup of at least 12 months in the remaining 18

Table C-7. General test details of comparative accuracy studies (continued)

Study	Imaging Tests of Interest	Order of Tests Performed	Elapsed Time Between Imaging Tests	Number of Test Readers per Scan	Prior Experience of These Readers With This Imaging Test	Other Reported Details About the Readers	Reference Standard Determination Based on:
Heinrich et al. 2005 ⁶⁶	MDCT vs. PET/CT	MDCT was always first	Median: 10 days	4	NR	At least 2 nuclear medicine physicians and radiologists. All CT images were viewed separately to identify additional lesions without FDG uptake using soft tissue, lung, and bone window leveling	EUS-FNA of primary tumor and FNA of metastatic lesions, serial CA 19-9 levels, and diagnostic laparoscopy
Agarwal et al. 2004 ⁵⁴	MDCT vs. EUS-FNA	MDCT was always first	NR	NR	NR	CT: radiologists who specialize in body imaging. EUS-FNA: Cytologist could make the preliminary diagnosis	Definitive cytology, surgical pathology, or development of metastatic disease
DeWitt et al. 2004 ⁵⁰	MDCT vs. EUS-FNA	EUS-FNA was always first	At most one week	3	MDCT: they were "Experienced." EUS-FNA: All had at least 1000 prior EUS exams	3 gastroenterologists	For diagnosis: Either 1) intraoperative exam or 2) EUS-FNA or previously obtained cytology and subsequent clinical follow-up. For resectability and T staging: Intraoperative exam (only R0) was considered resectable.
Lemke et al. 2004 ⁶⁷	MDCT vs. PET/CT	MDCT was always first	Median 3 days (range 1-6)	2	"Experienced"	Radiologists reviewed images using standardized questionnaires	Surgical resection (53), exploratory surgery (25), percutaneous needle aspiration biopsy (16), and clinical follow-up (10)
Soriano et al. 2004 ⁶⁹	MDCT vs. MRI	Pseudo-random order depending on the available of test technologies	NR	NR	NR	NR	Surgical findings in all
Rieber et al. 2000 ⁶¹	MDCT vs. MRI	MDCT performed first	NR	3	NR	Radiologists	histological findings for all cases

Table C-8. MDCT details of comparative accuracy studies

Study	MDCT: 4 vs. 16 vs. 64 Detector Row or Other	MDCT: Slice Thickness (if NR, Then Record Machine Name)	MDCT: Whether Reformats Used (e.g., Coronal, Sagittal) or Only Axial	MDCT: Contrast Y or N	MDCT: Type of Contrast	MDCT: Phases of Enhancement Dynamic vs. Routine; Arterial/Portal Venous/Equilibrium Means Dynamic
Fang et al. 2012 ⁴³	64	0.67 mm	Y	Y	80-100 mL Iopamiro	Dual phase
Herrmann et al. 2012 ⁶⁴	NR	NR	NR	NR	NR	NR
Tellez-Avila et al. 2012 ⁶⁸	16 or 64	3mm–5mm	Coronal reformatted images	Y	120 mL of Conray was given 45 seconds before CT examination. 40 mL of ioditrast M60 was diluted in 1,000 mL of water and given to all patients orally 1 hour before CT imaging	Dynamic
Holzapfel et al. 2011 ⁷⁰	64	0.6 mm	Y	Y	120 mL Imeron 300	Dual-phase
Koelblinger et al. 2011 ⁵⁸	64	0.6 mm	Y	Y	150 mL Iomeprol	Dynamic
Motosugi et al. 2011 ⁵⁷	16	5 mm	NR	Y	300 mg/mL Omnipaque 300	Dynamic
Rao et al. 2011 ⁵⁵	16	0.75 mm and 0.625 mm	Y	Y	300mg Ultravist	Three-phase
Shami et al. 2011 ⁷³	-	-	-	-	-	-
Takakura et al. 2011 ⁵⁶	64	Definition, Siemens, Erlangen, Germany	Not specified	Yes	(Iopamiron 370, Bayer Schering Pharma, Berlin, Germany)	Dual (arterial and delayed presumably from 90 second delay)
Imai et al. 2010 ⁷¹	64	0.5 mm	NR	Y	Iopamiron 2 mL/kg	Dual-phase
Lee et al. 2010 ⁶²	4	1.25 mm	Y	Y	Iopromide 150 mL	Dual phase
Kauhanen et al. 2009 ⁵⁹	64	5 mm	N	Y	Iomerol 400 mg/mL 1.5mL contrast/kg	Four-phase
Farma et al. 2008 ⁷²	NR	NR	NR	NR	NR	NR
Saif et al. 2008 ⁶⁵	4	1 to 3 mm	N	Yes	Gastrograffin	NR
Schick et al. 2008 ⁵¹	16	0.75 mm upper abdomen	Y	Y	140 mL Iomeprol	Dual-phase
Casneuf et al. 2007 ⁶³	16	3 mm	NR	Y	140mL Iodixanol 320 mg iodine per mL	Venous
Tamm et al. 2007 ⁵³	4	2.5 mm first phase, 5 mm second phase	N	Y	150mL Ioversol 350 mg Iodine/mL	Dual-phase
Mehmet Ertuk et al. 2006 ⁶⁰	16	0.5 mm	Y	Y	350 mg/mL Iomeron	Three-phase

Table C-8. MDCT details of comparative accuracy studies (continued)

Study	MDCT: 4 vs. 16 vs. 64 Detector Row or Other	MDCT: Slice Thickness (if NR, Then Record Machine Name)	MDCT: Whether Reformats Used (e.g., Coronal, Sagittal) or Only Axial	MDCT: Contrast Y or N	MDCT: Type of Contrast	MDCT: Phases of Enhancement Dynamic vs. Routine; Arterial/Portal Venous/Equilibrium Means Dynamic
Heinrich et al. 2005 ⁶⁶	4	5 mm	Axial	Y	Oral contrast	NR
Agarwal et al. 2004 ⁵⁴	NR	1.25 mm (parenchymal phase); 2.5 mm (portal phase)	NR	Y	150 mL of nonionic contrast material (Optiray 320, Mallinckrodt Inc., St. Louis, MO)	Dynamic
DeWitt et al. 2004 ⁵⁰	4	first phase 1.3 mm effective section thickness, second phase 3.2 mm effective section thickness	Sometimes (NR percentage of procedures)	Y	150 mL Isovue-300, 300 mg Iodine/mL	Dual phase
Lemke et al. 2004 ⁶⁷	NR	NR	NR	Y	100 mL iopromide (Ultravist 370, Schering AG)	Dynamic
Soriano et al. 2004 ⁶⁹	4	8mm	Y	Y	Iohexol 64.75g	Dual-phase
Rieber et al. 2000 ⁶¹	NR	NR	NR	Y	150 mL iopromide (Ultravist 300, Schering, Berlin)	Dynamic

Table C-9. EUS-FNA details of comparative accuracy studies

Study	EUS FNA Technology Name for EUS	EUS-FNA Needle Type	EUS-FNA Needle Size	How Many Patients Received FNA?	Other EUS-FNA Details
Fang et al. 2012 ⁴³	-	-	-	-	-
Herrmann et al. 2012 ⁶⁴	-	-	-	-	-
Tellez-Avila et al. 2012 ⁶⁸	Linear GF UCT-140 echoendoscope (Olympus, American Corp, Melville, NY) with an Aloka console SSD 5500. Used with an 8 cm long 22 or 19- gauge EchoTip Needle	EchoTip Needle	8 cm long 22- or 19- gauge EchoTip needle	21 but only 17/19 had adequate tissue samples for histologic evaluation	
Holzapfel et al. 2011 ⁷⁰	-	-	-	-	-
Koelblinger et al. 2011 ⁵⁸	-	-	-	-	-
Motosugi et al. 2011 ⁵⁷	-	-	-	-	-
Rao et al. 2011 ⁵⁵	-	-	-	-	-
Shami et al. 2011 ⁷³	Olympus GF-UCT140 or GF-UC140P	NR	NR	NR	NR
Takakura et al. 2011 ⁵⁶	-	-	-	-	-
Imai et al. 2010 ⁷¹	-	-	-	-	-
Lee et al. 2010 ⁶²	-	-	-	-	-
Kauhanen et al. 2009 ⁵⁹	-	-	-	-	-
Farma et al. 2008 ⁷²	-	-	-	-	-
Saif et al. 2008 ⁶⁵	-	-	-	-	-
Schick et al. 2008 ⁵¹	Hitachi FG 38vx	NR	22 gauge	29	Transduodenal approach for pancreatic head lesions, or transgastric approach for body/tail lesions
Casneuf et al. 2007 ⁶³	-	-	-	-	-
Tamm et al. 2007 ⁵³	Olympus EUM-30 and Pentax FG-32A	NR	NR	NR	NR

Table C-9. EUS-FNA details of comparative accuracy studies (continued)

Study	EUS FNA Technology Name for EUS	EUS-FNA Needle Type	EUS-FNA Needle Size	How Many Patients Received FNA?	Other EUS-FNA Details
Mehmet Ertuk et al. 2006 ⁶⁰	-	-	-	-	-
Heinrich et al. 2005 ⁶⁶	-	-	-	-	-
Agarwal et al. 2004 ⁵⁴	Olympus EUM-30 and Pentax FG-32A	Echo-tip (Wilson Cook, Winston Salem, NC)	NR	81	EUS-FNA was considered positive only if a definitive cytologic diagnosis of malignancy could be made with fine needle aspirates.
DeWitt et al. 2004 ⁵⁰	Either Olympus GF-UM130 or Pentax GF-36UX or Olympus GF-UC140P	Wilson-Cook Medical	22 gauge	NR	On-site cytopathologist
Lemke et al. 2004 ⁶⁷	-	-	-	-	-
Soriano et al. 2004 ⁶⁹	-	-	-	-	-
Rieber et al. 2000 ⁶¹	-	-	-	-	-

Table C-10. MRI details of comparative accuracy studies

Study	MRI: Magnet Strength	MRI: Contrast Y or N	MRI: Type of Contrast	MRI: Phases of Enhancement Dynamic vs. Routine; Arterial/Portal Venous/Equilibrium Means Dynamic	MRI: Diffusion-weighted Y or N	MRI: Type of Coil (Body/Pelvic or Endorectal)
Fang et al. 2012 ⁴³	-	-	-	-	-	-
Herrmann et al. 2012 ⁶⁴	-	-	-	-	-	-
Tellez-Avila et al. 2012 ⁶⁸	-	-	-	-	-	-
Holzapfel et al. 2011 ⁷⁰	1.5 T	N	NA	None	Y	2–6 channel-body-phased array coils anterior and two spine clusters posterior
Koelblinger et al. 2011 ⁵⁸	3 T (Trio Tim)	Y	0.1 mmol/kg gadobenate dimeglumine	Three-phase	N	Surface coils
Motosugi et al. 2011 ⁵⁷	1.5 T	Y	gadovetic acid (0.025 mmol per kilogram of body weight)	Dynamic	N (diffusion weighted images obtained but not used in this study)	NR
Rao et al. 2011 ⁵⁵	1.5 T	Y	30 mL Magnevist	Dynamic	N	NR
Shami et al. 2011 ⁷³	1.5 T Magnetom Sonata, Symphony and Avanta (Siemens)	Y	10–20 cc gadopentetate dimeglumine	Three-phase	N	Body coil
Takakura et al. 2011 ⁵⁶	1.5 T	N (not relevant only looking at DWI)	NA	NA	Y	12-channel body and spine matrix coil combination
Imai et al. 2010 ⁷¹	1.5 T	N	NA	None	N	NR
Lee et al. 2010 ⁶²	1.5 T	Y	Gadolinium	Dual-phase	N	Body coil
Kauhanen et al. 2009 ⁵⁹	1.5 T	Y	Gadolinium 0.2 mL/kg	Dynamic	N	Surface coil
Farma et al. 2008 ⁷²	-	-	-	-	-	-
Saif et al. 2008 ⁶⁵	-	-	-	-	-	-
Schick et al. 2008 ⁵¹	-	-	-	-	-	-

Table C-10. MRI details of comparative accuracy studies (continued)

Study	MRI: Magnet Strength	MRI: Contrast Y or N	MRI: Type of Contrast	MRI: Phases of Enhancement Dynamic vs. Routine; Arterial/Portal Venous/Equilibrium Means Dynamic	MRI: Diffusion-weighted Y or N	MRI: Type of Coil (Body/Pelvic or Endorectal)
Casneuf et al. 2007 ⁶³	-	-	-	-	-	-
Tamm et al. 2007 ⁵³	-	-	-	-	-	-
Mehmet Ertuk et al. 2006 ⁶⁰	1.5 T	Y	20 mL gadolinium	Three-phase	N	NR
Heinrich et al. 2005 ⁶⁶	-	-	-	-	-	-
Agarwal et al. 2004 ⁵⁴	-	-	-	-	-	-
DeWitt et al. 2004 ⁵⁰	-	-	-	-	-	-
Lemke et al. 2004 ⁶⁷	-	-	-	-	-	-
Soriano et al. 2004 ⁶⁹	1.0 T	Y	Gadopentate dimeglumine 0.1 mmol/kg	Dynamic	N	body
Rieber et al. 2000 ⁶¹	1.5 T	Y	Mn-DPDP 5 μmol kg(-1)	NR	Y	body

Table C-11. PET/CT details of comparative accuracy studies

Study	PET: Isotope	PET: Mean Dose of Isotope	PET: Uptake Time	Integrated or Superimposed
Fang et al. 2012 ⁴³	-	-	-	-
Herrmann et al. 2012 ⁶⁴	FDG	300–400 MBq	90 min	Integrated
Tellez-Avila et al. 2012 ⁶⁸	-	-	-	-
Holzapfel et al. 2011 ⁷⁰	-	-	-	-
Koelblinger et al. 2011 ⁵⁸	-	-	-	-
Motosugi et al. 2011 ⁵⁷	-	-	-	-
Rao et al. 2011 ⁵⁵	-	-	-	-
Shami et al. 2011 ⁷³	-	-	-	-
Takakura et al. 2011 ⁵⁶	-	-	-	-
Imai et al. 2010 ⁷¹	-	-	-	-
Lee et al. 2010 ⁶²	-	-	-	-
Kauhanen et al. 2009 ⁵⁹	FDG	366 +/- 15 MBq	60 minutes	Integrated
Farma et al. 2008 ⁷²	FDG	296-555 MBq (8-15 mCi)	90 minutes	Integrated
Saif et al. 2008 ⁶⁵	FDG	10 mCi	60 minutes	Integrated
Schick et al. 2008 ⁵¹	FDG	4 MBq/kg	60 minutes	Y
Casneuf et al. 2007 ⁶³	FDG	4 MBq/kg	60 minutes	Integrated
Tamm et al. 2007 ⁵³	-	-	-	-
Mehmet Ertuk et al. 2006 ⁶⁰	-	-	-	-
Heinrich et al. 2005 ⁶⁶	FDG	350 to 450 MBq	60 minutes	Integrated
Agarwal et al. 2004 ⁵⁴	-	-	-	-
DeWitt et al. 2004 ⁵⁰	-	-	-	-
Lemke et al. 2004 ⁶⁷	FDG	5 MBq/kg	60 to 90 minutes	NR
Soriano et al. 2004 ⁶⁹	-	-	-	-
Rieber et al. 2000 ⁶¹	-	-	-	-

Table C-12. Comparative accuracy data for tests of interest in included studies

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Fang et al. 2012 ⁴³	Resectability without staging	MDCT angiography without 3D reconstruction	MDCT angiography with 3D reconstruction	89.5% (17/19)	78.9% (30/38)	100% (19/19)	100% (38/38)	Yes	Unresectability defined as a positive
Tamm et al. 2007 ⁵³	Diagnosis	MDCT	EUS-FNA	97% (96/99)	72.2% (13/18)	82.8% (82/99)	94.4% (17/18)	No	For MDCT, the test results are based on a consensus of 3 independent readers. The study also reported results for EUS (tp=98, fp=9, fn=1, tn=9) and stated "to fairly compare EUS with MDCT, we scored only the EUS-FNA biopsy results for the first endoscopic procedure performed at our institution."
Agarwal et al. 2004 ⁵⁴	Diagnosis	MDCT	EUS-FNA	74.6% (53/71)	70% (7/10)	88.7% (63/71)	100% (10/10)	Yes	MDCT values are based on studies' Spiral CT-1 results - "probable" masses counted as negative
Agarwal et al. 2004 ⁵⁴	Diagnosis	MDCT	EUS-FNA	85.9% (61/71)	40% (4/10)	88.7% (63/71)	100% (10/10)	Yes	MDCT values are based on studies' Spiral CT-2 results - "probable" masses counted as positive

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
DeWitt et al. 2004 ⁵⁰	Diagnosis	MDCT	EUS-FNA	86.3% (69/80)	62.5% (15/24)	97.5% (78/80)	62.5% (15/24)	Yes	After the two imaging tests, within 3 weeks a surgeon examined the patient and the imaging results to determine eligibility for resection. The 9 patients who were deemed by both tests to have a pancreatic mass but were later found to not have pancreatic cancer were all counted as false positives. Cross-classified data: Actual +, test 1+, test 2+: 68. Actual +, test 1+, test 2-: 1. Actual +, test 1-, test 2+: 10. Actual +, test 1-, test 2-: 1. Actual -, test 1-, test 2-: 15. Actual -, test 1-, test 2+: 0. Actual -, test 1+, test 2-: 0. Actual -, test 1+, test 2+: 9.
Koelblinger et al. 2011 ⁵⁸	Diagnosis	MDCT	MRI	97.7% (42/43)	96.2% (25/26)	97.7% (42/43)	92.3% (24/26)	Yes	These are data for reader 1. Extracted data included those with pancreatic adenocarcinoma (N=43) and those with normal pancreas (N=26).

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Koelblinger et al. 2011 ⁵⁸	Diagnosis	MDCT	MRI	93% (40/43)	96.2% (25/26)	95.3% (41/43)	96.2% (25/26)	Yes	These are data for reader 2. Extracted data included those with pancreatic adenocarcinoma (N=43) and those with normal pancreas (N=26).
Motosugi et al. 2011 ⁵⁷	Diagnosis	MDCT	MRI	94.4% (51/54)	97.8% (45/46)	96.3% (52/54)	97.8% (45/46)	Yes	Reviewer 1 results
Motosugi et al. 2011 ⁵⁷	Diagnosis	MDCT	MRI	96.3% (52/54)	97.8% (45/46)	98.1% (53/54)	97.8% (45/46)	Yes	Reviewer 2 results
Motosugi et al. 2011 ⁵⁷	Diagnosis	MDCT	MRI	96.3% (52/54)	97.8% (45/46)	98.1% (53/54)	97.8% (45/46)	Yes	Reviewer 3 results
Rao et al. 2011 ⁵⁵	Diagnosis	MDCT	MRI	84% (21/25)	94.1% (16/17)	87.5% (7/8)	50% (4/8)	Yes	These are the data for reader A. We considered adenocarcinomas and metastasis to be positives, whereas neuroendocrine tumors and solid papillary tumors and intrapancreatic accessory spleens to be negatives.
Rao et al. 2011 ⁵⁵	Diagnosis	MDCT	MRI	96% (24/25)	88.2% (15/17)	100% (8/8)	62.5% (5/8)	Yes	These are the data for reader B. We considered adenocarcinomas and metastasis to be positives, whereas neuroendocrine tumors and solid papillary tumors and intrapancreatic accessory spleens to be negatives.

