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META-ANALYSIS

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Systematic Review and Meta-Analysis of Diagnostic Accuracy of Endoscopic Ultrasound (EUS)-Guided Fine-Needle Aspiration (FNA) Using 22-gauge and 25-gauge Needles for Pancreatic Masses

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) has been used for detecting pancreatic cancer. We aimed to compare the diagnostic yield of both 22-gauge and 25-gauge EUS-FNA for the detection of pancreatic cancer.

Material/Methods: We searched the electronic databases including PubMed, EMBASE, Web of Science, Scopus, and Cochrane Library up to June 13, 2017. Two reviewers independently screened studies and extracted data.

Results: We analyzed data from 1824 patients from 16 included studies. The estimated pooled data for the 22-gauge needles reported sensitivity was 0.89 (0.83–0.93), specificity was 1.00 (0.74–1.00), positive LR was 485.28 (2.55–92 000) and negative LR was 0.11 (0.07–0.17). Results for the 25-gauge needles showed the pooled sensitivity, specificity, positive and negative LR was 0.90 (0.86–0.93), 0.99 (0.89–1.00), 59.53 (7.99–443.66), and 0.10 (0.07–0.14), respectively. The 25-gauge needle had significantly higher pooled sensitivity than the 22-gauge needle (0.90 *vs.* 0.87, χ^2=5.26, *P*=0.02) while there was no difference in the pooled specificity (0.96 *vs.* 0.98, χ^2=2.12, *P*=0.15). The quality of most studies was assessed favorable using QUADAS-2 (quality assessment of diagnostic accuracy studies-2).

Conclusions: Our findings revealed that the 25-gauge EUS-FNA used for pancreatic lesions could have a higher diagnostic yield than using 22-gauge EUS-FNA. Nevertheless, well-designed prospective studies recruiting more patients are needed.

MeSH Keywords: **Diagnosis • Endoscopic Ultrasound-Guided Fine Needle Aspiration • Pancreatic Neoplasms**

Abbreviations: **EUS** – endoscopic ultrasound; **FNA** – fine-needle aspiration; **QUADAS-2** – quality assessment of diagnostic accuracy studies-2; **PRISMA** – Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **TP** – true positive; **FP** – false positive; **FN** – false negative; **TN** – true negative; **LR** – likelihood ratios; **DOR** – diagnostic odds ratio; **AUC-ROC** – receiver operating characteristic curve; **CA19-9** – carbohydrate antigen 19-9; **CEA** – carcinoembryonic antigen

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Background

Pancreatic cancer is the fourth fatal cause of cancer-related death in the world, and lacks definite diagnostic markers and causes poor prognosis, with a 5-year survival rate of only 1% to 4% [1]. Judging whether the pancreatic tumors are benign or malignant is crucial in choosing the optimal management. The ability to achieve the diagnosis of pancreatic cancer in asymptomatic patients can enable patients to have curative resection and better prognosis. Although many diagnostic imaging and biomarkers, like carbohydrate antigen 19-9 (CA19-9) and carcinoembryonic antigen (CEA), for this disease have been studied, most of these generated suboptimal results owing to their limited sensitivity, specificity, and positive predictive value [2,3].

In recent years, emerging minimally invasive tests for pancreatic cancer have been reported and endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is a promising diagnostic tool for pancreatic cancer. Numerous studies have suggested favorable accuracy of EUS-FNA for solid pancreatic lesions using the 22-gauge or the 25-gauge needle. The effectivity and accuracy of EUS-FNA are susceptible to some factors such as site, size, needle type, and operational experience. Needle selection for EUS-guided sampling can be complicated. Larger-bore needles might not always offer high-quality specimens [4]. Although 22-gauge needles could result in more samples, it could also add the risk of procedure-related complications like pancreatitis, hemorrhage, abdominal pain, perforation, and hypotension [5]. A previous study showed that the presence of bloody contamination and cellular debris in the 22-gauge needle made the pathological examinations difficult [6]. In EUS, the 25-gauge needle had less sampling but could more smoothly enter into the torqued trans-duodenal position for sampling pancreatic head or uncinate process lesions.

To date, only a small number of studies have been published in recent years related to which needles provided the better diagnostic yield, and results have been inconsistent. We performed this meta-analysis to contrast the differences in diagnostic yield of EUS-guided 22-gauge FNA with a 25-gauge EUS-FNA in sampling the pancreatic lesions.