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Takakura et al. 2011 ⁵⁶	Diagnosis	MDCT	MRI	81.8% (27/33)	88% (44/50)	78.8% (26/33)	88% (44/50)	No	Reported sensitivity and specificity were based on four readers; confidence intervals were calculated as if there had been four times as many patients as there actually were (i.e., the footnote to Table 2 indicates a denominator of 332 even though there were only 83 patients). Prevalence was 39%. We estimated counts for 83 patients based on reported prevalence and accuracy percentages
Kauhanen et al. 2009 ⁵⁹	Diagnosis	MDCT	MRI	85% (17/20)	66.7% (12/18)	85% (17/20)	72.2% (13/18)	Yes	-
Mehmet Ertuk et al. 2006 ⁶⁰	Diagnosis	MDCT	MRI	83.3% (20/24)	85.7% (18/21)	83.3% (20/24)	100% (21/21)	Yes	This is reader 1
Mehmet Ertuk et al. 2006 ⁶⁰	Diagnosis	MDCT	MRI	83.3% (20/24)	90.5% (19/21)	83.3% (20/24)	95.2% (20/21)	Yes	This is reader 2
Mehmet Ertuk et al. 2006 ⁶⁰	Diagnosis	MDCT	MRI	83.3% (20/24)	90.5% (19/21)	83.3% (20/24)	100% (21/21)	Yes	This is reader 3
Rieber et al. 2000 ⁶¹	Diagnosis	MDCT	MRI	100% (8/8)	75% (9/12)	87.5% (7/8)	75% (9/12)	Yes	-
Herrmann et al. 2012 ⁶⁴	Diagnosis	MDCT	PET/CT	88% (22/25)	0% (0/6)	96% (24/25)	16.7% (1/6)	Yes	-
Kauhanen et al. 2009 ⁵⁹	Diagnosis	MDCT	PET/CT	85% (17/20)	66.7% (12/18)	85% (17/20)	94.4% (17/18)	Yes	-
Saif et al. 2008 ⁶⁵	Diagnosis	MDCT	PET/CT	91.7% (11/12)	25% (1/4)	100% (11/11)	80% (4/5)	No	These data are per lesion, not per patient

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Casneuf et al. 2007 ⁶³	Diagnosis	MDCT	PET/CT	87.5% (21/24)	90% (9/10)	91.7% (22/24)	90% (9/10)	No	Lymph node accuracy data excluded because results not provided for PET/CT. The text conflicted with the table; our extraction is the numbers provided in the text. Table 3a stated that the sensitivity of CT was 92.0%, whereas the text implied 87.5%. Table 3a stated that the sensitivity of PET/CT was 84.0%, whereas the text implied 91.7%. Table 3a stated that the specificity of CT was 88.8%, whereas the text implied 90%. Table 3a stated that the sensitivity of PET/CT was 88.8%, whereas the text implied 90%. Lesions-by-lesion reporting was not extracted because authors did not report denominators for either MDCT or PET/CT.
Heinrich et al. 2005 ⁶⁶	Diagnosis	MDCT	PET/CT	93.5% (43/46)	23.1% (3/13)	89.1% (41/46)	69.2% (9/13)	Yes	Counts for contrast enhanced CT were based on reported sensitivity and specificity

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Lemke et al. 2004 ⁶⁷	Diagnosis	MDCT	PET/CT	76.6% (49/64)	63.9% (23/36)	89.1% (57/64)	63.9% (23/36)	No	PET and CT were fused for only 100 of 104 patients, and the data are based only on these 100 patients
Schick et al. 2008 ⁵¹	Diagnosis	EUS-FNA	PET/CT	80.8% (21/26)	84.2% (16/19)	88.9% (24/27)	73.7% (14/19)	Yes	One patient did not receive EUS-FNA because other tests made the diagnosis obvious.
Kauhanen et al. 2009 ⁵⁹	Diagnosis	MRI	PET/CT	85% (17/20)	72.2% (13/18)	85% (17/20)	94.4% (17/18)	Yes	–
DeWitt et al. 2004 ⁵⁰	Resectability without staging	MDCT	EUS-FNA	64% (18/28)	92% (23/25)	68% (19/28)	88% (22/25)	Yes	This only includes the 53 patients with pancreatic cancer who had surgery. In the data to the left, true unresectability is a "positive," and true resectability is a "negative."
Koelblinger et al. 2011 ⁵⁸	Resectability without staging	MDCT	MRI	75% (6/8)	86.7% (13/15)	75% (6/8)	93.3% (14/15)	Yes	These are data for reader 1. Extracted data included those with pancreatic adenocarcinoma who underwent surgery (N=23). Table 4 in the article reports a resectable case as a positive, but we extracted a resectable as a negative to be consistent in evidence tables.

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Koelbinger et al. 2011 ⁵⁸	Resectability without staging	MDCT	MRI	62.5% (5/8)	86.7% (13/15)	50% (4/8)	93.3% (14/15)	Yes	These are data for reader 2. Extracted data included those with pancreatic adenocarcinoma who underwent surgery (N=23). Table 4 in the article reports a resectable case as a positive, but we extracted a resectable as a negative to be consistent in evidence tables.
Lee et al. 2010 ⁶²	Resectability without staging	MDCT	MRI	64.7% (11/17)	89.7% (35/39)	41.2% (7/17)	89.7% (35/39)	Yes	These are the data for reader 1.
Lee et al. 2010 ⁶²	Resectability without staging	MDCT	MRI	58.8% (10/17)	89.7% (35/39)	29.4% (5/17)	89.7% (35/39)	Yes	These are the data for reader 2
DeWitt et al. 2004 ⁵⁰	T staging	MDCT	EUS-FNA	Accurate T stage in 41% (20/49); overstaged T in 14% (7/49), understaged T in 44% (22/49)	See the cell to the left	Accurate T stage in 67% (33/49); overstaged T in 18% (9/49), understaged T in 14% (7/49)	See the cell to the left	Yes	–
Tellez-Avila et al. 2012 ⁶⁸	Vessel involvement	MDCT	EUS-FNA	55.6% (10/18)	93.8% (30/32)	61.1% (11/18)	90.6% (29/32)	No	Arteries or veins. Reported cross-classified results in text contained inconsistencies therefore were not extracted
Tellez-Avila et al. 2012 ⁶⁸	Vessel involvement	MDCT	EUS-FNA	66.7% (6/9)	90.2% (37/41)	66.7% (6/9)	100% (41/41)	No	Arteries only

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Tellez-Avila et al. 2012 ⁶⁸	Vessel involvement	MDCT	EUS-FNA	30% (3/10)	89.7% (35/39)	80% (8/10)	87.5% (35/40)	No	Veins only. Text said 11 positives, but the percentages in Table 3 imply 10 positives
Soriano et al. 2004 ⁶⁹	T staging	MDCT	MRI	MDCT of 59 patients provided an accurate T stage in 73% (CI 62% to 84%), overstaging in 2% (CI 0%-6%), and understaging in 25% (CI 14%-36%).	See the cell to the left	MRI of 53 patients provided an accurate T stage in 62% (CI 49% to 75%), overstaging in 6% (CI 0%-12%), and understaging in 32% (CI 19%-45%).	See the cell to the left	Yes	Authors did not report how CIS were calculated, but their intervals are similar to those obtained using method 3 of Newcombe et al. 1998. ¹⁷⁰
Soriano et al. 2004 ⁶⁹	N staging	MDCT	MRI	37.5% (9/24)	79.4% (27/34)	15% (3/20)	93.3% (28/30)	Yes	Counts determined based on reported information in Table 2 of the article

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Holzapfel et al. 2011 ⁷⁰	M staging	MDCT	MRI	53.3% (8/15)	81% (17/21)	86.7% (13/15)	95.5% (42/44)	Yes	Data are per lesion. There were 15 positive metastases in the liver (7 patients), so the denominator for sensitivity was 15 for both tests. However, for specificity, the two tests had different denominators. MDCT specificity data involve a denominator of 21 "no metastasis," whereas MRI specificity data involve a denominator of 44 "benign lesions" (see Tables 1 and 2 of the article).
Motosugi et al. 2011 ⁵⁷	M staging	MDCT	MRI	60% (9/15)	94.9% (37/39)	73.3% (11/15)	94.9% (37/39)	Yes	Reviewer 1 results
Motosugi et al. 2011 ⁵⁷	M staging	MDCT	MRI	60% (9/15)	97.4% (38/39)	86.7% (13/15)	100% (39/39)	Yes	Reviewer 2 results
Motosugi et al. 2011 ⁵⁷	M staging	MDCT	MRI	60% (9/15)	97.4% (38/39)	86.7% (13/15)	100% (39/39)	Yes	Reviewer 3 results
Imai et al. 2010 ⁷¹	M staging	MDCT	MRI	0% (0/6)	79.4% (50/63)	0% (0/6)	96.8% (61/63)	Yes	Determination of para aortic lymph node metastasis
Kauhanen et al. 2009 ⁵⁹	M staging	MDCT	MRI	57.1% (4/7)	85.7% (6/7)	57.1% (4/7)	85.7% (6/7)	Yes	–
Soriano et al. 2004 ⁶⁹	M staging	MDCT	MRI	54.5% (6/11)	95.8% (46/48)	30% (3/10)	95.3% (41/43)	Yes	Counts determined based on reported information in Table 2 of the article

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Soriano et al. 2004 ⁶⁹	Precise staging	MDCT	MRI	MDCT of 59 patients provided an accurate TNM stage in 46% (CI 33% to 59%), overstaging in 8% (CI 1%-15%), and understaging in 46% (CI 33%-59%).	See the cell to the left	MRI of 53 patients provided an accurate TNM stage in 36% (CI 23% to 49%), overstaging in 7% (CI 0%-14%), and understaging in 57% (CI 44%-70%).	See the cell to the left	Yes	Authors did not report how CIS were calculated, but their intervals are similar to those obtained using method 3 of Newcombe et al. 1998. ¹⁷⁰
Koelblinger et al. 2011 ⁵⁸	Vessel involvement	MDCT	MRI	90% (9/10)	97.5% (119/122)	80% (8/10)	95.9% (117/122)	Yes	These are data for reader 1. Extracted data included those who had surgical reference standard (22 patients, 132 vessels)
Koelblinger et al. 2011 ⁵⁸	Vessel involvement	MDCT	MRI	70% (7/10)	98.4% (120/122)	50% (5/10)	98.4% (120/122)	Yes	These are data for reader 2. Extracted data included those who had surgical reference standard (22 patients, 132 vessels)
Lee et al. 2010 ⁶²	Vessel involvement	MDCT	MRI	60.7% (17/28)	96.4% (187/194)	57.1% (16/28)	97.9% (190/194)	Yes	These are the data for reader 1. The totals include 222 major vessels assessed during surgery among 47 patients out of 56 patients total

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Lee et al. 2010 ⁶²	Vessel involvement	MDCT	MRI	64.3% (18/28)	94.3% (183/194)	57.1% (16/28)	99% (192/194)	Yes	These are the data for reader 2. The totals include 222 major vessels assessed during surgery among 47 patients out of 56 patients total
Soriano et al. 2004 ⁶⁹	Vessel involvement	MDCT	MRI	66.7% (16/24)	94.3% (33/35)	59.1% (13/22)	83.9% (26/31)	Yes	Counts determined based on reported information in Table 2 of the article
Soriano et al. 2004 ⁶⁹	Resectability after staging	MDCT	MRI	66.7% (18/27)	96.9% (31/32)	56.5% (13/23)	90% (27/30)	Yes	Authors reported data defining unresectable as a negative, but we recorded data with unresectable as a positive. Precise counts not determinable because not all patients received either test (59 received CT and 53 received MRI).
Lemke et al. 2004 ⁶⁷	N staging	MDCT	PET/CT	25.8% (8/31)	75% (12/16)	32.3% (10/31)	75% (12/16)	No	Only based on those with complete histologic analysis (47 of 104 patients)
Kauhanen et al. 2009 ⁵⁹	M staging	MDCT	PET/CT	57.1% (4/7)	85.7% (6/7)	85.7% (6/7)	100% (7/7)	Yes	–
Farma et al. 2008 ⁷²	M staging	MDCT	PET/CT	56.5% (13/23)	91.5% (54/59)	60.9% (14/23)	100% (59/59)	Yes	Counts calculated based on Table 4 of the article

Table C-12. Comparative accuracy data for tests of interest in included studies (continued)

Study	Clinical Purpose	Test 1 Name	Test 2 Name	Test 1 Sensitivity	Test 1 Specificity	Test 2 Sensitivity	Test 2 Specificity	No Internal Discrepancies in Reported Data?	Comments
Shami et al. 2011 ⁷³	Precise staging	EUS-FNA	MRI	EUS-FNA resulted in an accurate stage for 34/48 patients who had undergone surgical exploration.	See the cell to the left	MRI resulted in an accurate stage for 36/48 patients who had undergone surgical exploration.	See the cell to the left	Yes	EUS-FNA understaged 13/48, and overstaged 1/48. Of the 34 correctly staged, 34 were stage 2 and below, and 0 was stage 3 or above. MRI understaged 12/48, and overstaged 0/48. Of the 36 correctly staged, 35 were stage 2 and below, and 1 was stage 3 or above.
Kauhanen et al. 2009 ⁵⁹	M staging	MRI	PET/CT	57.1% (4/7)	85.7% (6/7)	85.7% (6/7)	100% (7/7)	Yes	

Harms Studies

Table C-13. General information in pancreas-specific studies included for harms data

Study	Country	Names of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Bang et al. 2013 ⁹⁴	USA	University of Alabama at Birmingham	October 2011 to November 2011	Prospective	One author was a consultant for Boston Scientific Corporation which was the manufacturer for the needles used, however the study compared techniques rather than needles. No statement about conflicts of interest.
Hayashi et al. 2013 ¹³¹	Japan	Hokkaido University Hospital	January 2006 to August 2009, or September 2009 to April 2011	Prospective	"The authors do not have any interests to disclose"

Table C-13. General information in pancreas-specific studies included for harms data (continued)

Study	Country	Names of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Ikezawa et al. 2012 ¹⁰⁴	Japan	Osaka Medical Center for Cancer and Cardiovascular Diseases	April 2006 to March 2009	Retrospective	"The authors declare that they have no conflicts of interest"
Ootaki et al. 2012 ¹³²	USA	Cleveland Clinic	January 2007 to December 2009	Retrospective	Support was provided solely from institutional and/or departmental sources. One doctor is a consultant for Olympus America
Ranney et al. 2012 ⁹⁵	USA	Tertiary referral center - University of Alabama at Birmingham	January 2006 to December 2010	Retrospective	One author is a consultant for Boston scientific and Olympus medical systems
Siddiqui et al. 2012 ¹⁰⁵	Lebanon	Division of Gastroenterology, American University of Beirut	June 2000 to March 2011	Retrospective	Funded by Thomas Jefferson University Hospital. "The authors attest that they have no commercial associations (e.g. equity ownership or interest, consultancy, patent and licensing agreement, or institutional and corporate association(s) that might be a conflict of interest in relation to the submitted manuscript."
Attila et al. 2011 ⁹⁶	USA	Oregon Health and Science University	March 1998 to March 2007	Retrospective	NR
Beane et al. 2011 ¹⁰⁶	USA	Indiana University School of Medicine	January 2002 to May 2009	Retrospective	NR
Choi et al. 2011 ⁹³	South Korea	Samsung Medical Center	July 2009 to December 2009	Prospective	NR
Fabbri et al. 2011 ⁷⁴	Italy	Unit of Gastroenterology and Digestive Endoscopy, AUSL Bologna Bellaria-Maggiore Hospital, Bologna, Italy	September 2007 to December 2008	Prospective	NR
Fisher et al. 2011 ¹¹⁹	USA	Dartmouth-Hitchcock Medical Center	Since 1998	Retrospective	"The authors did not receive funding for this work"
Iglesias-Garcia et al. 2011 ¹¹⁸	Spain	University Hospital of Santiago de Compostela	NR	Retrospective	"Financial support: None." "Potential competing interests: None."
Itoi et al. 2011 ¹³³	Japan	Tokyo Medical University	July 2002 to September 2010	Retrospective	NR

Table C-13. General information in pancreas-specific studies included for harms data (continued)

Study	Country	Names of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Kopelman et al. 2011 ¹⁰⁷	Israel	Hillel-Yaffe Medical Centre, Hadera	NR	Prospective	NR
Kubiliun et al. 2011 ⁹⁷	USA	University of Miami,	January 2009 through December 2010	Prospective	NR
Reddymasu et al. 2011 ¹⁰²	USA	Kansas University Medical Center	January 2002 to December 2008	Retrospective	"Conflict of interest: None"
Carrara et al. 2010 ⁷⁵	Italy	Division of Gastroenterology & Gastrointestinal Endoscopy, Vita-Salute San Raffaele University	2005 to 2008	Retrospective	NR
Kliment et al. 2010 ¹²⁷	Czech Republic	Non-university tertiary referral center, likely CGB Laboratory in Ostrava	January 1 2007 to August 31 2007	Prospective	"The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper."
Song et al. 2010 ¹⁷¹	Korea	University of Ulsan College of Medicine, Asan Medical Center,	March 2007 to April 2008	Prospective	NR
Chang et al. 2009 ¹²¹	South Korea	Asan Medical Center	January 2007 to December 2007	Retrospective	NR
Fisher et al. 2009 ¹⁰⁸	Australia	Sir Charles Gairdner Hospital	March 2003 to November 2006	Prospective	NR
Hikichi et al. 2009 ^{92,172}	Japan	Fukushima Medical University Hospital	September 2001 to October 2005	Retrospective	NR
Siddiqui et al. 2009 ⁹⁸	USA	Tertiary Referral Centers at Yale University School of Medicine, New Haven, Connecticut and Virginia Piper Cancer Institute, Minneapolis, MN	February 2007 to June 2008	Prospective	NR
Yusuf et al. 2009 ¹²⁰	USA	SUNY Downstate Medical Center	February 2001 to June 2007	Retrospective	"Competing interest: None"
Zamboni et al. 2009 ¹²⁹	Italy	University Hospital Rossi	January 2004 to June 2008	Retrospective	NR
Al-Haddad et al. 2008 ¹³⁰	USA	Mayo Clinic College of Medicine in Jacksonville FL	March 2005 to March 2006.	Prospective	NR

Table C-13. General information in pancreas-specific studies included for harms data (continued)

Study	Country	Names of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Ramirez-Luna et al. 2008 ⁹⁹	Mexico	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán.	March 2005 to March 2006.	Retrospective	NR
Shah et al. 2008 ¹²⁸	USA	University of Miami Hospital and Clinics	March 2004 to April 2007	Retrospective	NR
Eloubeidi et al. 2007 ^{109,122-126}	USA	University of Alabama at Birmingham	July 2000 to December 2005	Prospective	NR
Rocca et al. 2007 ¹³⁴	Italy	Molinette Hospital and ASO Ordine Mauriziano	October 2001 to March 2006	Prospective	"Conflict of interest statement: None declared." Partly supported by a grant from Fondazione IBD Inlus
Bournet et al. 2006 ¹¹¹	France	University affiliated tertiary care referral center	October 2001 to September 2004	Prospective	NR
Mahnke et al. 2006 ¹¹⁰	USA	Anschutz Outpatient Pavilion of University of Colorado Hospital's Centers for Advanced Medicine	March 2003 to February 2004	Prospective	Research and Educational grants and honorarium from Olympus American (One Dr.)
Wittmann et al. 2006 ¹⁰⁰	United Kingdom	University College London Medical School	May 2002 to April 2005	Prospective	NR
Mortensen et al. 2005 ¹¹²	Denmark	Center for Surgical Ultrasound at Department of Surgical Gastroenterology, Odense University Hospital	December 1991 to December 2002 (complications assessment); 2000 to 2002 (patient tolerability assessment)	Prospective	NR
Ryozawa et al. 2005 ¹⁰¹	Japan	Yamaguchi University Hospital and 8 other hospitals in Japan	July 2000 to March 2003	Retrospective	NR
Eloubeidi et al. 2004 ⁷⁶	USA	Multicenter (27 programs of which 19 returned completed datasheet)	Survey of mean 4 years (range 11 months to 9 years) in 19 centers – no dates given (paper published in 2004)	Largely retrospective but had two prospective cohorts in subgroup analysis	NR
Gress et al. 2002 ¹¹³	USA	Winthrop University Hospital	NR	Prospective	NR

Table C-13. General information in pancreas-specific studies included for harms data (continued)

Study	Country	Names of Clinic(s)	Range of Dates When Patients Received Imaging Tests	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest
Harewood et al. 2002 ¹¹⁴	USA	Mayo Clinic, Rochester NY and St Vincent's Hospital in Indianapolis IN	1994 to 1999	Prospective	NR
Fritscher-Ravens et al. 2001 ¹⁰³	Germany	NR	NR	Prospective	NR
Gress et al. 2001 ¹¹⁶	USA	Indiana University Medical Center	August 1992 to December 1996	Prospective	NR
O'Toole et al. 2001 ¹¹⁵	France	Two centers	January 1998 to October 1999	Retrospective	NR
Voss et al. 2000 ¹¹⁷	France	Beaujon Hospital	January 1995 to March 1998	Retrospective	NR
Sakamoto et al. 2008 ⁷⁹	Japan	Kink University	March 2002 to August 2006	Prospective	Supported by the Japan Society for Promotion of Science, Research and Development Committee Program, the Japan Research Foundation for Clinical Pharmacology, and the Japanese Foundation for Research and Promotion of Endoscopy
Agarwal et al. 2004 ⁵⁴	USA	MD Anderson Cancer Center	November 2000 to November 2001	Retrospective	NR

NR=Not reported

Table C-14. Patient characteristics in pancreas-specific studies included for harms data

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Bang et al. 2013 ⁹⁴	Solid noncystic pancreatic lesion referred for EUS-FNA, had not undergone EUS-FNA at other facilities	54	52% (28/54)	63.8 (range 30–88)	36 Pancreatic head/uncinate cancer, 18 pancreatic body/tail cancer	–
Hayashi et al. 2013 ¹³¹	Had EUS-FNA, dynamic CT discovered a representative finding of pancreatic ductal adenocarcinoma, no EUS-FNA performed previously	138	55% (76/138)	66.9	112 pancreatic ductal adenocarcinoma, 3 neuroendocrine carcinoma, 2 serious cystic neoplasm, 1 solid pseudopapillary neoplasm, 1 intraductal papillary mucinous adenoma, 1 metastasis from gastric carcinoma, 5 autoimmune pancreatitis, 5 alcoholic chronic pancreatitis, 8 unknown disease	Age was calculated by the EPC based on a weighted average of the age data reported in Table 1 of the article.
Ikezawa et al. 2012 ¹⁰⁴	Had pancreatic adenocarcinoma confirmed by histologic and/or cytological findings obtained by either ERCP or EUS-FNA, did not have carcinomatous peritonitis or had follow-up less than 30 days	56	38% (21/56)	64.2	NR	–
Ootaki et al. 2012 ¹³²	Patients who presented with solid pancreatic lesions based on previous imaging studies and patients found to have a pancreatic mass undetected on previous imaging studies were included.	371	48% (177/371)	general Anesthesia group: 63 (SD 14); conscious sedation group: 66 (SD 12)	279 patients successfully diagnosed (specifics not provided), 92 patients had failed diagnoses (specifics not provided)	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Ranney et al. 2012 ⁹⁵	consecutive patients with obstructive jaundice secondary to solid pancreatic mass lesions who underwent EUS-FNA over a 5-year period	214	36% (77/214)	Patients with stents: Median 68 (58–75); Patients no stents: Median 69 (63–78)	Patients with stents: 106 pancreatic cancer, 15 chronic pancreatitis, 22 neuroendocrine or metastatic cancer, 7 indeterminate/atypical. Patients with no stents: 49 pancreatic cancer, 2 chronic pancreatitis, 9 other cancer, 4 indeterminate/atypical	–
Siddiqui et al. 2012 ¹⁰⁵	Obstructive jaundice and a solid pancreatic head or uncinata mass found on either 1) transabdominal ultrasound 2) CT or 3) MRI and were in the institution's endoscopy database, and had ERCP whose brush cytology was pathologically interpreted as non-diagnostic or negative for malignancy, and underwent EUS-FNA for diagnosis, and had a biliary stent.	677	49% (332/677)	65.9 (range 41–87)	589 adenocarcinoma, 14 neuroendocrine tumor, 4 lymphoma, 13 metastasis, 57 benign	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Attila et al. 2011 ⁹⁶	Patients 80 years of age or older	232	60% (140/232)	83.8 (SD 1.4, 80–97)	19 AdenoCA, 2 suspicious for malignancy, 1 renal cell carcinoma, 10 negative for malignancy, 1 neuroendocrine, 2 reactive changes, 1 mucinous adenocCA, 1 mucinous neoplasm with dysplastic features	232 represents the entire patient population, but Only 60 patients were evaluated for by EUS-FNA for pancreatic mass lesions. Final diagnoses column represents n=60 for pancreatic mass lesions. Other indications for EUS-FNA evaluation were pancreatic cystic lesions, dilated CBD in the setting of jaundice and/or stricture, evaluation of mediastinal lesions - final diagnoses for these indications are not included in the column.
Beane et al. 2011 ¹⁰⁶	Underwent EUS-FNA for any indication (210 of 483 were for either pancreatic cyst or pancreatic mass), informed consent, platelet count >50000/nL, hemoglobin >8 g/dL, international normalized ratio less than or equal to 1.5 28 days prior to EUS-FNA, medically stable to have moderate sedation	483	44% (212/483)	NR	NR	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Choi et al. 2011 ⁹³	Underwent EUS-FNA for suspected pancreatic malignancy	58	43% (25/58)	59	36 pancreas cancer, 3 malignant IPMN, 2 cholangiocarcinoma, 1 lymphoma, 1 AoV cancer, 1 metastasis, 3 benign serous cystadenoma, 3 benign simple cyst, 2 benign IPMN, 1 benign desmoid tumor, 1 benign GIST, 1 benign inflammation, 1 benign granuloma, 1 benign fibroadipose tissue, 1 benign neuroendocrine tumor	–
Fabbri et al. 2011 ⁷⁴	Diagnosed or suspected solid pancreatobiliary lesions according to clinical evaluation and CT scan.	50	40% (20/50)	68.2 (SD: 7.4 years)	Cytologic diagnosis positive for malignancy found in 40 cases with 25 gauge needle and in 34 cases with 22 gauge needle. Aspirate suspicious for malignancy found in 4 cases with 24 gauge needle and in 6 cases with 22 gauge needle. Final cytologic diagnosis was primary pancreatic adenocarcinoma in 45 (90%) lesions, neuroendocrine in 1 (2%) and 2 inflammatory pseudotumoral masses.	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Fisher et al. 2011 ¹¹⁹	Age 18+, referred for EUS-FNA at this institution for evaluation of pancreatic head or neck masses, had pancreatic adenocarcinoma, nonadenocarcinomas, no body or tail adenocarcinomas	170	55% (94/170)	68.2	170 pancreatic adenocarcinoma of head or neck	–
Iglesias-Garcia et al. 2011 ¹¹⁸	Underwent EUS-FNA of solid pancreatic mass over a two-year period. No EUS-FNAs performed previously	182	40% (73/182)	60.5	115 pancreatic adenocarcinoma, 40 inflammatory mass, 11 neuroendocrine tumor, 8 serous cystadenoma with solid appearance, 4 metastasis, 2 cystadenoma with solid appearance, 1 lymphoma, 1 teratoma	Age is a weighted average based on reported information
Itoi et al. 2011 ¹³³	Underwent EUS-FNA and had pancreatic solid mass	356	42% (151/356)	68.2 (range 34–86)	266 pancreatic cancer, 6 endocrine tumor, 7 serous cystadenoma, 3 renal cell carcinoma, 1 lung cancer, 1 solid pseudopapillary neoplasm, 1 shwanoma, 1 malignant lymphoma, 1 desmoid tumor, 54 mass-forming pancreatitis, 15 autoimmune pancreatitis	–
Kopelman et al. 2011 ¹⁰⁷	Underwent EUS-FNA for suspected pancreatic solid lesion, no coagulopathy	102	40% (41/102)	65	50 adenocarcinoma, 8 neuroendocrine tumors, 8 mucinous tumors, 36 benign pancreatic disease	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Kubiliun et al. 2011 ⁹⁷	All patients undergoing EUS-FNA for the evaluation of solid pancreatic masses	69	48% (33/69)	65 (38–88)	Pancreatic adenocarcinoma	Started with 206 patients but they only used people with nondiag path for whom FISH was performed)
Reddymasu et al. 2011 ¹⁰²	Underwent upper abdominal EUS for a pancreas-related indication at this institution, no previous diagnosis of pancreatic cancer, no obvious neoplastic lesion on transabdominal imaging	326	66% (216/326)	57 (range 17–93)	22 pancreatic head adenocarcinoma, 4 pancreatic body adenocarcinoma, 1 pancreatic neck adenocarcinoma, 3 ampullary adenocarcinoma, 3 other pancreaticobiliary malignancy, 56 chronic pancreatitis, 223 benign	–
Carrara et al. 2010 ⁷⁵	Patients with complications related to EUS-FNA of solid and cystic pancreatic lesions done in the tertiary care university hospital.	1034	NR	NR	NR	–
Kliment et al. 2010 ¹²⁷	Suspected pancreatic cancer diagnoses as a solid mass on CT or MRI or abdominal ultrasound or as a double duct sign on ERCP, and had a solid pancreatic mass detected by EUS. Age ≥18, ability to give informed consent, no high risk for bleeding after EUS-FNA, no large diameter vessel interposed between the needle tip and pancreatic mass.	207	42% (86/207)	62.2 (range 33–89)	155 adenocarcinoma, 4 neuroendocrine tumor, 3 other neoplasia, 1 paraganglioma, 44 benign	–
Song et al. 2010 ¹⁷¹	125 consecutive patients with solid pancreatic/peripancreatic mass	115	48% (55/115)	57.68±11.93 years	Adeno, neuroendocrine, cholangio (bile duct), lymphoma, mets, leiomyosarc	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Chang et al. 2009 ¹²¹	Underwent EUS-FNA for pancreatic and peripancreatic lesions, not pancreatic cystic lesion, had adequate follow-up to determine the final nature of the lesion (authors did not define adequacy)	139	46% (64/139)	57 (range 13–85)	88 pancreatic adenocarcinoma, 2 pancreatic neuroendocrine tumor, 8 solid pseudopapillary tumor, 6 pancreatic metastasis, 3 lymphoma, 6 GIST, 1 malignant rhaboid tumor, 2 metastatic stomach cancer or MUO, 1 adrenal metastasis, 1 pheochromocytoma, 1 undifferentiated sarcomatoid cancer	–
Fisher et al. 2009 ¹⁰⁸	Had EUS-FNA, solid pancreatic lesion(s) (7 patients had 2 lesions, the other 86 had 1 lesion)	93	42% (39/93)	60.6 (range 15–83)	By lesion (N=100): 70 adenocarcinoma, 10 neuroendocrine, 3 lymphoma, 4 other malignancies, 13 benign	–
Hikichi et al. 2009 ^{92,172}	Had EUS-FNA for pancreatic mass and had final diagnoses and had given informed consent	73	33% (24/73)	62	50 ductal adenocarcinoma, 2 malignant endocrine carcinoma, 2 malignant lymphoma, 1 acinar cell carcinoma, 1 carcoma, 1 metastatic tumor, 10 chronic pancreatitis, 5 autoimmune pancreatitis, 1 benign endocrine tumor	Overall age was calculated based on Table 1 of the article.
Siddiqui et al. 2009 ⁹⁸	Suspected pancreatic mass	133	37% (49/133)	70.4	110 adenocarcinoma, 4 neuroendocrine tumor, 1 pseudopapillary tumor, 5 metastatic malignancy, 2 negative, 9 suspicious and/or atypical	

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Yusuf et al. 2009 ¹²⁰	Underwent EUS-FNA of pancreatic masses using either 22-gauge or 25-gauge needle at this institution	842	44% (370/842)	66.4	314 adenocarcinoma, 272 negative for malignancy, 79 atypical/inconclusive, 36 blood/nondiagnostic, 23 mucinous neoplasm, 20 Hypocellular/acellular, 30 Neuroendocrine tumor, 14 Chronic pancreatitis, 6 Serous cystadenoma, 45 Other	Age calculated based on weighted average of those receiving 22-gauge or 25-gauge needles
Zamboni et al. 2009 ¹²⁹	Underwent EUS-FNA of pancreatic masses at this institution, already evaluated by CT^ or MRI or sonography and patient was referred for biopsy, platelet count at least 50,000/mL, informed consent	545	48% (262/545)	62 (range 25–86)	422 pancreatic adenocarcinoma, 22 neuroendocrine tumor, 18 atypia, 13 pancreatitis, 5 neoplasm undefinable origin, 2 neoplasm with massive necrosis, 4 lymphoma, 2 pseudopapillary tumor, 36 nondiagnostic, 18 normal parenchyma, 1 pseudocyst	–
Al-Haddad et al. 2008 ¹³⁰	If clinical suspicion of pancreatic cancer was based on: obstructive jaundice with biliary stricture seen on ERCP (n=47), suspected pancreatic mass on CT (n=19), and two or more episodes of acute pancreatitis in 6 months without predisposing factors (n=15)	81	51% (41/81)	66.4 (SD 10.5)	71 malignant and 10 benign	of the 71 malignant tumors: 58 were located in the pancreatic head, five in the uncinate process, and eight in the neck, body or tail of the pancreas)

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Ramirez-Luna et al. 2008 ⁹⁹	patients with clinical, biochemical and/or radiological suspicion (Ultrasound, CT, MRI) of a pancreatic lesion that underwent EUS	53	83% (44/53)	61 (17–87)	Adeno, cystadeno, IPMN, neuroendocrine, NHL, renal mets	–
Shah et al. 2008 ¹²⁸	Patients had a prior imaging study demonstrating a pancreatic mass or clinical and radiological data suggested the presence of a pancreatic tumor; procedures involving solid pancreatic lesions only were selected for this review	72	43% (31/72)	65.9 (SD: 12.3; 27–94)	Pathological diagnosis: 62 (86.1%) malignant pancreatic masses (35 died pancreatic cancer, 17 alive and surgical confirmation, 10 progression of disease); 10 (13.9%) benign pancreatic masses (5 no progression, 5 underwent surgery). Location of Mass: 58 (80.6%) head/uncinate; 14 (19.4%) neck/body/tail	Study compared EUS-FNA to EUS-FNA+TCB; data for this study is only from the EUS-FNA group
Eloubeidi et al. 2007 ^{109,122-126}	Had EUS-FNA, suspected pancreatic cancer, informed consent, no abnormal coagulation profile	547	40% (NR)	64	73% pancreatic adenocarcinoma, 7.3% other lesions, 19% pancreatitis, 1% indeterminate	–
Rocca et al. 2007 ¹³⁴	Received EUS-FNA at one of two units, pathological imaging of pancreas or periampullary region, suspicious for pancreatic cancer	293	47% (138/293)	65.9 (range 58.6–73.6)	193 malignant, 100 benign (other details not reported)	–
Bournet et al. 2006 ¹¹¹	patients undergoing interventional EUS	224	45% (101/224)	61 (SD 10.7), Range 25–81	NR	–
Mahnke et al. 2006 ¹¹⁰	patients undergoing ERCP and/or EUS at the center	160	NR separately for EUS-FNA group	NR separately for EUS-FNA group	NR	Study compared ERCP to EUS with and without FNA; only EUS-FNA data reported.

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Wittmann et al. 2006 ¹⁰⁰	Underwent EUS-guided tissue sampling, had inconclusive diagnosis after previous percutaneous biopsy OR easier or safer access to the lesion using EUS OR small lesion size precluding percutaneous biopsy, lesions <2 cm only received FNA whereas lesions 2cm+ received both FNA and trucut biopsy	159	45% (71/159)	61	83 pancreas lesions, 55 mediastinum, 9 esophagus, 7 stomach, 2 rectum, 1 hepatic hilum, 1 hypopharynx, 1 duodenum (data were reported specifically for the 83 pancreas lesions)	–
Mortensen et al. 2005 ¹¹²	all patients who had undergone EUS and registered Prospectively	670	NR separately for EUS-FNA group	NR	369 of 670 malignant; 301 benign	*EUS-FNA was performed in 670 of 3324 EUS assessments
Ryozawa et al. 2005 ¹⁰¹	Pancreatic lesions or parapancreatic disease and underwent EUS-FNA one of the study institutions	52	29% (15/52)	62.5 (range 33–85)	29 pancreatic ductal adenocarcinoma, 2 acinar cell carcinoma, 1 bile duct cancer, 8 chronic pancreatitis, 10 benign pancreatic cyst, 2 pancreatic abscess	–
Eloubeidi et al. 2004 ⁷⁶	List of centers in the US that offer training in EUS contacted by email to EUS program director with invitation to participate. Requested information included total number EUS-FNAs of solid pancreatic masses performed, duration of time over which these procedures were performed and whether any case of acute pancreatitis.	27 programs contacted – 19 programs (70%) returned completed data sheet	NA	NA	Patient specific information not provided – rather self-reported episode of acute pancreatitis at EUS training centers with measure of severity.	–

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Gress et al. 2002 ¹¹³	Referred for EUS-FNA at this institution, provided informed consent	100	44% (44/100)	64.2	83 pancreas head mass, 14 pancreas body mass, 3 pancreas tail mass	Mean age calculated based on a weighted average of men's and women's average age
Harewood et al. 2002 ¹¹⁴	Known or suspected solid pancreatic mass, seen at one of two institutions, informed consent, biopsy requested by referring physician	185	34% (63/185)	65.2	155 adenocarcinoma, 7 neuroendocrine, 2 lymphoma, 20 chronic pancreatitis, 1 lipoma	–
Fritscher-Ravens et al. 2001 ¹⁰³	Patients with focal pancreatic masses detected on CT	114	NR	NR	112 patients with adequate material obtained from EUS-FNA: 65 primary pancreatic malignancy, 12 metastatic tumor, 35 benign lesion	–
Gress et al. 2001 ¹¹⁶	referred for further evaluation of suspected pancreatic cancer, had negative ERCP sampling and subsequently underwent CT-guided biopsy, patients with negative results on CT-guided biopsy who subsequently underwent ERCP with sampling, patients with negative results on CT-guided biopsy who did not have sampling at ERCP	102	43% (44/102)	Mean 63.6, Median 65	61 pancreatic cancer, 41 no pancreatic cancer	–
O'Toole et al. 2001 ¹¹⁵	Patients with suspected lesions involving or adjacent to upper or lower GI tract	322	47% (151/322)	59.5	NR	248/322 had pancreas investigation; data specific to pancreatic.

Table C-14. Patient characteristics in pancreas-specific studies included for harms data (continued)

Study	Patient Enrollment Criteria	Number of Patients Included	% Female	Age (Mean, Range)	Specific Final Diagnoses	Comments
Voss et al. 2000 ¹¹⁷	Underwent EUS-FNA for the diagnosis of solid pancreatic mass at this institution, did not have easily accessible metastases that could be biopsied more easily, not a purely cystic tumor or pseudocyst	99	NR	NR	59 pancreatic adenocarcinoma, 15 neuroendocrine tumor, 5 IPMN, 1 cystic and papillary tumor, 10 pancreatitis	–
Sakamoto et al. 2008 ⁷⁹	Suspected of having a pancreatic solid tumor due to abnormal screening findings on EUS or CT, informed consent	119	39% (47/119)	68.7	119 pancreatic carcinoma, 16 inflammatory pseudotumors, 19 endocrine tumors, 2 metastatic pancreatic tumor from renal cell carcinoma	Patient characteristics not reported specifically for the 98/156 who received EUS-FNA. Reported characteristics are for the 119/156 patients who had pancreatic ductal carcinoma.
Agarwal et al. 2004 ⁵⁴	Primary pancreatic neoplasm and underwent distal pancreatectomy, no previous pancreatic resection, no metastatic neoplasm, represented in the institution's database	179	64% (114/179)	61 (range 19–86)	57 adenocarcinoma, 42 cystic neoplasm, 14 serous, 28 mucinous, 33 IPMN, 34 endocrine neoplasm	The N of 179 includes only those who received EUS and FNA.

CT=Computed tomography; ERCP=endoscopic retrograde cholangiopancreatography; EUS=endoscopic ultrasound; EUS-FNA=Endoscopic ultrasound - fine needle aspiration; FISH=fluorescence in situ hybridization; GI=gastrointestinal; GIST=gastrointestinal stromal tumor; IPMN=intraductal papillary mucinous neoplasm; mL=milliliter; MRI=magnetic resonance imaging; NR=not reported; SD=standard deviation

Table C-15. Testing characteristics in pancreas-specific studies included for harms data

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Bang et al. 2013 ⁹⁴	EUS-FNA	Device: Olympus UCT140 Needle Type: Expect needle, Needle Size: 22G or 25G	25G via transduodenal route for head/uncinate lesions. 22G via transgastric route for body/tail lesions	54/54	1	NR	NR
Hayashi et al. 2013 ¹³¹	EUS-FNA	Device: GF-UCT240P-AL5 (Olympus) Needle Type: Echotip Needle Size: 22G	NR	138/138	2	NR	Endosonographers underwent extensive training for review of cytological smear alongside a pathologist (T.H.) during routine EUS-FNA for pancreatic lesion in period 1. Endosonographers were taught to identify normal pancreatic cells (ductal epithelium, acinar cell, and islet cell) in direct smear to easily detect atypical epithelial cells within abundant cell clusters.

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Ikezawa et al. 2012 ¹⁰⁴	EUS-FNA	Device: UCT2000 (Olympus) Needle Type: Echotip Needle Size: 22G or 25G	Transgastric approach in 26 patients, transduodenal in 29 patients, and small intestine after total gastrectomy in 1 patient	56/56	2	NR	NR
Ootaki et al. 2012 ¹³²	EUS-FNA	NR	NR	371/371	NR	NR	NR
Ranney et al. 2012 ⁹⁵	EUS-FNA	Device: UCT 140 (Olympus) Needle Type: Echotip Needle Size: 22G or 25G	NR	214/214	1	NR	NR
Siddiqui et al. 2012 ¹⁰⁵	EUS-FNA	Device: GF UCT 140 (Olympus) or UCT 160 (Olympus) Needle Type: Echotip Needle Size: 22G	Transduodenal approach	677/677	NR	Experienced faculty endoscopists who had performed greater than 500 EUS procedures	NR
Attila et al. 2011 ⁹⁶	EUS-FNA	Device: GF-UC140P AL5 (Olympus) and GF-UM160 (Olympus) or FG36UX (Pentax) Needle Type: Wilson Cook Needle Size: 19G or 22G	NR	95/95	NR	NR	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Device: GF-UC140P (Olympus) Needle Type: Echotip Ultra Needle Size: 19G, 22G, or 25G	NR	179/179	6 gastroenterologists	Extensive experience with pancreatic EUS	The number of passes per site, needle gauge, use of a stylet, and suction were left to the discretion of the endosonographer. Any procedure-related complications occurring after EUS-guided FNA were recorded independently.
Choi et al. 2011 ⁹³	EUS-FNA	Device: GF-UCT240P-AL5 (Olympus) Needle Type: Endocoil or Echotip Needle Size: 22G or 25G	NR	58/58	NR	NR	NR
Fabbri et al. 2011 ⁷⁴	EUS-FNA	Device: NR Needle Type: EchoTip Ultra with HDFNA (Cook Endoscopy) Needle Size: 19G, 22G, or 25G	140 cm long stainless steel needle within a spiral steel sheath surrounded by a Teflon cover. Prospective comparative study with randomization of needle sequence.	50/50	3	1 Endoscopist with current case volume of 700 cases per year. 2 on-site pathologists experienced in gastrointestinal cytology	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Fisher et al. 2011 ¹¹⁹	EUS-FNA	Device: Olympus linear echoendoscopes Needle Type: Echotip, Olympus Needle (not specified), or unknown needle Size: 22G or 25G	Echotip for 42%, Olympus for 24%, combination for 9%, unknown for 23% 22G for 54%, 25G for 35%, combination needle for 11%, unknown for 0.6%	170/170	NR	Expert endosonographers	NR
Iglesias-Garcia et al. 2011 ¹¹⁸	EUS-FNA	Device: EG-3870UTK (Pentax) Needle Type: Wilson-Cook (name not specified) Needle Size: 22G	Transduodenal approach for pancreatic head lesions, or transgastric approach for body/tail lesions	182/182	2	NR	NR
Itoi et al. 2011 ¹³³	EUS-FNA	Device: GF UCT 2000 (Olympus) or UCT 240 (Olympus) Needle Type: Echotip and Echotip Ultra aspiration needles or trucut needles (Quickcore) Needle Size: 19G, 22G, or 25G	The trucut needles were reserved for body/tail masses.	356/356	NR	NR	NR
Kopelman et al. 2011 ¹⁰⁷	EUS-FNA	Device: 5 MHz frequency 36UX - FG EUS (Pentax) Needle Type: Wilson Cook Medical (name not specified) Needle Size 22G	Transduodenal approach for pancreatic head lesions, or transgastric approach for body/tail lesions	102/102	1	Experienced examiner	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Kubiliun et al. 2011 ⁹⁷	EUS-FNA	Device: UC-30P or UCT 140 (Olympus) Needle Type: EchoTip (Cook Endoscopy) Needle Size: 22G	On-site cytopathologist. If on-site read was non-diagnostic then patients referred for FISH which was the test of interest	69/69	1	NR	Endoscopist performed all EUS-FNA procedures
Reddymasu et al. 2011 ¹⁰²	EUS-FNA	Device: EG-3630UR (Pentax) Needle Type: NR Needle Size: NR	NR	326/NR	2	Mojtaba Olyaei, MD performs approximately 800 procedures per year and Syed Jafri, MD performs approximately 500 EUS examinations per year.	NR
Carrara et al. 2010 ⁷⁵	EUS-FNA	Device: FG36UX (Pentax) or EG3830UT (Pentax) Needle Type: Wilson Cook (name not specified) Needle Size: 22G or 25G	NR	1,034/1,034	1	NR	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Kliment et al. 2010 ¹²⁷	EUS-FNA	Device: GF-UC140 (Olympus) Needle Type: AL EZ-Shot Needle Size: 22G	NR	207/207	2	Experienced	Depending on the echoendoscopist's decision, when clinically relevant, EUS-FNA of ascitic fluid, suspicious lymph node, liver mass or other site was performed before sampling pancreatic mass. number of needle passes depended on the echoendoscopist's decision
Song et al. 2010 ¹⁷¹	EUS-FNA	Device: GF-UCT 240 (Olympus) Needle Type: ECHO 3-22 or ECHO 19 (Cook Endoscopy) Needle Size: 19G or 22G	NR	117/177	NR	NR	NR
Chang et al. 2009 ¹²¹	EUS-FNA	Device: GF-UM 2000 (Olympus) or GF-UCT 240 (Olympus) Needle Type: Echotip-22ECHO or Echotip-ECHO 19 or trucut needle quick-core Needle Size: 19G or 22G	NR	139/139	2	Experienced endosographers	Needle type used determined by the operator at will