Material and Methods

Search strategy

We conducted this systematic review and meta-analysis according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [7], and performed a systematic literature search from PubMed, EMBASE, Web of Science, Scopus, and Cochrane Library up to June 13, 2017 using the following words: 22-gauge, 25-gauge, EUS, endoscopic ultrasonography, FNA, pancreatic, cancer (Supplementary Text 1). We checked and found the potential published studies in additional literatures and previous meta-analyses [2,3]. All studies were searched with no language limitations. In cases where the necessary information was not available in articles, we also tried to email corresponding authors to obtain the required data.

Inclusion criteria

Studies fulfilling the following criteria were eligible for assessing diagnostic accuracy for pancreatic cancer: 1) reference standard for pancreatic cancer diagnosed by pathology on surgical specimen, or clinical follow-up (clinical and/or imaging studies) beyond 6 months indicating whether there was tumor progression or not; 2) access to the values of true positive (TP), false positive (FP), false negative (FN), and true negative (TN) of both 22-gauge and 25-gauge EUS-FNA.

Exclusion criteria

Studies were excluded if the following items were present: 1) review, guidelines and meeting abstracts; 2) study population overlapped with other studies; 3) non-human studies. Two reviewers independently checked and screened the studies from the literature. Disagreements existing were finally decided through a third reviewer.

Data extraction and quality assessment

Two individuals extracted data from the eligible articles using a predefined protocol, including author, type of study, country, race, number of patients, tumor size, site, age, gender, the reference standard category, length of follow-up, and complications. If potential diagnostic data were not available in a paper, an email was sent to the authors for these data. All studies in this meta-analysis underwent quality assessment using the quality assessment of diagnostic accuracy studies-2 (QUADAS-2). The tool comprised 4 key domains (patient selection, index test, reference standard, and flow of patients through the study) were each rated based on the risk of bias, and the first 3 domains were also appraised for concerns about applicability [8]. Any disagreements were resolved by discussion between authors.

Statistical analysis

For the existing or derived 2×2 contingency tables deriving from TP, FP, FN, and TN on the basis of consistency between biopsy result and surgical pathology or clinical radiologic result. In the eligible studies, we evaluated values of sensitivity and specificity and 95% confidence interval (CI). We evaluated

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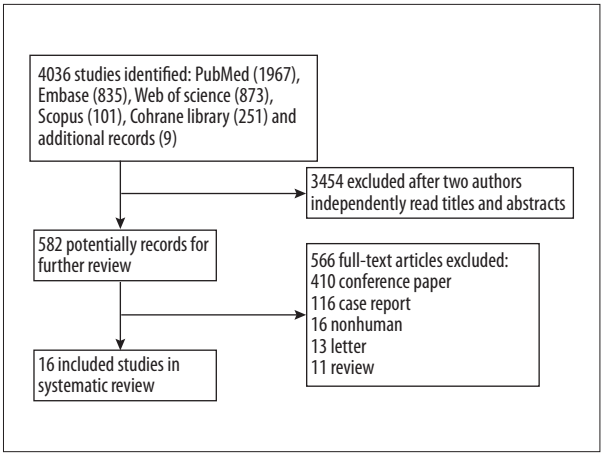

Figure 1. Study selection.

the pooled sensitivity, specificity, positive and negative likelihood ratios (LR), the diagnostic odds ratio (DOR), and the receiver operating characteristic curve (AUC-ROC) of EUS-guided FNA for pancreatic cancer using a bivariate mixed-effects regression model. We estimated statistical heterogeneity via the I^2 statistic [9]. Threshold effect was estimated through the Spearmen correlation coefficient. We used funnel plots and Egger's test to detect a potential publication bias [10]. We ruled that $P<0.05$ was statistical significant as for 2-sided tests. All statistical analyses were processed with Stata 12.0.

Results

Characteristics of eligible studies in the final analysis

Of 4036 records screened for titles or abstracts, 4020 papers were excluded and finally we found 16 articles that fulfilled the inclusion criteria (Figure 1), which comprised 6 retrospective and 10 prospective studies [11–26]. The baseline characteristics of the included studies are displayed in Table 1. Seven of the 16 included studies were done in Asian countries, 6 in North American countries, and 3 in European countries. Of 1824 recruited patients, 1108 patients with pancreatic masses underwent biopsies using 22-gauge needles and 877 patients by 25-gauge needles. Regarding the results of the quality estimation according to QUADAS-2, most studies were considered as favorable quality, part of which had unclear blind methods and length of follow-up (Table 2).