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Device: UC-140P (Olympus) Needle Type: Wilson-Cook (name not specified) Needle Size: 22G	Trangastric approach for 27 body/tail lesions, and transduodenal for the 73 head lesions	93/93	2	Gastroenterologist or supervised EUS fellow.	NR
Hikichi et al. 2009 ^{92,172}	EUS-FNA	Device: GF-UCT240-AL5 (Olympus) or GF-U240P-AL5 (Olympus), FG-36UX (Pentax), or EUB-6000 (Hitachi) Needle Type: Echotip or NA-10J-I (Olympus) or NA-200H-8022 (Olympus) Needle Size: 22G	–	73/73	10	A.I. had 13 years' experience with EUS at the beginning of period 1, and T.H. had 7 years' experience with EUS at the beginning of period 1. The other eight operators were trainees with at least 5 years' experience of EUS at beginning of period 1 or 2.	When the endosonographers or cytopathologist indicated the amounts of cell samples were adequate, the procedure was stopped.
Siddiqui et al. 2009 ⁹⁸	EUS-FNA	Device: GF-UCT 140 series (Olympus) Needle Type: Endocoil or Echotip (Wilson Cook) Needle Size: 22G or 25G	22 gauge: mean needle passes 2.6 (SD 1.2), needle malfunction in 11 patients. 25 gauge: mean needle passes 2.6 (1.2), needle malfunction in 10 patients	133/133	NR	NR	NR
Yusuf et al. 2009 ¹²⁰	EUS-FNA	Device: GF-UM20 (Olympus), FG36UX (Pentax), FG38UX (Pentax) Needle Type: Echotip Needle Size: 22G or 25G	NR	842/842	NR	Experienced endosonographers trained in radial and linear array endosonography and EUS-guided FNA.	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Zamboni et al. 2009 ¹²⁹	EUS-FNA	Device: Sequoia 512 6.0 Needle Type: Menghini Needle Size: 20G or 21G	Anterior abdominal approach for all cases	545 / 545	NR	All biopsies were performed in our department on an inpatient basis by members of our interventional ultrasound team.	NR
Al-Haddad et al. 2008 ¹³⁰	EUS-FNA	Device: UC30P (Olympus), UCT140 (Olympus), GFUM-130 (Olympus), or GF-UE-160 (Olympus) Needle Type: Echotip (Wilson-Cook) Needle Size 19G, 22G, or 25G	NR	210 / 210	3	Attending endosonographers performed all the procedures and were assisted by fellows in over 90% of cases. Two of the three attending endosonographers underwent third-tier EUS training and had all previously performed more than 1,000 procedures independently.	NR
Ramirez-Luna et al. 2008 ⁹⁹	EUS-FNA	Device: GF UCT-140 (Olympus) Needle Type: ECHO TIP (Wilson-Cook) Needle Size: 19G or 22G	NR	52 / 52	1	“Experienced”	Endoscopist performed all EUS-FNA procedures

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Shah et al. 2008 ¹²⁸	EUS-FNA	Device: GF-UC140P (Olympus) and GF-UCT140 (Olympus) with Aloka processor Needle Type: Echotip (Wilson- Cook) Needle Size: 22G	10 mL suction	72/72	2	"Experienced"	NR
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	EUS-FNA Olympus UC-30P or UC 140T Echotip 22 gauge	EUS-FNA Olympus UC-30P or UC 140T Echotip 22 gauge	547/547	1	NR	Any symptoms reported by the patient during recovery time were carefully assessed and documented by the endoscopist.
Rocca et al. 2007 ¹³⁴	EUS-FNA	Device: GF-UCP140 (Olympus), 38UX (Pentax), or 36UX Needle Type: ECHO-3-22 Needle Size: 22G	NR	293/232	NR	NR	NR
Bournet et al. 2006 ¹¹¹	EUS-FNA	Device: GF-UC30P (Olympus) or FG36UX (Pentax) Needle Type: EUS-N1 (Wilson Cook) Needle Size: 22G or 19G	maximum of 3 to 4 needle passes generally done, only one needle pass for cystic tumors, mean time for procedure 24.7 minutes (SD 5)	224/224	NR	NR	NR
Mahnke et al. 2006 ¹¹⁰	EUS-FNA	NR	NR	160/160	NR	NR	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Wittmann et al. 2006 ¹⁰⁰	EUS-FNA	Device: GIF UC 30P (Olympus) or 38UX (Pentax) Needle Type: Echotip Needle Size: 22G	NR	83/83	1	Experienced	Usually a day-case procedure
Mortensen et al. 2005 ¹¹²	EUS-FNA	NR	NR	670 of 3,324/ 670 of 3,324	NR	NR	NR
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Device: GIF UC30P (Olympus) or GF-UC2000P-OL5 (Olympus) Needle Type: NA10J-1 or NA-11J-KB or Echotip Needle Size: NR	NR	52/52	1	One well-trained endoscopist (S.R.) performed EUS-FNA in all patients.	NR
Eloubeidi et al. 2004 ⁷⁶	EUS-FNA	Device: NR Needle Type: NR Needle Size: NR	NR	NA – 19 of 27 training programs responded to questionnaire. List of centers in which training in EUS is offered obtained from Web site of the American Society for Gastrointestinal Endoscopy	NR	NR	NR
Gress et al. 2002 ¹¹³	EUS-FNA	Device: EUM-20 (Olympus) and FG32UA GIP (Pentax) Needle Type: Mediglobe Needle Size: 22G	Transduodenal approach for pancreatic head lesions, or transgastric approach for body/tail lesions	100/100	2	Experienced	NR

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Harewood et al. 2002 ¹¹⁴	EUS-FNA	Device: GF-UM20 (Olympus), GF-UM30 (Olympus), GF-UC30P (Olympus), or FG-32UA (Pentax) Needle Type: Wilson-Cook (name not specified) Needle Size: 22G	Transduodenal approach for pancreatic head lesions, or transgastric approach for body/tail lesions	185/185	1	Experienced	NR
Fritscher-Ravens et al. 2001 ¹⁰³	EUS-FNA	Device: FG-34UX (Pentax) or GIF-UC30P (Olympus) Needle Type: Wilson-Cook (name not specified) Needle Size: 22G	All procedures performed by a single examiner who received additional training in preparing aspirated material and assessing cellular adequacy.	114 (112 had adequate sampling)/ 114 (112 had adequate sampling)	1	Experienced cytopathologist	Was not present during the EUS procedure and was blinded to the details of the cases
Gress et al. 2001 ¹¹⁶	EUS-FNA	Device: EUM-20 (Olympus) or FG32UA (Pentax) Needle Type: Wilson Cook or GID/Mediglobe Needle Size: 23G 4 cm (Wilson) or 22G 10 cm (GID/Mediglobe)	Median number of passes of biopsy was 3.4 (range 2 to 9)	102/102	1	Particular competence in pathologic-anatomical diagnosis	Pathologist

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
O'Toole et al. 2001 ¹¹⁵	EUS-FNA	Device: GF-UM20 (Olympus), FG-32UA (Pentax) Needle Type: Hancke-Vilman GIP (Pentax) or Hexa Medical or NA-10J-1 (Olympus) Needle Size: 22G 12 cm (Hancke-Vilman GIP or Hexa Medical) or 22G 6 cm (Olympus)	Mean number of passes 2.1 per lesion (SD 1.0). Procedure performed in 2 centers by 3 experienced endosonographers	322/322	NR	NR	NR
Voss et al. 2000 ¹¹⁷	EUS-FNA	Device: FG 32 UA (Pentax) 120 degree Needle Type: NR Needle Size: 22G	Transduodenal approach for pancreatic head lesions, or transgastric approach for body/tail lesions	99/90	NR	NR	NR
Sakamoto et al. 2008 ⁷⁹	MDCT, EUS-FNA	MDCT Device: Toshiba Aquillion (Toshiba medical systems) MDCT Slice Thickness: 5mm MDCT Reformats: NR MDCT Contrast: 100 mL Optiray 320 MDCT Phases of Enhancement: NR EUS-FNA Device: GF-UCT240-AL5 (Olympus) Needle Type: Echotip Needle Size: 22G	NR	156/98	2	Qualified by the Japan Gastroenterological Endoscopy Society	To prevent inter-operator variability, all procedures were performed by the same operators using the same examination protocol

Table C-15. Testing characteristics in pancreas-specific studies included for harms data (continued)

Study	Test	Test Technology	Additional Test Details	Number of Patients in Study Received Test/ Number of Patients Received EUS-FNA	Number of Test Readers	Reader Prior Experience	Additional Reader Details
Agarwal et al. 2004 ⁵⁴¹	MDCT vs. EUS-FNA	MDCT Device: NR MDCT Slice Thickness: 1.25 mm (parenchymal phase), 2.5 mm (portal phase) MDCT Reformats: NR MDCT Contrast: 150 mL Optiray 320 (Mallinckrodt Inc.) MDCT Phases of Enhancement: Dynamic EUS-FNA Device: EUM-30 (Olympus) and FG-32A (Olympus) Needle Type: Echo-tip (Wilson Cook) Needle Size: NR	EUS-FNA was considered positive only if a definitive cytologic diagnosis of malignancy could be made with fine needle aspirates.	81/81	NR	NR	CT: radiologists who specialize in body imaging. EUS-FNA: Cytologist could make the preliminary diagnosis

¹ Order of tests performed (MDCT was always first); elapsed time between imaging tests NR

EUS=Endoscopic ultrasound; EUS-FNA=endoscopic ultrasound-fine needle aspiration; G=gauge; MDCT=multi-detector computed tomography; mm=millimeter; MRI=magnetic resonance imaging; NR=not reported

Table C-16. Harms reported in included pancreas-specific studies

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Bang et al. 2013 ⁹⁴	EUS-FNA	Any	0% (0/54)	54	0	–
Hayashi et al. 2013 ¹³¹	EUS-FNA	Punctures resulting in peripancreatic abscess and requiring antibiotics	0.7% (1/138)	138	1	–
Ikezawa et al. 2012 ¹⁰⁴	EUS-FNA	Mild pancreatitis treated conservatively	1.8% (1/56)	56	1	–
Ikezawa et al. 2012 ¹⁰⁴	EUS-FNA	EUS-FNA-induced peritoneal carcinomatous peritonitis	17.9% (10/56)	56	10	Average length of follow-up 599 days
Ootaki et al. 2012 ¹³²	EUS-FNA	Self-limited bleeding during or after EUS-FNA (in conscious sedation group)	0.5% (2/371)	371	2	–
Ranney et al. 2012 ⁹⁵	EUS-FNA	Any	0% (0/214)	214	0	–
Siddiqui et al. 2012 ¹⁰⁵	EUS-FNA	Bowel perforations	0% (0/677)	677	0	–
Siddiqui et al. 2012 ¹⁰⁵	EUS-FNA	Significant intra-procedural bleeding after FNA	0% (0/677)	677	0	–
Siddiqui et al. 2012 ¹⁰⁵	EUS-FNA	Mild acute pancreatitis (resolved within one day)	0.3% (2/677)	677	2	–
Siddiqui et al. 2012 ¹⁰⁵	EUS-FNA	Abdominal pain	0.1% (1/677)	677	1	One day after the procedure
Attila et al. 2011 ⁹⁶	EUS-FNA	Any	0% (0/95)	95	0	*95 of 232 had EUS-FNA
Choi et al. 2011 ⁹³	EUS-FNA	Any significant procedure-related complications such as bleeding or pancreatitis	0% (0/58)	58	0	–
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Acute pancreatitis requiring hospital admission and conservative treatment	1.1% (2/179)	179	2	Post procedural
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Brief hypoxia requiring temporary airway support	0.6% (1/179)	179	1	Intraoperative

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Overall morbidity	39.7% (71/179)	179	71	Post procedural. Morbidities included pancreatic fistulas, or surgical site infections, or hemorrhage, or drainage required.
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Surgical site infection	6.7% (12/179)	179	12	Post procedural
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Pancreatic fistula	15.1% (27/179)	179	27	Post procedural
Beane et al. 2011 ¹⁰⁶	EUS-FNA	Drainage procedures	3.4% (6/179)	179	6	Post procedural
Fabbri et al. 2011 ⁷⁴	EUS-FNA	ANY	0% (0/50)	50	0	–
Fisher et al. 2011 ¹¹⁹	EUS-FNA	Pancreatitis	2.4% (4/170)	170	4	–
Fisher et al. 2011 ¹¹⁹	EUS-FNA	Bleeding (self-limited)	0% (0/170)	170	0	–
Fisher et al. 2011 ¹¹⁹	EUS-FNA	Perforation	0.6% (1/170)	170	1	–
Fisher et al. 2011 ¹¹⁹	EUS-FNA	Bile leak	0.6% (1/170)	170	1	–
Iglesias-Garcia et al. 2011 ¹¹⁸	EUS-FNA	Mild acute pancreatitis, requiring hospitalization for 4-5 days	1.1% (2/182)	182	2	–
Iglesias-Garcia et al. 2011 ¹¹⁸	EUS-FNA	Bleeding at site of gastric puncture	0.5% (1/182)	182	1	–
Iglesias-Garcia et al. 2011 ¹¹⁸	EUS-FNA	Mortality due to the procedure	0% (0/182)	182	0	–
Itoi et al. 2011 ¹³³	EUS-FNA	Procedure-related bleeding, treated by conservative therapy without blood transfusion	0.6% (2/356)	356	2	–
Itoi et al. 2011 ¹³³	EUS-FNA	Any morbidity other than procedure-related bleeding	0% (0/356)	356	0	–
Kubiliun et al. 2011 ⁹⁷	EUS FNA	Any	0% (0/69)	69	0	Nurse called patients 24-48 hours after the procedure
Kopelman et al. 2011 ¹⁰⁷	EUS-FNA	Any morbidity other than mild pancreatitis	0% (0/102)	102	0	–

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Kopelman et al. 2011 ¹⁰⁷	EUS-FNA	Mild pancreatitis resolved spontaneously	1% (1/102)	102	1	–
Reddymasu et al. 2011 ¹⁰²	EUS-FNA	Any	0% (0/326)	326	0	–
Kliment et al. 2010 ¹²⁷	EUS-FNA	Any major complications	0% (0/207)	207	0	–
Kliment et al. 2010 ¹²⁷	EUS-FNA	Minor pain treated with a single dose of analgesics	1% (2/207)	207	2	–
Kliment et al. 2010 ¹²⁷	EUS-FNA	Minor bleeding without treatment necessary	1.4% (3/207)	207	3	–
Carrara et al. 2010 ⁷⁵	EUS-FNA	Mild intracystic hemorrhage*	0.6% (6/1034)	1034	6	*Indications for EUS-FNA: 3 IPMNs, 1 Chronic Pancreatitis, 1 Cysto-Adeno, 1 Cystic AdenoCA
Carrara et al. 2010 ⁷⁵	EUS-FNA	Mild intracystic and retroperitoneal hemorrhage	0.1% (1/1034)	1034	1	*Indication for EUS-FNA was IPMN
Carrara et al. 2010 ⁷⁵	EUS-FNA	Mild endoductal hemorrhage	0.2% (2/1034)	1034	2	*Indications for EUS-FNA: 1 AdenoCA, 1 Chronic Pancreatitis
Carrara et al. 2010 ⁷⁵	EUS-FNA	Mild hemorrhage	0.1% (1/1034)	1034	1	Indication for EUS-FNA was AdenoCA
Carrara et al. 2010 ⁷⁵	EUS-FNA	Moderate acute pancreatitis	0.1% (1/1034)	1034	1	Indication for EUS-FNA was NET
Carrara et al. 2010 ⁷⁵	EUS-FNA	Severe acute pancreatitis	0.1% (1/1034)	1034	1	Indication for EUS-FNA was acute pancreatitis
Carrara et al. 2010 ⁷⁵	EUS-FNA	Severe perforation/death	0.1% (1/1034)	1034	1	Indication for EUS-FNA was neuroendocrine tumor
Song et al. 2010 ¹⁷¹	EUS FNA	Elevated pancreas enzyme without abdominal pain (chem pancreatitis)	2.6% (3/117)	117	3	Don't specify what time interval they followed patients out to for complications
Chang et al. 2009 ¹²¹	EUS-FNA	Threefold increase in serum amylase	7.9% (11/139)	139	11	–
Chang et al. 2009 ¹²¹	EUS-FNA	"Clinical" pancreatitis (did not define "clinical")	0% (0/139)	139	0	–
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Minor mucosal bleeding requiring adrenaline injection	1.1% (1/93)	93	1	–
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Pain requiring hospital re-admission	1.1% (1/93)	93	1	–

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Mild self-limiting mucosal bleeding, stopped without intervention	4.3% (4/93)	93	4	Intraprocedural
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Puncture of the superior mesenteric vein	1.1% (1/93)	93	1	–
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Perforation	0% (0/93)	93	0	–
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Pancreatitis	0% (0/93)	93	0	–
Fisher et al. 2009 ¹⁰⁸	EUS-FNA	Sepsis	0% (0/93)	93	0	–
Hikichi et al. 2009 ^{92,172}	EUS-FNA	Any major complications	0% (0/73)	73	0	–
Hikichi et al. 2009 ^{92,172}	EUS-FNA	Pancreatitis	0% (0/53)	53	0	The lack of pancreatitis was reported by the secondary publication ¹⁷² which had enrolled 53 patients between 1/2001 and 12/2003
Hikichi et al. 2009 ^{92,172}	EUS-FNA	Tumor seeding	0% (0/53)	53	0	The lack of seeding was reported by the secondary publication ¹⁷² which had enrolled 53 patients between 1/2001 and 12/2003
Siddiqui et al. 2009 ⁹⁸	EUS-FNA	Any	0% (0/133)	133	0	–
Yusuf et al. 2009 ¹²⁰	EUS-FNA	Mild pancreatitis	1.3% (11/842)	842	11	–
Zamboni et al. 2009 ¹²⁹	EUS-FNA	Any major complications	0% (0/545)	545	0	–
Zamboni et al. 2009 ¹²⁹	EUS-FNA	Abdominal fluid, no adverse consequences	0.4% (2/545)	545	2	–
Zamboni et al. 2009 ¹²⁹	EUS-FNA	Pain after the procedure, not clinically significant	1.1% (6/545)	545	6	–
Al-Haddad et al. 2008 ¹³⁰	EUS-FNA	Moderately severe abdominal pain within 2 hours, requiring hospital admission	1% (2/210)	210	2	–
Al-Haddad et al. 2008 ¹³⁰	EUS-FNA	Moderate abdominal pain requiring ER admission but no hospital stay and treated with oral analgesics	0.5% (1/210)	210	1	–

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Al-Haddad et al. 2008 ¹³⁰	EUS-FNA	Any complications at 30 day follow-up	0% (0/210)	210	0	–
Ramirez-Luna et al. 2008 ⁹⁹	EUS FNA	Any	0% (0/52)	52	0	Evaluated for 4 hours after the procedure for complications
Sakamoto et al. 2008 ⁷⁹	EUS-FNA	Intra-abdominal abscess	0% (0/98)	98	0	–
Sakamoto et al. 2008 ⁷⁹	EUS-FNA	Bleeding from FNA site	0% (0/98)	98	0	–
Sakamoto et al. 2008 ⁷⁹	EUS-FNA	Increase in ascites	0% (0/98)	98	0	–
Sakamoto et al. 2008 ⁷⁹	EUS-FNA	Any other complications	0% (0/98)	98	0	–
Sakamoto et al. 2008 ⁷⁹	EUS-FNA	Seeding in the needle tract	0% (0/98)	98	0	–
Sakamoto et al. 2008 ⁷⁹	MDCT	Allergic eruption to contrast agent	1.9% (3/156)	156	3	–
Shah et al. 2008 ¹²⁸	EUS-FNA	periduodenal bleeding	0.8% (1/123)	123	1	Did not separate harms of EUS-FNA vs. EUS-FNA+TCB
Shah et al. 2008 ¹²⁸	EUS-FNA	Hematoma	0.8% (1/123)	123	1	Did not separate harms of EUS-FNA vs. EUS-FNA+TCB
Shah et al. 2008 ¹²⁸	EUS-FNA	Abdominal pain	1.6% (2/123)	123	2	Did not separate harms of EUS-FNA vs. EUS-FNA+TCB
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Major complication: acute pancreatitis	0.9% (5/547)	547	5	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Major complication: Severe pain	0.5% (3/547)	547	3	Post procedural
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Major complication: Fever requiring intravenous antibiotics	0.4% (2/547)	547	2	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Major complication: Reversal medication usage	0.2% (1/547)	547	1	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Minor complication: sore throat	0.2% (1/547)	547	1	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Minor complication: vomiting	0.2% (1/547)	547	1	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Minor complication: abdominal pain	0.9% (5/547)	547	5	–

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Minor complication: fever	0.2% (1/547)	547	1	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Minor complication: exaggerated bleeding	0.4% (2/547)	547	2	–
Eloubeidi et al. 2007 ^{109,122-126}	EUS-FNA	Hypoxia from over sedation	0.3% (1/300)	300	1	This data point was reported by a secondary publication from this institution. ¹²⁴
Rocca et al. 2007 ¹³⁴	EUS-FNA	Major complications noted after procedures	0% (0/293)	293	0	–
Rocca et al. 2007 ¹³⁴	EUS-FNA	Mortality due to the procedure	0% (0/293)	293	0	–
Rocca et al. 2007 ¹³⁴	EUS-FNA	Minor intracystic hemorrhage	0.3% (1/293)	293	1	–
Rocca et al. 2007 ¹³⁴	EUS-FNA	Minor transient hyperthermia	0.3% (1/293)	293	1	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Mortality	0% (0/224)	224	0	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Any	2.2% (5/224)	224	5	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Pancreatitis	0.4% (1/224)	224	1	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Upper gastrointestinal bleeding	0.4% (1/224)	224	1	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Perforation, duodenal	0.4% (1/224)	224	1	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Infection	0.4% (1/224)	224	1	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Pleuropericarditis	0.4% (1/224)	224	1	–
Bournet et al. 2006 ¹¹¹	EUS-FNA	Complications related to celiac block procedures for anesthesia	0% (0/224)	224	0	–
Mahnke et al. 2006 ¹¹⁰	EUS-FNA*	Mild bleeding	0.3% (1/310)	310	1	Data not specific to those who received FNA
Mahnke et al. 2006 ¹¹⁰	EUS-FNA*	Moderate pancreatitis	0.3% (1/310)	310	1	Data not specific to those who received FNA

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Mahnke et al. 2006 ¹¹⁰	EUS-FNA*	Unplanned primary care evaluation	0.6% (2/310)	310	2	Data not specific to those who received FNA
Mahnke et al. 2006 ¹¹⁰	EUS-FNA*	Unplanned emergency department evaluation	0.3% (1/310)	310	1	Data not specific to those who received FNA
Mahnke et al. 2006 ¹¹⁰	EUS-FNA*	Use of reversal agent	0.6% (2/310)	310	2	Data not specific to those who received FNA
Mahnke et al. 2006 ¹¹⁰	EUS-FNA*	Infection	0.6% (2/310)	310	2	Data not specific to those who received FNA
Wittmann et al. 2006 ¹⁰⁰	EUS-FNA	Any complications	0% (0/83)	83	0	The N of 83 represents those who received EUS-FNA alone of the pancreas
Mortensen et al. 2005 ¹¹²	EUS-FNA	Acute pancreatitis	0.1% (1/670)	670	1	Full recovery with conservative treatment
Mortensen et al. 2005 ¹¹²	EUS-FNA	Massive gastrointestinal bleeding	0.1% (1/670)	670	1	Happened 6 hours after procedure, patient died from massive gastrointestinal bleeding, Autopsy revealed disseminated cancer but no bleeding from EUS-FNA puncture areas
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Any complications	0% (0/52)	52	0	1 day of monitoring after the procedure
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Any complications	0% (0/52)	52	0	–
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Pancreatitis	0% (0/52)	52	0	–
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Hemorrhage	0% (0/52)	52	0	–
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Infection	0% (0/52)	52	0	–
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Tumor seeding	0% (0/52)	52	0	Authors reported this as "cancer dissemination"
Ryozawa et al. 2005 ¹⁰¹	EUS-FNA	Perforation	0% (0/52)	52	0	–

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Eloubeidi et al. 2004 ⁷⁶	EUS-FNA	Acute pancreatitis	0.64% (14/4,909)	4,909	14	Rate for 2 of 17 centers suggesting that the frequency of pancreatitis (0.26%) in retrospective cohort was underreported. Pancreatitis was classified as mild in 10 cases, moderate in 3 cases, and severe in 1 case. One death occurred after the development of pancreatitis but patient noted to have multiple co-morbid conditions and ultimate cause of death was deemed pulmonary embolism.
Gress et al. 2002 ¹¹³	EUS-FNA	Acute pancreatitis	2% (2/100)	100	2	Occurred within four hours of EUS-FNA
Gress et al. 2002 ¹¹³	EUS-FNA	Any complications other than acute pancreatitis	0% (0/100)	100	0	–
Harewood et al. 2002 ¹¹⁴	EUS-FNA	Mild pancreatitis requiring 2-day hospital stay	0.5% (1/185)	185	1	–
Fritscher-Ravens et al. 2001 ¹⁰³	EUS-FNA	Any	0% (0/114)	114	0	–
Gress et al. 2001 ¹¹⁶	EUS-FNA	Substantial gastric mucosal bleeding with clot formation	2% (2/102)	102	2	Resolved spontaneously
Gress et al. 2001 ¹¹⁶	EUS-FNA	Pancreatitis	1% (1/102)	102	1	Patient had history of pancreatitis and at the time was recovering from an attack
O'Toole et al. 2001 ¹¹⁵	EUS-FNA	Acute pancreatitis	1.2% (3/248)	248	3	Complications occurred more frequently in cystic lesions
O'Toole et al. 2001 ¹¹⁵	EUS-FNA	Aspiration pneumonia	0.4% (1/248)	248	1	Complications occurred more frequently in cystic lesions
Voss et al. 2000 ¹¹⁷	EUS-FNA	Any	5.1% (5/99)	99	5	–
Voss et al. 2000 ¹¹⁷	EUS-FNA	Bleeding	4% (4/99)	99	4	Intraprocedural
Voss et al. 2000 ¹¹⁷	EUS-FNA	Abdominal pain and pyrexia, resolved spontaneously	1% (1/99)	99	1	–
Voss et al. 2000 ¹¹⁷	EUS-FNA	Acute pancreatitis	0% (0/99)	99	0	–

Table C-16. Harms reported in included pancreas-specific studies (continued)

Study	Test	Harm	Rate	Number of Patients at Risk of Harm	Number of Patients Experienced Harm	Comments
Sakamoto et al. 2008 ⁷⁹	EUS-FNA	Abdominal pain, transient	2% (2/98)	98	2	–
Agarwal et al. 2004 ⁵⁴	Both MDCT and EUS-FNA	Abdominal pain	2.5% (2/81)	81	2	Post procedure pain that subsided completely within 24 hours. Complications were not reported separately for each test

AdenoCA=Adenocarcinoma; ER=emergency room; EUS-FNA=endoscopic ultrasound - fine needle aspiration; IPMN=intraductal papillary mucinous neoplasm; TCB=tru-cut biopsy

Table C-17. Harms from MRI in included non-pancreatic-cancer studies

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Semelka et al. 2013 ¹⁴²	Proof-of-concept	59	Patients with orders for brain or abdominal MRI scans	52 (range, 5–85)	52.5	0	Not applicable	Setting: Department of Radiology at a U.S. university hospital Timing: NR CA: gadobutrol (Gadavist; Bayer) vs. gadobenate dimeglumine (MultiHance; Bracco)
Albiin et al. 2012 ¹⁴³	Efficacy	31 31 patients received 0.8 g and 0.4 g, 30 patients received 0.2 g	Healthy	24.3 (range, 18–48)	56.2%	≥1 AE 25 (80.6%) at 0.8 g, 18 (58.1%) at 0.4 g, and 10 (33.3%) at 0.2 g ≥1 ADR 22 (71.0%) at 0.8 g, 13 (41.9%) at 0.4 g, and 7 (23.3%) at 0.2 g	Mild ADRs/AEs 32 at 0.8 g, 14 at 0.4 g, 6 at 0.2g Moderate ADRs/AEs 6 at 0.8 g, 1 at 0.4 g, 1 at 0.2 g Severe ADRs/AEs 1 at 0.8 g, 1 at 0.2 g Most common ADRs were diarrhea, nausea, headache and fatigue.	Setting: University hospital, Sweden Timing: Feb. to May 2010 CA: manganese chloride tetrahydrate (CMC-001) “Liver MRI using 0.8 g CMC-001 has the highest efficacy and still acceptable ADRs and should therefore be preferred.”
Bredart et al. 2012 ¹⁵⁰	Prospective, non-randomized, multicenter	365	At risk for breast cancer	59.1% <50 years, 26.9% 50–59 years, 14% ≥60	0	NR	Significant MRI discomfort was due to immobility (37.5%), lying in the tunnel (20.6%), noise of the machine (64.6%), or panic feelings during MRI (6.1%).	Setting: 21 cancer centers, teaching hospitals, or private clinics in France Timing: Nov. 2006 to June 2008

Table C-17. Harms from MRI in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Maurer et al. 2012 ¹⁴⁴	Post-marketing surveillance	84,621 50% neurological exams, 12.2% internal organs, 32.1% musculo-skeletal system, 2.3% MR angiographies, 4.9% not specified	19,354 (22.9%) were considered at risk 11.4% history of allergies, 6.6% hypertension, 2.3% CHD, 1.9% CNS disorders, 1.3% bronchial asthma, 1.3% beta-blocker treatment, 1.2% cardiac insufficiency, 0.9% renal failure, 0.8% history of allergic reaction to contrast medium, 1.3% liver dysfunction, 1.3% other	52.0±16.9	45.4	285 (0.34%) 421 AEs	65 different AEs were reported. 10 most common included nausea (0.2%), vomiting (0.1%) and less than 1% of patients had the following symptoms: pruritus, urticaria, dizziness, feeling of warmth, retching, sweating increased, paresthesia, and taste alteration. Serious AEs: 8 (<0.01%) 3 of these patients had life-threatening AEs, 1 of the 3 had inpatient treatment. "A causal relationship with GD-DOTA was considered probable in 1 patient, possible in 4 patients, and doubtful in 3 patients."	Setting: 129 German radiology centers Timing: Jan. 2004 to Jan. 2010 CA: gadoteric acid (Gd-DOTA, Dotarem®), manually injected in 74.5%, automated injection in 25.5% Classification: WHO Adverse Reaction Terminology (1998) Allergies and history of allergic reaction to contrast medium were significantly associated (at 0.001 level) with increased risk of adverse events. Renal failure, liver dysfunction or betablocker intake were not associated with increased risk of adverse events.

Table C-17. Harms from MRI in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Voth et al. 2011 ⁷⁷	Integrated retrospective analysis (34 clinical studies)	4,549 Received gadobutrol (Gadovist/Gadavist) 1,844 received comparator contrast agents	Severe renal impairment: 38 gadobutrol, 5 comparator Moderate renal impairment: 328 gadobutrol, 132 comparator Mild renal impairment: 846 gadobutrol, 416 comparator Impaired liver function: 214 gadobutrol, 82 comparator Cardiovascular disease: 1,506 gadobutrol, 435 comparator History of allergies: 462 gadobutrol History of allergies to contrast agents: 33 gadobutrol	54.2±16.6 gadobutrol 54.7±14.5 comparator	58.5% gadobutrol 52.7% comparator	182 (4.0%) gadobutrol-related 74 of 1,844 (4.0%) related to comparators	Serious AEs: 21 17 (0.4%) gadobutrol, 4 (0.2%) comparator Drug-related serious AEs: 1 (<0.1%) gadobutrol	Setting: 55.3% Europe, 7.2% U.S./Canada, 7.7% South/Central America, 29.6% Asia, 0.3% Australia Timing: Trials conducted between 1993 and 2009 CA: gadobutrol (Gadovist/Gadavist); comparator contrast agents included gadopentetate dimeglumine (Magnevist, N= 912), gadoteridol (ProHance, N=555), gadoversetamide (OptiMark, N=227), or gadodiamide (Omniscan, N=150). Classification: MedDRA v. 12.1 “Gadobutrol was well tolerated by patients with impaired liver or kidney function, and by patients with cardiovascular disease.”

Table C-17. Harms from MRI in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Forsting and Palkowitsch 2010 ¹⁴⁵	Integrated retrospective analysis (6 clinical studies)	14,299 14.7% MRA	NR	53.7	46.6	78 (0.55%) 82.4% occurred within 5 minutes of administration, 1 patient had an ADR 9 hours post-injection	Serious: 2 (0.01%) gadobutrol-related; 1 severe anaphylactoid reaction, 1 itching/swelling of throat Most frequently reported: nausea (0.25%)	Setting: 300 radiology centers in Europe and Canada Timing: 2000 to 2007 CA: gadobutrol “Gadobutrol 1.0M is well tolerated and has a good safety profile. The occurrence of ADRs observed following the intravenous injection of gadobutrol is comparable with the published data of other Gd-based contrast agents.”
Ichikawa et al. 2010 ¹⁴⁶	Multicenter, open-label, prospective Phase III	178	Suspected focal hepatic lesions	66 (range, 31–82)	72.4	44 (24.7%)	Mild: 56 Moderate: 6	Setting: 15 radiology departments in Japan Timing: Aug. 2001 to July 2003 CA: Combined unenhanced and gadoxetic acid disodium (Gd-EOB-DTPA)

Table C-17. Harms from MRI in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Ishiguchi and Takahashi 2010 ¹⁴⁷	Post-marketing surveillance	3,444	Liver disorder: 9.52% Kidney disorder: 2.85%	1% <15 years, 58.51% 15 to <65 years, 40.30% ≥65	49.45	32 (0.93%)	Mild: 36 (0.49% gastrointestinal-related disorders most commonly reported) Moderate: 4 2 patients with nausea, 2 with abnormal liver function	Setting: Department of Radiology at a medical university in Japan Timing: March 2001 to March 2005 CA: Gadoterate Meglumine (Gd-DOTA) “Statistically significant risk factors for experiencing adverse reactions were general condition, liver disorder, kidney disorder, complication, concomitant treatments, and Gd-DOTA dose.”
Leander et al. 2010 ¹⁴⁸	Crossover randomized	18	Healthy	25.0	100	19 AEs	19 mild gastrointestinal	Setting: Swedish university hospital Timing: NR CA: oral Manganese (MnCl ₂)
Hammerstingl et al. 2009 ¹⁴⁹	Multicenter, Phase III, randomized, inter-individually controlled comparison	572 292 gadobutrol, 280 gadopentetate	Patients with known focal lesions of the liver or suspected liver lesions	–	–	24 (4.2%) 10 (3.4%) gadobutrol, 21 (5.0%) gadopentetate	4 AEs definitely related to agents, 14 AEs possibly/probably related to agents No serious or severe AEs were reported.	Setting: 25 centers in 8 European countries Timing: NR CA: gadobutrol (Gadovist), gadopentetate (Magnevist)

Table C-17. Harms from MRI in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Shah-Patel et al. 2009 ⁷⁸	Retro-spective chart review	106,800 total 49,731 MRI	NR	Range 18–86	NR	15 (0.03)	<u>Mild:</u> 4 Itching or hives <u>Moderate:</u> 6 Vomiting: 3, Lightheaded sensation: 1 Fall: 1, Headache: 1 <u>Severe:</u> 1 Shortness of breath (before examination) <u>Others:</u> 4 Infiltrations at IV site: 2 Mild burns due to contact with magnetic resonance coil during the examination	Setting: Outpatient radiology in New York, NY Timing: over 4 years Total harms: 59 (0.06%) CA: gadopentetate dimeglumine (Magnevist; Berlex) Patients requiring assistance from emergency medical services: 18 (31%)

ADR=Adverse drug event; AE=adverse event; CA=contrast agent; CHD=coronary heart disease; CNS=central nervous system; Gd=gadolinium; Gd-DTPA=Gd-diethylenetriamine penta-acetic acid; MRA=magnetic resonance angiography; NR=not reported; NSF=nephrogenic systemic fibrosis

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Kim et al. 2013 ⁸⁰	Prospective cohort	1,048	Renal disease: 20 Cardiovascular disease: 38 Other allergic disease: 91	55.1±14.5	47.8	61 (5.8%)	<p><u>Immediate reactions:</u> Mild: 51 Moderate: 1</p> <p><u>Nonimmediate reaction:</u> Mild: 8 Moderate: 1</p>	<p>Setting: Seoul National University Bundang Hospital, Korea</p> <p>Timing: July to November 2010</p> <p>Contrast medium (CM): 721 (68.8%) Iopromide, 323 (0.8%) Iomeprol, 3 (0.3%) Iohexol, and 1 (0.1%) Iodixanol</p> <p>“RCM skin testing for screening is of no clinical utility in predicting hypersensitivity reactions.”</p>

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Kobayashi et al. 2013 ⁸¹	Retrospective cohort	36,472	Diabetes: 7,138 (19.5%) Hypertension: 10,461 (28.6%) Dyslipidemia: 5,972 (16.4%)	58.3	52	779 (2.1%)	<u>Acute adverse reactions (mild):</u> 756 Nausea/vomiting, rash, coughing/sneezing <u>Severe reactions:</u> 23 Shock, hypotension, desaturation, and airway obstruction	Setting: A community hospital in Tokyo, Japan Timing: April 2004 to March 2011 CM: non-ionic low-osmolar contrast agents such as iopamidol, iohexol, ioversol or iomeprol In multivariate logistic regression analysis, an adverse reaction history to contrast agents, urticaria, allergic history to drugs other than contrast agents, contrast agent concentration >70%, age <50 years, and total contrast agent dose >65 grams were significant predictors of an acute adverse reaction.

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Davenport et al. 2012 ⁸²	Retrospective database review	24,826 injections of IV iopamidol 12,684 injections during warming period, 12,142 injections during no warming		51 (range, 1–79 years) period 1 52 (range 4–90 years), period 2	42% period 1, 28% period 2	177 (0.7%) Warming: 82 No warming: 95	<p><u>Iopamidol 300 (no warming): 69</u> Extravasations: 23 Allergic-like reactions: 46 (41 mild, 5 moderate)</p> <p><u>Iopamidol 300 (warming): 74</u> Extravasations: 32 Allergic-like reactions: 42 (33 mild, 8 moderate, 1 severe [patient developed pulseless electric activity after injection and although use of CPR returned the patient to normal sinus rhythm, an infected sternotomy wound reopened, and became infected. The patient died 2 months later of complications related to the infected site.])</p> <p><u>Iopamidol 370 (no warming): 26</u> Extravasations: 18 Allergic-like reactions: 8 (6 mild, 2 moderate)</p> <p><u>Iopamidol 370 (warming): 8</u> Extravasations: 5 Allergic-like reactions: 3 (all mild)</p>	<p>Setting: Duke University Medical Center, Durham, NC</p> <p>Timing: March 14, 2010 to April 19, 2011 (period 1), October 1, 2010 to April 19, 2011 (period 2)</p> <p>CM: Iopamidol 300 for CT exams, Iopamidol 370 for CT angiographic exams</p> <p>“Extrinsic warming (to 37 C) does not appear to affect adverse event rates for intravenous injections of Iopamidol 300 of less than 6 m:/sec but is associated with a significant reduction in extravasation and overall adverse event rates for the more viscous Iopamidol 370.”</p>

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Jung et al. 2012 ⁹⁰	Retrospective chart review	47,338	Medical history of 50 patients with cutaneous adverse reactions (CARs): 17 malignant neoplasm, 13 hypertension, 6 diabetes mellitus, 5 allergic history, 5 renal disease, 3 past adverse reactions to contrast medium, 2 tuberculosis, 2 hepatitis	0 to >80 years; focus on CARs occurring in 50 patients (age range 18 to 81)	58	62 (0.13%) 50 (80.7% of overall AEs) CARs	<u>Severe reactions</u> : 16 (25.8% of overall AEs) Dizziness, severe generalized urticaria, hypotension, and facial edema <u>Immediate CARs</u> : 46 (92% of CARs) Urticaria: 39 (78%) Angioedemna: 5 (10%) Erythema: 1 (2%) Pruritus without rash: 1 (2%) <u>Delayed CARs</u> : 4 (8% of CARs) Maculopapular rash: 4 (8%)	Setting: Seoul, Korea Timing: Aug. 2005 to Nov. 2009 CM: nonionic monomers including iomeprol, iopamidol, iopromide, and ioversol
Kingston et al. 2012 ⁸³	Prospective cohort	26,854 CT and CTA (50)	Multiple clinical factors and comorbidities	NR	NR	119 (0.44%)	<u>Extravasations</u> : 119 (0.44%) 39 (0.34%) cannulations performed in the hospital, 80 performed prior Extravasation occurred at the elbow (71.4%), forearm (10.9%), wrist (6.7%) and hand (7.6%).	Setting: a hospital in Australia Timing: Sept. 2004 to April 2008 CM: nonionic IV (Ultravist 300) “Presence of cancer, hypertension, smoking and recent surgery was associated with higher extravasation rates.”

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Mitchell et al. 2012 ⁸⁴	Prospective consecutive cohort	633 174 CTPA for PE 459 non-CTPA	<u>CTPA:</u> Anemia: 11% DM: 19% History of hypertension: 54% Vascular disease: 15% Congestive heart failure: 12% Baseline renal insufficiency: 10% <u>Non-CTPA:</u> Anemia: 13% DM: 17% History of hypertension: 39% Vascular disease: 8% Congestive heart failure: 5% Baseline renal insufficiency: 10%	CTPA: 50±16 Non-CTPA: 46±15	CTPA: 34 Non-CTPA: 46	–	<u>CIN</u> CTPA: 25 (14%, 95% Confidence Interval 10% to 20%) Non-CTPA: 45 (9.8%) <u>Severe renal failure:</u> 3 CTPA <u>Death from renal failure:</u> 2 CTPA <u>All-cause 45-day mortality rate:</u> 15 CTPA: 6 (3%), death due to renal failure (6), patients with CIN (4) Non-CTPA: 9 (2%)	Setting: a large U.S. academic tertiary care center Timing: June 2007 to January 2009 CM: NR “Development of CIN was associated with an increased risk of death from any cause (relative risk = 12, 95% Confidence Interval: 3 to 53).”

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Vogl et al. 2012 ⁸⁵	Observational, non-interventional, prospective, multicenter	10,836	5,033 (46.4%) had 1 to 7 concomitant diseases (including DM (6.9%) and renal insufficiency (0.9%) that could potentially influence tolerability of ioversol	60.9	48.1	30 (0.28%)	Mild: 26 Urticaria: 13 Nausea: 11 Erythema: 6 Serious: 4 Anaphylactoid adverse reactions requiring hospitalization: 3 Patients with ≥1 AE: 30	Setting: 72 centers in Germany Timing: August 2006 to April 2007 CM: ioversol
Cadwallader et al. 2011 ⁸⁶	Prospective audit	198 scans	Pancreatitis: 5.2% Biliary pathology: 11.2% Appendicitis: 12.6% Bowel obstruction: 9% Peptic ulcer disease: 3.2% Diverticular disease: 6.6% Postoperative complications: 3.6% No diagnosis: 13.2% Transferred specialty: 4.6% Other 30.8%	50.4 (range, 16–94)	44.4	41 (20.7%) scans didn't alter management and were deemed as unnecessarily exposing patients to CT radiation	Risk of fatal cancer induction female aged: 20: 1 in 1,675 30-50: 1 in 2,452 60: 1 in 3,070 70: 1 in 4,113 80: 1 in 7,130 Risk of fatal cancer induction male aged: 30-50: 1 in 2,523 60: 1 in 3,897 80: 1 in 4,289	Setting: Tertiary referral surgical unit Timing: March–May 2008 “The potential diagnostic benefits must outweigh the risks. Figures from the U.S. from 2007 suggest 19,500 CT scans were undertaken each day – the equivalent radiation dose of up to 5,850,000 chest radiographs.”

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Hatakeyama et al. 2011 ⁸⁷	Retrospective chart review	50 (64 CTAs)	Peritoneal Dialysis	55.0±13.1	68	2 (0.04%)	Mild: 1 Skin disorder Serious: 1 Atrial fibrillation	Setting: A hospital and research institute in Japan Timing: 2002 to 2009 CM: Iopamidol, a low osmolar nonionic
Loh et al. 2010 ⁸⁸	Prospective surveillance	539 258 iohexol (51 CTA, 209 CT) 281 control (un-enhanced CT)	NR	53.05±14.9	57.7% iohexol 46.9% control	87 (16.1%) 76 (29.4%) iohexol 11 (3.9%) Control	Delayed adverse reactions (DAR) 37 (14.3%) iohexol, 7 (2.5%) control; p<0.0001 Skin rashes or itching Iohexol: 13 (5.0%), Control: 2 (0.71%); P=0.00273 Patients with cutaneous DARs Iohexol: 26 (10.1%), Control: 2 (0.71%); P<0.0001 Skin redness (p=.0055), skin swelling (p=.0117) and headache (p=.0246) also occurred statistically more frequently in the iohexol group.	Setting: Tertiary academic medical center Timing: 2006 to 2008 CM: iohexol “This study substantiates a frequent occurrence of DARs at contrast-enhanced CT compared with that in control subjects.”

Table C-18. Harms from MDCT in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Ozbulbul et al. 2010 ⁸⁹	Prospective	52 MDCT coronary angio- graphy	Suspected coronary artery disease	56.4±13.6 iodixanol (N=28) 54.1±17.1 iopamidol (N=24)	38	32 (61.5%)	<u>Moderate</u> : 32 (61.5%) Intense injection-related heat: Iodixanol: 11 (39.3%) Iopamidol: 20 (83.3%) Nausea: Iodixanol: 1 (3.5%), Iopamidol: 6 (25%) Dizziness: Iodixanol: 0, Iopamidol: 3 (12.5%)	Setting: radiology department, Turkey Timing: Jan. 2008 to June 2008 CM: iopamidol 370 (a low-osmolar) vs. iodixanol 320 (an iso- osmolar) “Iodixanol 320 causes less frequent sensation of heat on intravenous injection. This means more comfort and success in following the breath-hold commands of patients during scanning.”
Shah-Patel et al. 2009 ⁷⁸	Retrospective chart review	106,800 total 33,321 CT	NR	Range 18–86	NR	35 (0.10%)	<u>Mild</u> : 17 Itching or hives, most often related to iodine-based intravenous contrast injections <u>Moderate</u> : 7 Falls: 3, Nasal congestion: 1, Nausea: 2 Dizziness: 1 <u>Severe</u> : 5 Shortness of breath after IV injection: 5 <u>Others</u> : 6 Infiltrations at IV site: 5, Hematoma at IV site: 1	Setting: Outpatient radiology center in New York, NY Timing: over 4 years CM: iopromide (Ultravist 300)

CECT=Contrast-enhanced computed tomography; CIN=contrast-induced neuropathy; CPR=cardiopulmonary resuscitation; CTA=CT angiography; CTPA=CECT of the pulmonary arteries; PE=pulmonary embolism; SCr=serum creatinine

Table C-19. Harms from EUS in included non-pancreatic-cancer studies

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events (%)	Notes
Coté et al. 2010 ¹³⁶	Prospective analysis of sedation-related complications	799 423, EUS, 336 ERCP, and 40 small-bowel enteroscopy	NR 60.5% patients classified as ASA Class III or higher (severe systemic disease, not incapacitating), 0.5% had a Mallampati score equal to 4	57.8±16.5	46.6	115 (14.4%)	Airway modifications (AMs): 154 events (115 patients); 1 AM in 88 (76.5%) patients, 2 AMs in 15 (13.1%) patients, 3 AMs in 12 (10.4%) patients Hypoxemia (SpO ₂ <90%): 102 (12.8%) Hypotension requiring vasopressors: 4 (0.5%) Procedure termination: 5 (0.6%)	Setting: One tertiary care medical center in St. Louis, MO Timing: Procedures from May 2008 to November 2008 In multivariate analysis, male gender (Odds Ratio (OR) 1.75 (95% Confidence Interval (CI): 1.08 to 2.85; p=0.02), ASA class ≥3 (OR 1.90 (95% CI: 1.11 to 3.25; p=.02) and body mass index (OR 1.05 (95% CI: 1.01 to 1.09; p=0.009) were independent predictors of AMs.
Eloubeidi et al. 2009 ¹⁴⁰	Prospective study of frequency and management of cervical esophageal perforation-EUS by a single experienced endo-sonographer	4,894 patients underwent upper EUS procedures	Indications for EUS: Pancreaticobiliary (58%) Esophageal (14%) Mediastinal (14%) Gastric (9%) Celiac blocks (1%) Other (4%)	59.7 ±14.3	54	3 (0.06%)	Cervical esophageal perforation (3 patients) at the time of intubation with EUS 1 of 3 patients reported chest pains, 2 of 3 patients had excessive salivation and sore throat 1 of 3 patients showed crepitus at bedside exam	Setting: One University Hospital, Birmingham, AL Timing: July 2000 to July 2007 All patients were immediately admitted, underwent surgical repair with neck incision and recovered completely. All patients resumed swallowing without complications.

Table C-19. Harms from EUS in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events (%)	Notes
Kalaitzakis et al. 2011 ¹³⁸	Retrospective case control	4,624	NR	60	43% of patients with unplanned events*	9 (0.2%)	Allergic reaction to sedation:3 Desaturation: 2 Supraventricular tachycardia: 2 Duodenal perforation: 1 Gallbladder perforation: 1 Patients admitted to hospital: 4	Setting: One tertiary referral centre in London, United Kingdom Timing: January 2001 to December 2007
Niv et al. 2011 ¹³⁹	Retrospective review of physician reporting Focus on severe events	10,647 ERCP and EUS	NR	69.3±14.3	21.4%	42 (.4%) serious adverse events According to Heinrich's Iceberg model, the authors estimate 957 adverse events with minor damages and 9900 adverse events with marginal damage or no damage.	Serious: 42 (EUS, ERCP) Perforation: 29 (69%) Bleeding: 2 (4.8%) Cardiovascular and respiratory event: 1 (4.8%) Teeth trauma: 2 (2.4%) Other: 8 (19.0%) Outcome: Residual damage: 18 (42.9%) Complete healing: 6 (14.3%) Death: 15 (35.7%) Unknown: 3 (7.1%)	Setting: Israel health institutes covered by one insurer Timing: 7 year period (2000 to 2006)

Table C-19. Harms from EUS in included non-pancreatic-cancer studies (continued)

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events (%)	Notes
Schilling et al. 2009 ¹³⁷	Prospective randomized Focus on sedation-related AEs	151 Midazolam/meperidine group: 75 (19 EUS) Propofol: 76 (15 EUS)	<u>Midazolam</u> Bile duct stone: 24 (32%) Exclusion of bile duct stones: 10 (13%) Pancreatic cancer: 10 (13%) Other: 42% <u>Propofol</u> Bile duct stone: 22 (29%) Exclusion of bile duct stones: 8 (10%) Pancreatic cancer: 12 (16%) Other: 45% 47.6% ASAIII 17.8% ASA IV	Midazolam: 83.2 (range 80–96) Propofol: 82.4 (range 80–92)	Midazolam: 35 Propofol: 33	30 overall; not reported by device	Minor: 30 (EUS, ERCP, and DBE) Hypoxemia (minor events): 16 7 Midazolam, 9 Propofol Bradycardia: 8 3 Midazolam, 5 Propofol Arterial hypotension: 6 2 Midazolam, 4 Propofol Overall complication rate Midazolam: 16% Propofol: 23.7%, p>0.05	Setting: Diakonie Hospital Mannheim, Mannheim, Germany Timing: March 2006 to June 2007

* Unplanned events defined as any deviation from the preprocedure plan including adverse events as a result of the direct effect of the endoscope on sites or organs transversed or treated during the procedure (e.g, perforation); indirect effects in organs not directly involved in the procedure (e.g., heart); equipment malfunction; or sedation issues

AE=adverse events; ASA=American Society of Anesthesiologists; ERCP=endoscopic retrograde cholangiopancreatography; EUS=endoscopic ultrasound; NR=not reported

Table C-20. Harms from PET/CT in included non-pancreatic-cancer studies

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Shah-Patel et al. 2009 ⁷⁸	Retrospective chart review	106,800 total 3,359 PET/CT	NR	Range 18-86	NR	5 (0.14)	Mild: 1 Itching or hives Severe: 4 Chest pain: 2 (1 before exam and 1 after FDG injection) Shortness of breath after IV injection: 2 (1 patient was premedicated for a known allergy to IV contrast)	Setting: Outpatient radiology in New York, NY Timing: over 4 years Total harms: 59 (0.06%) Patients requiring assistance from emergency medical services: 18 (31%)

F18-FDG=Fluorine-18-labeled fluorodeoxyglucose; NR=not reported

Table C-21. Harms from EUS-FNA in included non-pancreatic-cancer studies

Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
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Study	Study Design	N Patients	Diagnosis	Age, Years (Mean±SD)	% Male	N Harmed (%)	Adverse Events	Notes
Katanuma et al. 2013 ¹³⁵	Retrospective database review	316	Pancreatic cancer: 4 PNET: 3 Chronic pancreatitis: 1	66.5±11.5 (range, 23–92)	54	11 (3.4%)	Pancreatitis: 6 (1 moderate, 5 mild) Abdominal pain: 4 (mild) Bleeding: 1 (mild)	In univariate analysis, tumors ≤20 mm in diameter (p<0.001), PNETs (p=0.012) and procedures using an increased length of needle penetration (e.g., the puncture needle had to traverse normal pancreatic tissue) (p=0.048) were statistically significantly associated with complications. In multivariate analysis, tumors measuring ≤20 mm in diameter (OR 18.48; 95% CI 3.55 to 96.17; p<0.001) and PNETs (OR 36.50; 95% CI 1.73 to 771.83; p=0.021) were significant independent risk factors.

CI=Confidence interval; OR=odds ratio; PNET=pancreatic neuroendocrine tumors

Table C-22. Physical and chemical characteristics of all currently marketed Gadolinium agents for MRI

Generic Name	Trade Name	Company	Acronym	Charge	Type	Dose (mml/kg)	Concentration (M)
Gadobenate dimeglumine	Multihance	Bracco	Gd-BOPTA	Di-ionic	Liver-specific	0.1	0.5
Gadobutrol	Gadovist	Bayer-Schering	Gd-BT-DO3A	Nonionic	ECF	0.1	1.0
Gadoterate meglumine	Dotarem	Guerbet	Gd-DOTA	Ionic	ECF	0.1	0.5
Gadopentetate dimeglumine	Magnevist	Bayer-Schering	Gd-DTPA	Di-ionic	ECF***	0.1	0.5
Gadodiamide	Omniscan	GE-Healthcare	Gd-DTPA-BMA	Nonionic	ECF	0.1	0.5
Gadoversetamide	OptiMark	Covidien	Gd-DTPA-BMEA	Nonionic	ECF	0.1	0.5
Gadoxetic acid disodium salt	Primovist*	Bayer-Schering	Gd-EOB-DTPA	Di-ionic	Liver-specific	0.025	0.25
Gadoteridol	Prohance	Bracco	Gd-HP-DO3A	Nonionic	ECF	0.1	0.5
Gadofosveset trisodium	Vasovist**	EPIX/Lantheus Medical Imaging	MS325	Tri-ionic	Blood-pool	0.03	0.25

* Tradename is Primovist in Europe and Asia but Eovist in USA.

** Tradename is Ablavar in USA and Canada.

***ECF=Extracellular fluid

Taken from Chang et al.¹⁵¹

Screening Studies

Table C-23. General study information of screening studies

Study	Country	Location	Dates	Prospective or Retrospective	Funding Source and Disclosed Potential Conflicts of Interest	Length of Follow-up	How was Reference Standard Determined?	Comments
Canto et al. 2012 ¹⁶⁰	USA	Johns Hopkins University, Brigham Dana Farber, Mayo Clinic, MD Anderson, UCLA	NR	Prospective	NCI, Lustgarten Foundtn, Folfe Foundtn, Olympus, Cook Med, Karp Fund, ChiRho; no COIs	Average 2.4 years	NR	CAPS 3
Al-Sukhni et al. 2012 ¹⁶²	Canada	Univ Toronto	2003–2011	Prospective	Pancrease Cancer Canada, NIH-PACGENE (grant); Princess Margaret Hosp Found Fund; COIs not mentioned	Average 4.2 years	NR	–
Verna et al. 2010 ¹⁶¹	USA	Columbia/NY Prebs	NR	Prospective	Grant from Hirshberg Foundation; no COIs	NR	NR	–
Langer et al. 2009 ¹⁶³	Germany	Philips Univ, Marburg	June 2002–December 2007	Prospective	Deutsche Krebshilfe (grant); no COI	NR	NR	–
Vasen et al. 2011 ¹⁵⁸	Netherlands	Leiden Univ Med Center	Jan 1 2000–Jan 1 2010	Prospective	ZonMW (org that supports govt), no COI	Average 4 years	NR	–
Canto et al. 2006 ^{159,173}	USA	Johns Hopkins University	2001–2004	Prospective	NCI grant, Rolfe found, Rangos Charit Fund, Clayton Fund, NIH grant; no COI mentioned	NR	NR	CAPS 2

Table C-24. Patient characteristics of screening studies

Study	Patient Enrollment Criteria	Number of Control not Included in the Included pt	Number of Patients Included/Imaged	Number Female	Mean Age	PJS	Breast/Ovarian Cancer	FPC (not Specified, # Relatives)	FPC (≥2 Relatives)	FPC (≥3 Relatives)	Fam Hx Panc Cancer- 2 FDR+	Fam Hx panc Cancer - Other	p16 Mutation	STK11 mut	BRCA1/2 Combined	BRCA 1 mut	BRCA 2 mut	Hered Pancreatitis	FDR of Mult Prim Cancer pt Including	HNPCC	FAMM	Other non-panc Cancers
Canto et al. 2012 ¹⁶⁰	HRI at any of 5 sites	-	216	116	56.1	2	19	-	75	120	-	-	-	-	-	-	-	-	-	-	-	-
Al-Sukhni et al. 2012 ¹⁶²	HRI	-	175 included, 262 imaged*	173	NR	7	-	-	159	-	-	-	11	-	-	5	68	2	10	-	-	-
Verna et al. 2010 ¹⁶¹	Family history of pancreatic cancer, interest in risk of disease	3 avg risk; 14 mod; 32 high risk	41**	33	52	-	-	34	-	-	15	35	-	-	17	-	-	-	-	3	3	31
Langer et al. 2009 ¹⁶³	In a registry of high-risk family members	-	76	NR	60	-	-	-	44	32	-	-	-	-	-	-	2	-	-	-	-	-
Vasen et al. 2011 ¹⁵⁸	Dutch FAMM registry	-	79	48	56	-	-	-	-	-	-	37	79	-	-	-	-	-	-	-	-	-
Canto et al. 2006 ^{159,173}	High risk of Peutz-Jeghers syndrome or familiar pancreatic cancer	149 (mean 54 yo, 69 F)	78	44	52	6	-	72	-	-	-	-	-	-	-	-	-	-	-	-	-	-

* 30 withdrew, 6 no MRI (clausterphobia, pacemaker)

**10 neither EUS/MRI, 2 avg risk, 3 hr (young and one in tx for breast/ov ca); 5mod pt pref and young age of affected fam member

Table C-25. General test details of screening studies

Study	Imaging Test(s) of Interest	Order of Tests Performed	Number of Test Readers	Prior Experience of These Readers	Other Reported Details About the Readers	Number of Patients in This Study who Received This Test	If EUS-FNA, how Many Patients Received FNA?
Canto et al. 2012 ¹⁶⁰	MDCT, MRI, EUS +/- FNA	EUS+/-FNA always last	NR	"highly experienced radiologists and GI at 5 tertiary AMCs"	"blinded to results of other imaging tests"	216	12
Al-Sukhni et al. 2012 ¹⁶²	MRI annually (+/- CT/EUS/FNA)	MRI first	1	"MRI experienced"	blinded to pt risks	33 received MRI; NR the Ns for other tests	NR
Verna et al. 2010 ¹⁶¹	MRI, EUS +/- FNA	NR	NR	"a radiologist experienced in panc imaging, blinded to pt cancer risks"	NR	31 EUS-FNA, 7 ERCP, 33 MRI	6
Langer et al. 2009 ¹⁶³	MRA/MRCP, EUS +/- FNA	NR	1	"experienced investigator"	NR	NR	NR
Vasen et al. 2011 ¹⁵⁸	MRI	NR	NR	NR	NR	NR	NA
Canto et al. 2006 ^{159,173}	MDCT, EUS +/- FNA	EUS first, if abnormal then ERCP on separate visit	1	EUS-FNA: "experienced endosonographer"; ERCP: "experienced endoscopist"; CT: experienced CT radiologist unaware of EUS or ERCP findings	EUS-FNA was blinded to CT results	65 ERCP, NR the Ns for other tests	NR

Table C-26. CT details of screening studies

Study	MDCT: 4 vs. 16 vs. 64 Detector row or Other	MDCT: Slice Thickness (if NR, Then Record Machine Name)	MDCT: Whether Reformats Used (Coronal Sagittal) or Only Axial	MDCT: Contrast Y or N	MDCT: Type of Contrast	MDCT: Phases of Enhancement Dynamic vs. Routine; Arterial/Portal Venous/Equilibrium Means Dynamic
Canto et al. 2012 ¹⁶⁰	NR	0.5 and 3 mm	Axial, multiplanar, 3D rendering	Y	100-120 mL Omnipaque-350 or Visipaque-350	Dual phase 30 and 60s
Al-Sukhni et al. 2012 ¹⁶²	NR	NR	NR	NR	NR	NR
Verna et al. 2010 ¹⁶¹	–	–	–	–	–	–
Langer et al. 2009 ¹⁶³	–	–	–	–	–	–
Vasen et al. 2011 ¹⁵⁸	–	–	–	–	–	–
Canto et al. 2006 ^{159,173}	Spiral	1.24 mm	3D recon	Y	120 mL of Omnipaque-350	Dual phase

Table C-27. EUS-FNA details of screening studies

Study	EUS FNA Technology	EUS-FNA Needle Type	EUS-FNA Needle Size	Other EUS-FNA Details
Canto et al. 2012 ¹⁶⁰	Olympus GFUM20 or GFUE160-AL5) and Olympus CFUC140P, SSD-Alpha5, or Alpha10)	NR	NR	–
Al-Sukhni et al. 2012 ¹⁶²	NR	NR	NR	–
Verna et al. 2010 ¹⁶¹	GRUC140P and SSD-Alpha 5 Olympus	NR	NR	–
Langer et al. 2009 ¹⁶³	Pentax FG 32 UA	EUS bx needle, mult passes	21 G	"followed standardized procedure," cytology by experienced pathologist
Vasen et al. 2011 ¹⁵⁸	–	–	–	–
Canto et al. 2006 ^{159,173}	Olympus UM-130 or UM-160 radial and linear FG UCT1409-AL5	u/s aspiration needle wilson-cook	22G	Onsite cytopathologist review; also indept review by experienced cytopath unaware of clinical/radiologic findings

Table C-28. MRI details of screening studies

Study	MRI: Magnet Strength	MRI: Contrast Y or N	MRI: Type of Contrast	MRI: Phases of Enhancement Dynamic vs. Routine; Arterial/Portal Venous/Equilibrium Means Dynamic	MRI: Diffusion-Weighted Y or N	MRI: Type of Coil (Body/Pelvic or Endorectal)
Canto et al. 2012 ¹⁶⁰	1.5 T	Y	Human secretin and gadolinium	Arterial, portal venous, delayed phases (20s, 70s, 3m)	Y- T1/T2	Phased-array torso coil
Al-Sukhni et al. 2012 ¹⁶²	1.5 T	N	x	x	T2 weighted	4-8 surface array coil
Verna et al. 2010 ¹⁶¹	1.5 T	Y	Gadodiamide or gabobenate dimeglumine	–	T2	Body
Langer et al. 2009 ¹⁶³	1.5 T	Both	Magnevist and panc-spec Teslascan	Dynamic enhanced	T2/T1	–
Vasen et al. 2011 ¹⁵⁸	1.5 T	Y	Gadolinium dotarem	–	T2ax	Phased array torso coil
Canto et al. 2006 ^{159,173}	–	–	–	–	–	–

Table C-29. General data reported by screening studies for any imaging modality

Study	# HRI who Received Imaging	# HRI who had no Positive Imaging Throughout the Study	# HRI who had at Least one Positive Image, but not Concerning Enough to Result in Surgery or Biopsy (i.e., Pathological Study)	# who had at Least one Positive Image, and Received Either Surgery or Biopsy	True Positive (Pathology Confirmed Cancer)	Major False Positive (Surgery Indicated Benign Lesion)	Minor False Positive (Biopsy Indicated Benign Lesion, Therefore Surgery Avoided)	False Negative (Initial Imaging Missed Cancer, but Later Pathology Showed Cancer)
Canto et al. 2012 ¹⁶⁰	216	124	87	5	3	2	0	0
Al-Sukhni et al. 2012 ¹⁶²	175	91	78	6	2	2	0	2
Verna et al. 2010 ¹⁶¹	41	NR	NR	6	2	4	0	0
Langer et al. 2009 ¹⁶³	76	48	14	14	0	7	NR	0
Vasen et al. 2011 ¹⁵⁸	67	NR	NR	7	6	0	0	1
Canto et al. 2006 ^{159,173}	78	NR	NR	8	4	4	0	0

HRI=High risk individuals; NR=not reported

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Al-Sukhni et al. 2012 ¹⁶² Patient 1	57	1 FDR, 1 SDR panc ca	NR	4	NR	1.5 cm mass	NR	NA	Adenocarcinoma	Total pancreatectomy	30 months dz free, then local recurrence and died metastatic 6 months later
Al-Sukhni et al. 2012 ¹⁶² Patient 2	81	1 FDR, 2 SDR panc ca	NR	1	Normal- no cut off sign	Mult cysts, cut off head of panc periph duct	Before performed, weight loss jaundice, patient metastatic	NA	Adenocarcinoma	Percutaneous biopsy for metastatic disease	Within 2 months metastatic, 6 months died
Al-Sukhni et al. 2012 ¹⁶² Patient 3	65	BRCA2mut, 1 FDR	NR	5, patient missed year 4 exam	NR	3 cm mass	NR	NA	Adenocarcinoma	Biopsy	Liver mets, chemo
Al-Sukhni et al. 2012 ¹⁶² Patient 4	66	–	NR	1	NR	hypervasc lesion head of panc	NR	NA	Neuroendocrine tumor	Pancreatico- duodenectomy	6 years disease free
Al-Sukhni et al. 2012 ¹⁶² Patient 5	54	2 FDR,h/o uter canc	NR	1	NR	BD-IPMN x 2	NR	NA	PanIN-1a to PanIN-2	Distal pancreatectomy	Stable
Al-Sukhni et al. 2012 ¹⁶² Patient 6	54	1 FDR, 2 SDR panc ca	NR	1	NR	NR	BD-IPMN dysplastic cells	NA	BD-IPMN low- grade dysplasia, no cancer	Distal pancreatectomy (lap)	Stable
Study averages for Al-Sukhni et al. Patients 1-6 (above), patient follow-up = 50.4 Months	–	–	–	–	–	–	–	–	–	–	–

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Verna et al. 2010 ¹⁶¹ Patient 1	58	High	NR	1	NA	Mass with liver lesions	Mass with liver lesions	NR	Stage 4 pancreatic adenocarcinoma	FNA	NR
Verna et al. 2010 ¹⁶¹ Patient 2	61	High	NR	1	NA	NR	2cm mass	NR	Pancreatic carcinoma w IPMN and PanIN2	total pancreatectomy	NR
Verna et al. 2010 ¹⁶¹ Patient 3	47	High	NR	1	NA	NR	IPMN, irregular PD	IPMN, irregular PD	IPMN-B w mod dysplasia, mult PanIN2	distal pancreatectomy	NR
Verna et al. 2010 ¹⁶¹ Patient 4	56	High	NR	1	NA	NR	IPMN-B	IPMN-B	NR	distal pancreatectomy	NR
Verna et al. 2010 ¹⁶¹ Patient 5	40	Mod	NR	1	NA	IPMN-B	IPMN-B	NR	NR	distal pancreatectomy	NR
Verna et al. 2010 ¹⁶¹ Patient 6	45	Mod	–	1	NA	NR	1 cyst, elv cyst fluid	NR	Cyst, IPMN-B mod dysp, focal PanIN2	central pancreatectomy	NR
Study averages for Verna et al. Patients 1-6 (above), patient follow-up = NR	–	–	–	–	–	–	–	–	–	–	–

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Langer et al. 2009 ¹⁶³ Patient 1	NR	FPC	NR	NR	NA	hypointens e mass tail	diffuse changes, tail + hyperechoic nodule	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 2	NR	FPC	NR	NR	NA	hypointens e mass tail	diffuse changes, tail + hyperechoic nodule	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 3	NR	MPCS	NR	NR	NA	Normal	heterogenous mass, tail	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 4	NR	FPC	NR	NR	NA	Normal	diffuse changes, tail	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 5	NR	FPC	NR	NR	NA	Normal	diffuse changes, tail extrapanc nod	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 6	NR	MPCS	NR	NR	NA	Normal	diffuse changes, tail hyperechoic lesion	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 7	NR	FPC	NR	NR	NA	Normal	diffuse chnages, tail	NA	FNA- normal	FNA	NR
Langer et al. 2009 ¹⁶³ Patient 8	NR	Mod	93	NR	NA	Negative (panc), 2liver lesions	hypoechoic mass (head)	NA	No panc tumor, foc nodular hyperplasia in liver	Exploration, liver wedge resection	Incisional hernia
Langer et al. 2009 ¹⁶³ Patient 9	61	Mod	51	NR	NA	Negative	hypoechoic mass	NA	Serous oligocystic adenoma	Distal pancreatectomy + splenectomy	No pathologies

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Langer et al. 2009 ¹⁶³ Patient 10	61	High	60	NR	NA	Cystic lesion (head and tail)	Cystic lesion (head and tail)	NA	Serous oligocystic adenoma, lobular fibrosis PanIN1	Distal pancreatectomy + splenectomy	Cystic lesion prev known
Langer et al. 2009 ¹⁶³ Patient 11	54	Moderate	44	NR	NA	Hypochoic mass (tail)	Hypochoic mass (tail)	NA	Focal fibrosis PanIN1 + PanIN2	Distal pancreatectomy (spleen preserv)	No pathologies
Langer et al. 2009 ¹⁶³ Patient 12	42	Moderate	15	NR	NA	Cystic lesion (body)	Cystic lesion (body)	NA	Serous oligocystic adenoma	Distal pancreatectomy (spleen preserv)	No pathologies
Langer et al. 2009 ¹⁶³ Patient 13	54	High	12	NR	NA	Negative	Hypochoic mass (tail)	NA	Lobular fibrosis with PanIN1 + squms metaplasia	Distal pancreatectomy + splenectomy	No pathologies
Langer et al. 2009 ¹⁶³ Patient 14	53	Moderate	5	NR	NA	Hypochoic mass (tail)	Hypochoic mass (tail)	NA	Lobular fibrosis with PanIN1 + IPMN gastric type	Distal pancreatectomy (spleen preserv)	NIDDM
Study averages for Langer et al. Patients 1-14 (above), patient follow-up = 44 Months	–	–	–	–	–	–	–	–	–	–	–

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Vasen et al. 2011 ¹⁵⁸ Patient 1	62	NR	NR	1	NR	5 mm tumor head-body	NR	NA	Well diff adenocarc	Pancreaticoduodenectomy	Alive 22mos after dx
Vasen et al. 2011 ¹⁵⁸ Patient 2	49	NR	NR	1	NR	25 mm tumor tail	NR	NA	Mod diff adenocarcenoma	Distal pancreatectomy	Alive 17m after dx
Vasen et al. 2011 ¹⁵⁸ Patient 3	57	NR	NR	1 (overlooked at year 1, but visible in retrospect)	NR	10 mm tumor tail	NR	NA	Liver bx, poorly differentiated adenocarc	None- chemo – liver mets	Died from PC after 15mo
Vasen et al. 2011 ¹⁵⁸ Patient 4	55	NR	24	3	NR	12 mm tumor tail	NR	NA	Mod diff adenocarcenoma	Distal pancreatectomy	Died from pc after 22mo
Vasen et al. 2011 ¹⁵⁸ Patient 5	57	NR	28	2	NR	40 mm tumor tail	NR	NA	Mod diff adenocarcenoma	Distal pancreatectomy	Died after 22 mos
Vasen et al. 2011 ¹⁵⁸ Patient 6	70	NR	12	2	NR	20 mm tumor head-body	NR	NA	Mod diff adenocarcenoma	Resection pancreatic body and hemicolecotomy	Died from pc and met carcin after 5 mo
Vasen et al. 2011 ¹⁵⁸ Patient 7	55	NR	29	4	NR	10 mm tumor body	NR	NA	None – melanoma mets	No surgery, melanoma mets	Died from melanoma mets 12 mo
Study averages for Vasen et al. Patients 1-7 (above), patient follow-up = 48 Months	–	–	–	–	–	–	–	–	–	–	–

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Canto et al. 2006 ^{159,173} Patient 1	47	PJS personal and family hx	NR	1	Cystic lesion at uncinete process	NR	Cystic lesion at uncinete process	NR	IPMN w carcinoma in situ	Pancreatico-duodenectomy	NR
Canto et al. 2006 ^{159,173} Patient 2	NR	3 FDR	NR	1	Mult cysts in tail	NR	Lesion and dilated main duct w 2 small cysts	NR	BD-IPMN, PanIN-3 with poss microinvasive adenoca	Distal pancreatectomy	NR
Canto et al. 2006 ^{159,173} Patient 3	75	3 relatives	NR	1	IPMN	NR	Chronic pancr, 2 cystic lesions, MD dilation at head and body	Chronic pancr, 2 cystic lesions, MD dilation at head and body	Diffuse chronic pancreatitis, mult PanIN (1/2)	Pancreatico-duodenectomy	NR
Canto et al. 2006 ^{159,173} Patient 4	40	4 relatives NIDDM	NR	1	???	NR	Nodule in tail, mild pancreatitis	NR	Chronic pancreatitis, PanIN1-2	Distal pancreatectomy	NR
Canto et al. 2006 ^{159,173} Patient 5		3 relatives	NR	2	Enlarge-ment and changes in morphol-ogy of pancreatic head, IPMN, FNA mucinous duct epithelium	NR	Enlargement and changes in morphology of pancreatic head, IPMN, FNA mucinous duct epithelium	NR	2 benign BD-IPMN adenoma, chronic pancreatitis	Pancreatico-duodenectomy	NR

Table C-30. Screening studies: individual patient data for patients whose final diagnosis was based on surgery and/or biopsy (continued)

Study	Patient Age	Patient Risk	Patient Follow-up (Months)	# Year Lesion Found	CT Dx	MRI/MRCP Dx	EUS Dx	ERCP Dx	Final Pathology Dx	Final Procedure Performed	Follow-up
Canto et al. 2006 ^{159,173} Patient 6	NR	3 relatives	NR	2	Normal	NR	Focal panc duct dilation, at 1 year bd-IPMN, dilated main PD communicating cystic mass	Focal panc duct dilation, at 1 year bd-IPMN, dilated main PD communicating cystic mass	IPMN-adenoma, mild focal fibrosis, focal PanIN-1	Pancreatico-duodenectomy	NR
Canto et al. 2006 ^{159,173} Patient 7	76	5 relatives, BRCA2 mut, breast ca	NR	2	Normal pancreas initially, but ovarian mass; f/u CT cyst pancr duct uncinata	NR	Cyst communicating w panc duct in uncinata proc	NR	Adenocarcinoma	None	NR
Canto et al. 2006 ^{159,173} Patient 8	NR	2 FDR, 2 SDR	NR	2	Normal	NR	6 mm cyst head of pancr	NR	IPMN-adenoma, mult PanIN1-3	Pancreatico-duodenectomy	NR
Study averages for Canto et al. Patients 1-8 (above), patient follow-up = NR	–	–	–	–	–	–	–	–	–	–	–

Appendix D. Analyses and Risk of Bias Assessments

Analyses of Comparative Accuracy

Table D-1. Summary of Analyses of Comparative Accuracy

Comparison	Clinical Decision	# Studies	Measure	Test 1 Estimate and 95% CI ^a	Test 2 Estimate and 95% CI ^a	Logit Difference and 95% CI ^b	Statistically Significantly Different?	Precise Enough to Indicate Approximately Equivalent Accuracy?
MDCT angiography without 3D reconstruction vs. with 3D reconstruction	Resectability in those not staged	1	Sensitivity	89% (95% CI: 68% to 97%)	100% (95% CI: 83% to 100%)	-1.5 (-4.3 to 1.2)	No	NA
MDCT angiography without 3D reconstruction vs. with 3D reconstruction	Resectability in those not staged	1	Specificity	79% (95% CI: 64% to 89%)	100% (95% CI: 91% to 100%)	-3 (-5.5 to -0.5)	Yes	See above cell
MDCT vs. EUS-FNA	Diagnosis	3	Sensitivity	87% (95% CI: 82% to 91%)	89% (95% CI: 85% to 93%)	-0.2 (-0.8 to 0.4)	No	No
MDCT vs. EUS-FNA	Diagnosis	3	Specificity	67% (95% CI: 53% to 78%)	81% (95% CI: 68% to 90%)	-0.7 (-1.7 to 0.2)	No	See above cell
MDCT vs. MRI	Diagnosis	7	Sensitivity	89% (95% CI: 82% to 94%)	89% (95% CI: 81% to 94%)	-0.01 (-1.4 to 1.5)	No	Yes
MDCT vs. MRI	Diagnosis	7	Specificity	90% (95% CI: 80% to 95%)	89% (95% CI: 74% to 95%)	0.1 (-2.5 to 2.8)	No	See above cell
MDCT vs. PET/CT	Diagnosis	6	Sensitivity	85% (95% CI: 80% to 90%)	91% (95% CI: 85% to 94%)	-0.6 (-1.2 to 0.1)	No	NA
MDCT vs. PET/CT	Diagnosis	6	Specificity	55% (95% CI: 44% to 66%)	72% (95% CI: 61% to 81%)	-0.7 (-1.4 to -0.1)	Yes	See above cell
EUS-FNA vs. PET/CT	Diagnosis	1	Sensitivity	81% (95% CI: 62% to 91%)	89% (95% CI: 72% to 96%)	-0.6 (-2.1 to 0.8)	No	No
EUS-FNA vs. PET/CT	Diagnosis	1	Specificity	84% (95% CI: 62% to 94%)	74% (95% CI: 51% to 88%)	0.6 (-0.9 to 2.2)	No	See above cell

Table D-1. Summary of Analyses of Comparative Accuracy (continued)

Comparison	Clinical Decision	# Studies	Measure	Test 1 Estimate and 95% CI ^a	Test 2 Estimate and 95% CI ^a	Logit Difference and 95% CI ^b	Statistically Significantly Different?	Precise Enough to Indicate Approximately Equivalent Accuracy?
MRI vs. PET/CT	Diagnosis	1	Sensitivity	85% (95% CI: 64% to 95%)	85% (95% CI: 64% to 95%)	0 (-1.6 to 1.6)	No	No
MRI vs. PET/CT	Diagnosis	1	Specificity	72% (95% CI: 49% to 87%)	94% (95% CI: 74% to 99%)	-1.9 (-3.8 to 0.1)	No	See above cell
MDCT vs. EUS-FNA	Resectability in those not staged	1	Sensitivity	64% (95% CI: 46% to 79%)	68% (95% CI: 49% to 82%)	-0.2 (-1.2 to 0.9)	No	Yes
MDCT vs. EUS-FNA	Resectability in those not staged	1	Specificity	92% (95% CI: 75% to 98%)	88% (95% CI: 70% to 96%)	0.4 (-1.3 to 2.2)	No	See above cell
MDCT vs. MRI	Resectability in those not staged	2	Sensitivity	68% (95% CI: 47% to 85%)	52% (95% CI: 31% to 72%)	0.7 (-0.6 to 1.9)	No	No
MDCT vs. MRI	Resectability in those not staged	2	Specificity	89% (95% CI: 77% to 96%)	91% (95% CI: 80% to 97%)	-0.2 (-1.7 to 1.2)	No	See above cell
MDCT vs. EUS-FNA	T staging	1	T staging	Accurate T stage in 41% (95% CI: 20/49); overstaged T in 14% (95% CI: 7/49), understaged T in 44% (95% CI: 22/49)	Accurate T stage in 67% (95% CI: 33/49); overstaged T in 18% (95% CI: 9/49), understaged T in 14% (95% CI: 7/49)	RR 0.61 (0.41 to 0.90)	Yes	NA
MDCT vs. EUS-FNA	Vessel involvement	1	Sensitivity	56% (95% CI: 34% to 75%)	61% (95% CI: 39% to 80%)	-0.2 (-1.5 to 1)	No	No
MDCT vs. EUS-FNA	Vessel involvement	1	Specificity	94% (95% CI: 80% to 98%)	91% (95% CI: 76% to 97%)	0.4 (-1.3 to 2.1)	No	See above cell
MDCT vs. MRI	T staging	1	T staging	Accurate T stage in 73% (95% CI: CI 62% to 84%), overstaging in 2% (95% CI: CI 0%-6%), and understaging in 25% (95% CI: CI 14%-36%).	Accurate T stage in 62% (95% CI: CI 49% to 75%), overstaging in 6% (95% CI: CI 0%-12%), and understaging in 32% (95% CI: CI 19%-45%).	RR 1.17 (0.90 to 1.52)	No	No

Table D-1. Summary of Analyses of Comparative Accuracy (continued)

Comparison	Clinical Decision	# Studies	Measure	Test 1 Estimate and 95% CI ^a	Test 2 Estimate and 95% CI ^a	Logit Difference and 95% CI ^b	Statistically Significantly Different?	Precise Enough to Indicate Approximately Equivalent Accuracy?
MDCT vs. MRI	N staging	1	Sensitivity	38% (95% CI: 21% to 57%)	15% (95% CI: 5% to 36%)	1.2 (-0.2 to 2.6)	No	No
MDCT vs. MRI	N staging	1	Specificity	79% (95% CI: 63% to 90%)	93% (95% CI: 78% to 98%)	-1.3 (-2.8 to 0.2)	No	See above cell
MDCT vs. MRI	Metastases	5	Sensitivity	48% (95% CI: 31% to 66%)	50% (95% CI: 19% to 82%)	-0.09 (-1.2 to 1.0)	No	No
MDCT vs. MRI	Metastases	5	Specificity	90% (95% CI: 81% to 95%)	95% (95% CI: 91% to 98%)	-0.9 (-2.2 to 0.9)	No	See above cell
MDCT vs. MRI	Precise stage	1	Precise stage	Accurate TNM stage in 46% (95% CI: CI 33% to 59%), overstaging in 8% (95% CI: CI 1%-15%), and understaging in 46% (95% CI: CI 33%-59%).	Accurate TNM stage in 36% (95% CI: CI 23% to 49%), overstaging in 7% (95% CI: CI 0%-14%), and understaging in 57% (95% CI: CI 44%-70%).	RR 1.28 (0.81 to 2.01)	No	No
MDCT vs. MRI	Vessel involvement	2	Sensitivity	68% (95% CI: 55% to 79%)	62% (95% CI: 48% to 74%)	0.3 (-0.5 to 1.1)	No	Yes
MDCT vs. MRI	Vessel involvement	2	Specificity	97% (95% CI: 94% to 98%)	96% (95% CI: 93% to 98%)	0.3 (-0.6 to 1.2)	No	See above cell
MDCT vs. MRI	Resectability in those staged	1	Sensitivity	67% (95% CI: 48% to 81%)	57% (95% CI: 37% to 74%)	0.4 (-0.7 to 1.5)	No	No
MDCT vs. MRI	Resectability in those staged	1	Specificity	97% (95% CI: 84% to 99%)	90% (95% CI: 74% to 96%)	1.2 (-0.8 to 3.2)	No	See above cell
MDCT vs. PET/CT	N staging	1	Sensitivity	26% (95% CI: 14% to 43%)	32% (95% CI: 19% to 50%)	-0.3 (-1.4 to 0.8)	No	Yes
MDCT vs. PET/CT	N staging	1	Specificity	75% (95% CI: 50% to 90%)	75% (95% CI: 50% to 90%)	0 (-1.5 to 1.5)	No	See above cell
MDCT vs. PET/CT	Metastases	2	Sensitivity	57% (95% CI: 37% to 75%)	67% (95% CI: 47% to 83%)	-0.4 (-1.6 to 0.8)	No	NA
MDCT vs. PET/CT	Metastases	2	Specificity	91% (95% CI: 81% to 97%)	100% (95% CI: 95% to 100%)	-2.3 (-4.5 to -0.1)	Yes	See above cell

Table D-1. Summary of Analyses of Comparative Accuracy (continued)

Comparison	Clinical Decision	# Studies	Measure	Test 1 Estimate and 95% CI ^a	Test 2 Estimate and 95% CI ^a	Logit Difference and 95% CI ^b	Statistically Significantly Different?	Precise Enough to Indicate Approximately Equivalent Accuracy?
EUS-FNA vs. MRI	Precise stage	1	Precise stage	Accurate stage for 34/48 patients who had undergone surgical exploration. Of the 34, 34 were stage 2 and below, and 0 was stage 3 or above. The test understaged 13/48, and overstaged 1/48.	Accurate stage for 36/48 patients who had undergone surgical exploration. Of the 36, 35 were stage 2 and below, and 1 was stage 3 or above. The test understaged 12/48, and overstaged 0/48.	RR 0.94 (0.74 to 1.21)	No	Yes
MRI vs. PET/CT	Metastases	1	Sensitivity	57% (95% CI: 25% to 84%)	86% (95% CI: 48% to 97%)	-1.5 (-3.7 to 0.7)	No	No
MRI vs. PET/CT	Metastases	1	Specificity	86% (95% CI: 48% to 97%)	94% (95% CI: 64% to 100%)	-0.9 (-4 to 2.2)	No	See above cell

^a If multiple studies, this is the random-effects summary estimate, but if only one study, this is the single-study estimate

^b For most rows, this column indicates the results of statistical comparison of the two tests using equation 39 of Trikalinos.²⁵ A positive logit difference favors test 1, and a negative logit difference favors test 2. For rows with RR (relative risk), it is the results of the statistical comparison of the two rates using relative risk; RR>1 favors test 1 and RR<1 favors test 2.

NA – Not applicable since the question of equivalence does not apply when a statistically significant difference exists for either sensitivity or specificity

RR – Relative risk

Risk of Bias of Systematic Reviews

Modified AMSTAR Instrument^{19,174} for Systematic Reviews

The eight items in boldface below were required to be answered “Yes” in order for a systematic review to be considered low risk of bias. Otherwise, the review was rated moderate/high risk of bias.

1. Was an *a priori* design or protocol provided?
- 2. Was a comprehensive search strategy performed?**
- 2a. Was this strategy appropriate to address the relevant Key Question of the CER?**
3. Was a list of included and excluded studies provided?
- 4. Was the application of inclusion/exclusion criteria unbiased?**
- 4a. Are the inclusion/exclusion criteria appropriate to address the relevant Key Question of the CER?**
5. Was there duplicate study selection and data extraction?
6. Were the characteristics of the included studies provided?
- 7. Was the individual study quality assessed?**
- 7a. Was the method of study quality assessment consistent with that recommended by the Methods Guide?**
- 7b. Was the scientific quality of the individual studies used appropriately in formulating conclusions?
- 8. Were the methods used to combine the findings of studies appropriate?**
9. Was the likelihood of publication bias assessed?
- 10. Have the authors disclosed conflicts of interest?**

Table D-2. Risk of bias assessments of systematic reviews

Study	1	2	2a	3	4	4a	5 Sel.	5 Ext.	6	7	7a	7b	8	9	10	Meets Eight Most Important Criteria (Low Risk of Bias)
Madhoun et al. 2013 ²⁶	No	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	No	Yes	Yes
Puli et al. 2013 ¹⁶⁷	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	No
Chen et al. 2012 ²⁷	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes
Hewitt et al. 2012 ²⁸	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Wu et al. 2012 ³⁰	No	No	No	No	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes	No
Wu et al. 2012 ³¹	No	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No	No	Yes	No
Tang et al. 2009 ³²	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Zhao et al. 2009 ¹⁶⁸	No	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Hartwig et al. 2008 ¹⁶⁹	No	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes
Bipat et al. 2005 ²⁹	No	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No

Risk of bias criteria: 1–A priori design or protocol provided, 2–Comprehensive search performed, 2a–Search strategy appropriate to address key questions of this review, 3–Lists of both included and excluded studies provided, 4–Inclusion/exclusion criteria applied in an unbiased manner, 4a–Inclusion/exclusion criteria appropriate to address key questions of this review, 5 sel.–Study selection done in duplicate, 5 ext.–Data abstraction done in duplicate, 6–Characteristics of individual studies reported in evidence table, 7–Quality of each individual study assessed, 7a–Quality assessment consistent with that recommended by the Methods Guide, 7b–Quality of the individual studies used appropriately in formulating conclusions, 8–Data synthesis methods appropriate, 9–The likelihood of publication bias assessed in a qualitative or quantitative manner, 10–Conflicts of interest disclosed by authors. Questions 2, 2a, 4, 4a, 7, 7a, 8, and 10 were deemed “most important.”

Risk of Bias of Comparative Accuracy Studies

1. Did the study enroll all, consecutive, or a random sample of patients?
2. **Was the study unaffected by spectrum bias (e.g., patients with known status before the study, or patients selected for being difficult to diagnose/stage)?**
3. Was prior experience with the test (technicians, readers) similar for the two imaging tests being compared in the study?
4. **Were the imaging tests performed within one month of each other (to avoid the possibility that the patient's true condition changed between tests)?**
5. **Was knowledge of the other test complementary (either both tests were read with knowledge of the other results, or neither test was read with knowledge of the other)?**
6. **Did the interpreters have the same other information available at the time of interpretation for the two imaging tests (other clinical information, 3rd test results)?**
7. **Was each test's accuracy measuring using the same reference standard (or a similar proportion of patients who underwent different reference standards such as clinical follow-up and surgical findings)?**
8. **Were readers of both tests of interest blinded to the results of the reference standard (or the reference standard was unknowable until after the tests were read)?**
9. Were the people determining the reference standard unaware of the diagnostic test results?

We defined LOW risk of bias as a study that has a YES for the six boldfaced items above (#2, and #4-#8). We defined HIGH risk of bias as a study that has a NO (or Not Reported) for these six items. We defined MEDIUM risk of bias a study that meets neither the LOW nor the HIGH criteria.

Table D-3. Risk of bias assessments of comparative accuracy studies

Study	1	2	3	4	5	6	7	8	9	Comments	Risk of Bias
Fang et al. 2012 ⁴³	NR	Y	NR	Y	Y	Y	Y	Y	Y	–	Low
Herrmann et al. 2012 ⁶⁴	NR	Y	Y	N	Y	Y	Y	Y	NR	–	Moderate
Tellez-Avila et al. 2012 ⁶⁸	NR	Y	Y	NR	NR	NR	Y	Y	Y	Review of data obtained prospectively - EUS and CT - of pancreas lesion that then went to OR for surgical resection with goal of study being detection of vascular invasion, i.e., status of resectability. Not clearly stated but probably results of all tests to date available to all readers.	Moderate
Holzapfel et al. 2011 ⁷⁰	Y	Y	NR	Y	Y	Y	Y	Y	NR	Two radiologists looked at each images together and came to consensus. Analysis of MDCT and MRI images were spaced 4 weeks apart to avoid any learning bias	Low
Koelblinger et al. 2011 ⁵⁸	Y	Y	Y	Y	Y	Y	Y	Y	NR	Reading sessions for CT and MR were separated by at least 8 weeks to minimize recall bias, and images were presented to readers in a different randomized order	Low
Motosugi et al. 2011 ⁵⁷	NR	Y	N	Y	Y	Y	Y	Y	Y	–	Low
Rao et al. 2011 ⁵⁵	NR	N	Y	NR	Y	Y	Y	Y	NR	Bias against MRI because patients only had MRI if their case was more difficult (see Discussion section of the article). Small tumors only, which are harder to detect, thus possible spectrum bias.	Moderate
Shami et al. 2011 ⁷³	NR	Y	NR	NR	NR	NR	Y	Y	NR	Radiologists for MRI were blinded to EUS result, but did not report the order of the tests or whether EUS readers were blind to MRI result	Moderate
Takakura et al. 2011 ⁵⁶	NR	Y	Y	N	Y	Y	Y	Y	Y	Has flowchart for included patients, but doesn't say consecutive or all	Low
Imai et al. 2010 ⁷¹	NR	N	NR	NR	Y	Y	Y	Y	NR	Possible spectrum bias because authors imaged for the presence of a particular kind of mets that is hard to detect (para-aortic lymph node metastasis or PALN)	Moderate
Lee et al. 2010 ⁶²	Y	Y	Y	Y	Y	Y	Y	Y	NR	The interval between reads was 2 weeks to minimize learning bias.	Low
Kauhanen et al. 2009 ⁵⁹	Y	Y	NR	Y	Y	Y	Y	Y	NR	–	Low
Farma et al. 2008 ⁷²	NR	Y	NR	NR	NR	NR	Y	NR	Y	All patients had a peroperative biopsy performed by percutaneous or endoscopic means. Clinical, radiographic, and pathologic follow-up was evaluated for each patient	Moderate
Saif et al. 2008 ⁶⁵	NR	Y	NR	Y	Y	Y	Y	Y	NR	–	Low

Table D-3. Risk of bias assessments of comparative accuracy studies (continued)

Study	1	2	3	4	5	6	7	8	9	Comments	Risk of Bias
Schick et al. 2008 ⁵¹	Y	Y	NR	Y	NR	NR	Y	Y	NR	–	Moderate
Casneuf et al. 2007 ⁶³	Y	Y	NR	NR	N	Y	Y	Y	Y	One reader for MDCT, and two readers together for PET/CT (one of whom had read the MDCT image at least 2 months earlier, and one who had read the PET alone image 2 at least months earlier). For PET/CT they had to come to consensus. This design is a bias in favor of PET/CT because there were always 4 eyes on the PET/CT, whereas CT only had 2 eyes. In addition, the PET/CT assessment was probably influenced (improved?) by the two readers' prior memory of the two individual scans.	Moderate
Tamm et al. 2007 ⁵³	NR	Y	NR	NR	N	N	Y	Y	N	MDCT images were read without knowledge of clinical, pathologic, or surgical data, or EUS-FNA findings. EUS-FNA was performed with knowledge of the MDCT finding. Also the reference standard for some patients was determined by the FNA. This design is a bias in favor of EUS-FNA.	Moderate
Mehmet Ertuk et al. 2006 ⁶⁰	Y	N	NR	Y	Y	Y	Y	Y	Y	Patient statuses were all known beforehand, hence probably spectrum bias. MDCT was always read first. The interval between reads was 4 weeks to minimize learning bias.	Moderate
Heinrich et al. 2005 ⁶⁶	NR	Y	NR	Y	NR	NR	Y	NR	NR	Findings on PET/CT were compared with results of standard staging and validated by intraoperative findings and histology of the resected specimen or biopsies. For patients who were diagnosed to have benign pancreatic lesion by PET/CT and did not undergo resection, long-term outcome was assessed to confirm the diagnosis made by PET/CT	Moderate
Agarwal et al. 2004 ⁵⁴	Y	Y	NR	NR	NR	Y	Y	Y	Y	–	Moderate
DeWitt et al. 2004 ⁵⁰	NR	Y	Y	Y	Y	Y	Y	Y	N	Readers for neither test were blind to previous radiographic data. Readers of the 2nd test (which was always MDCT) were blind to results from the 1st (which was always EUS-FNA)	Low
Lemke et al. 2004 ⁶⁷	NR	Y	NR	Y	N	NR	Y	NR	NR	2 radiologists evaluated the original CT and PET images as well as the fused images in a randomized order in 3 different settings with an interval of 2 weeks each, using a standardized questionnaire.	Moderate
Soriano et al. 2004 ⁶⁹	Y	Y	NR	NR	Y	Y	Y	Y	Y	Surgeons only saw a combined report of all the imaging tests, and did not know individual imaging results	Low
Rieber et al. 2000 ⁶¹	NR	Y	NR	NR	N	Y	Y	Y	NR	Readers: 3 different radiologists blinded to all clinical data regarding the patient.	Moderate

Appendix E. Sensitivity Analyses for Meta-analyses Involving Multiple Readers per Study

Some comparative accuracy studies reported data separately for different readers. Our primary analyses discussed in the main report only used data from reader 1 for each such study. This appendix contains the results of sensitivity analysis of this choice, for two meta-analyses:

- MDCT versus MRI for diagnosis (a seven-study meta-analysis in which four of the seven studies reported multiple readers separately). Of the four studies, two reported three readers each, and two reported two readers each. Thus, we performed 35 sensitivity analyses ((2x3x2x3)-1 primary analysis).
- MDCT versus MRI for assessment of metastases (a five-study meta-analysis in which one of the five studies reported three readers separately. Thus, we performed 2 sensitivity analyses (3-1 primary analysis).

Sensitivity Analysis of MDCT vs. MRI for Diagnosis

The primary analysis yielded estimates for MDCT of 89% for sensitivity and 90% for specificity, whereas the estimates for MRI were 89% for sensitivity and 89% for specificity. The table below lists the results of the 35 sensitivity analyses; all analysis provided estimates that were very similar to the primary analysis.

Table E-1. Sensitivity analysis of MDCT vs. MRI for diagnosis

Which Readers were Used for the Four Studies Reporting Multiple Readers Separately	MDCT Sensitivity	MDCT Specificity	MRI Sensitivity	MRI Specificity
1,1,1,1 (primary analysis)	89% (95% CI: 82% to 94%)	90% (95% CI: 80% to 95%)	89% (95% CI: 81% to 94%)	89% (95% CI: 74% to 95%)
1,1,1,2	89% (95% CI: 83% to 94%)	90% (95% CI: 81% to 95%)	89% (95% CI: 80% to 94%)	88% (95% CI: 75% to 94%)
1,1,1,3	89% (95% CI: 83% to 94%)	90% (95% CI: 81% to 95%)	89% (95% CI: 81% to 94%)	89% (95% CI: 74% to 95%)
1,1,2,1	No convergence	No convergence	88% (95% CI: 80% to 93%)	90% (95% CI: 75% to 96%)
1,1,2,2	No convergence	No convergence	88% (95% CI: 80% to 93%)	89% (95% CI: 75% to 95%)
1,1,2,3	No convergence	No convergence	88% (95% CI: 80% to 93%)	90% (95% CI: 75% to 96%)
1,2,1,1	90% (95% CI: 82% to 94%)	90% (95% CI: 80% to 95%)	90% (95% CI: 80% to 95%)	89% (95% CI: 75% to 95%)

Table E-1. Sensitivity analysis of MDCT vs. MRI for diagnosis (continued)

Which Readers were Used for the Four Studies Reporting Multiple Readers Separately	MDCT Sensitivity	MDCT Specificity	MRI Sensitivity	MRI Specificity
1,2,1,2	90% (95% CI: 83% to 94%)	90% (95% CI: 81% to 95%)	90% (95% CI: 80% to 95%)	88% (95% CI: 75% to 94%)
1,2,1,3	90% (95% CI: 83% to 94%)	90% (95% CI: 81% to 95%)	90% (95% CI: 80% to 95%)	89% (95% CI: 75% to 95%)
1,2,2,1	89% (95% CI: 82% to 93%)	90% (95% CI: 80% to 95%)	89% (95% CI: 80% to 94%)	90% (95% CI: 75% to 96%)
1,2,2,2	89% (95% CI: 82% to 93%)	90% (95% CI: 81% to 95%)	89% (95% CI: 79% to 94%)	89% (95% CI: 75% to 95%)
1,2,2,3	89% (95% CI: 82% to 93%)	90% (95% CI: 81% to 95%)	89% (95% CI: 80% to 94%)	90% (95% CI: 75% to 96%)
1,3,1,1	90% (95% CI: 82% to 94%)	90% (95% CI: 80% to 95%)	90% (95% CI: 80% to 95%)	89% (95% CI: 75% to 95%)
1,3,1,2	90% (95% CI: 83% to 94%)	90% (95% CI: 81% to 95%)	90% (95% CI: 80% to 95%)	88% (95% CI: 75% to 94%)
1,3,1,3	90% (95% CI: 83% to 94%)	90% (95% CI: 81% to 95%)	90% (95% CI: 80% to 95%)	89% (95% CI: 75% to 95%)
1,3,2,1	89% (95% CI: 82% to 93%)	90% (95% CI: 80% to 95%)	89% (95% CI: 80% to 94%)	90% (95% CI: 75% to 96%)
1,3,2,2	89% (95% CI: 82% to 93%)	90% (95% CI: 81% to 95%)	89% (95% CI: 79% to 94%)	89% (95% CI: 75% to 95%)
1,3,2,3	89% (95% CI: 82% to 93%)	90% (95% CI: 81% to 95%)	89% (95% CI: 80% to 94%)	90% (95% CI: 75% to 96%)
2,1,1,1	91% (95% CI: 84% to 95%)	89% (95% CI: 80% to 95%)	91% (95% CI: 82% to 95%)	89% (95% CI: 77% to 95%)
2,1,1,2	91% (95% CI: 84% to 95%)	90% (95% CI: 81% to 95%)	90% (95% CI: 81% to 95%)	88% (95% CI: 78% to 94%)
2,1,1,3	91% (95% CI: 84% to 95%)	90% (95% CI: 81% to 95%)	91% (95% CI: 82% to 95%)	89% (95% CI: 77% to 95%)
2,1,2,1	90% (95% CI: 84% to 94%)	89% (95% CI: 79% to 94%)	90% (95% CI: 81% to 94%)	90% (95% CI: 78% to 96%)
2,1,2,2	No convergence	No convergence	89% (95% CI: 81% to 94%)	89% (95% CI: 78% to 95%)
2,1,2,3	No convergence	No convergence	90% (95% CI: 81% to 94%)	90% (95% CI: 78% to 96%)
2,2,1,1	92% (95% CI: 84% to 96%)	89% (95% CI: 80% to 95%)	92% (95% CI: 82% to 96%)	89% (95% CI: 78% to 95%)

Table E-1. Sensitivity analysis of MDCT vs. MRI for diagnosis (continued)

Which Readers were Used for the Four Studies Reporting Multiple Readers Separately	MDCT Sensitivity	MDCT Specificity	MRI Sensitivity	MRI Specificity
2,2,1,2	92% (95% CI: 84% to 96%)	90% (95% CI: 81% to 95%)	91% (95% CI: 81% to 96%)	88% (95% CI: 78% to 94%)
2,2,1,3	92% (95% CI: 84% to 96%)	90% (95% CI: 81% to 95%)	92% (95% CI: 82% to 96%)	89% (95% CI: 78% to 95%)
2,2,2,1	90% (95% CI: 84% to 94%)	89% (95% CI: 80% to 94%)	90% (95% CI: 81% to 95%)	90% (95% CI: 78% to 96%)
2,2,2,2	90% (95% CI: 84% to 94%)	90% (95% CI: 80% to 95%)	90% (95% CI: 81% to 95%)	89% (95% CI: 78% to 95%)
2,2,2,3	90% (95% CI: 84% to 94%)	90% (95% CI: 80% to 95%)	90% (95% CI: 81% to 95%)	90% (95% CI: 78% to 96%)
2,3,1,1	92% (95% CI: 84% to 96%)	89% (95% CI: 80% to 95%)	92% (95% CI: 82% to 96%)	89% (95% CI: 78% to 95%)
2,3,1,2	92% (95% CI: 84% to 96%)	90% (95% CI: 81% to 95%)	91% (95% CI: 81% to 96%)	88% (95% CI: 78% to 94%)
2,3,1,3	92% (95% CI: 84% to 96%)	90% (95% CI: 81% to 95%)	92% (95% CI: 82% to 96%)	89% (95% CI: 78% to 95%)
2,3,2,1	90% (95% CI: 84% to 94%)	89% (95% CI: 80% to 94%)	90% (95% CI: 81% to 95%)	90% (95% CI: 78% to 96%)
2,3,2,2	90% (95% CI: 84% to 94%)	90% (95% CI: 80% to 95%)	90% (95% CI: 81% to 95%)	89% (95% CI: 78% to 95%)
2,3,2,3	90% (95% CI: 84% to 94%)	90% (95% CI: 80% to 95%)	90% (95% CI: 81% to 95%)	90% (95% CI: 78% to 96%)

Note: “No convergence” means that the metandi command in stata did not converge on estimates, even after increasing the number of integration points to the maximum of 15.

Sensitivity Analysis of MDCT vs. MRI for Assessment of Metastases

The primary analysis yielded estimates for MDCT of 48% for sensitivity and 90% for specificity, whereas the estimates for MRI were 50% for sensitivity and 95% for specificity. The table below lists the results of the two sensitivity analyses; both provided estimates that were very similar to the primary analysis.

Table E-2. Sensitivity analysis of MDCT vs. MRI for assessment of metastases

Which Reader was Used for the Four Studies Reporting Multiple Readers Separately	MDCT Sensitivity	MDCT Specificity	MRI Sensitivity	MRI Specificity
1 (primary analysis)	48% (95% CI: 31% to 66%)	90% (95% CI: 81% to 95%)	50% (95% CI: 19% to 81%)	95% (95% CI: 91% to 98%)
2	48% (95% CI: 31% to 65%)	91% (95% CI: 81% to 96%)	54% (95% CI: 18% to 86%)	96% (95% CI: 93% to 98%)
3	48% (95% CI: 31% to 65%)	91% (95% CI: 81% to 96%)	54% (95% CI: 18% to 86%)	96% (95% CI: 93% to 98%)