Meta-analysis of accuracy of EUS-FNA for diagnosis of pancreatic cancers

Overall, the diagnostic accuracy of 22-gauge and 25-gauge needles was high. The pooled data for 22-gauge needles reported sensitivity of 0.89 (0.83–0.93), specificity of 1.00 (0.74–1.00), positive LR of 485.28 (2.55–92 000), and negative LR of 0.11 (0.07–0.17). And results for 25-gauge needles showed pooled sensitivity, specificity, positive LR, and negative LR of 0.90 (0.86–0.93), 0.99 (0.89–1.00), 59.53 (7.99–443.66), and 0.10 (0.07–0.14), respectively (Figure 2 and Supplementary Figure 1). We compared the diagnostic accuracy of these 2 types of needles, and found that the pooled sensitivity was significantly higher in the 25-gauge needle (0.90 *vs.* 0.87, $\chi^2=5.26$, $P=0.02$), and slightly non-significant in pooled specificity (0.96 *vs.* 0.98, $\chi^2=2.12$, $P=0.15$). The AUC of SROC plots was both 0.97 (0.95–0.98) in 22-gauge and 25-gauge EUS-FNA (Figure 3). Threshold effects were not significant in the 2 groups (25-gauge: $r=0.033$, $P=0.905$; 22-gauge: $r=0.190$, $P=0.480$).

Sensitivity analysis and publication bias

Sensitivity analysis showed robust results and no difference after every study was ruled out. However, some significant evidence of publication bias was detectable across studies (25-gauge: $t=-3.02$, $P=0.009$; 22-gauge: $t=-5.14$, $P<0.001$).

Discussion

Pancreatic cancer is a devastating disease with a great burden on patients, for which a rapid and correct diagnosis is necessary. Earlier diagnosis might increase survival by estimated 30% to 40% [3]. We carefully reviewed the included studies to appraise the diagnostic accuracy of EUS-guided FNA for pancreatic cancer comparing the 22-gauge needle and the 25-gauge needle. Results from the meta-analysis showed that the 25-gauge needle had significantly higher pooled sensitivity than the 22-gauge needle (0.90 *vs.* 0.87, $\chi^2=5.26$, $P=0.02$) while there was not a significant difference in pooled specificity (0.96 *vs.* 0.98, $\chi^2=2.12$, $P=0.15$).

The diagnostic accuracy across studies had a similar heterogeneity (22-gauge: sensitivities 0.59 to 1.00; specificities 0.50 to 1.00; 25-gauge: sensitivities 0.68 to 1.00; specificities 0.80 to 1.00), both of which might showed that the methods are favorable. The heterogeneity in individual studies might result from the difference of study quality, prevalence, distribution of lesions, tumor size, or sample size. Although the pooled assessment of sensitivity and negative LR were fine, we should make a cautious conclusion. DOR combined the negative and curvilinear correlations between sensitivities and specificities, and we noted heterogeneity from studies regarding the different thresholds [27]. Thus, DOR might provide evidence for finding and treating patients earlier. In addition, SROC curves for EUS-FNA in pancreatic cancers showed that the AUC values were approximately close to 1 (AUC=0.97), which represented a favorable method to diagnose this disease. Higher positive LR revealed greater chance predicting adverse results while lower negative LR showed greater probability of achieving

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Table 1. Patient characteristics of included studies.

Author	Type of study	Country	Number of patients (22G/25G)	Tumor size, mm (22G/25G)	Site (22G/25G)	Age (22G/25G)	Gender (M/F) (22G/25G)	Reference standard	Follow-up, months	Complication
Imazu H et al. 2009	Prospective	Japan	12/12	NA	8 head; 3 body; 1 tail	NA	NA	Surgical pathology	NA	No
Lee JH et al. 2009	Prospective	America	12/12	NA	7 head or uncinate process; 3 body; 2 peripancreatic region	NA	NA	Surgical pathology or clinical follow-up	12.44	No
Siddiqui UD et al. 2009	Prospective	America	64/67	30.2	83 head	70.4	35/29; 47/20	Surgical pathology or clinical follow-up	NA	No
Sakamoto H et al. 2009	Prospective	Japan	24/24	32.8	6 head; 6 uncinate process; 12 body or tail	NA	NA	Surgical pathology or clinical follow-up	12	NA
Yusuf TE et al. 2009	Retrospective	America	540/302	NA	410 head; 100 body; 23 tail/NA	65/69	300/240; 172/130	Surgical pathology or clinical follow-up	6.5	No
Siddiqui AA et al. 2010	Retrospective	America	26/17	NA	NA	65.8±11.2	NA	Surgical pathology or clinical follow-up	6	NA
Camellini L et al. 2011	Retrospective	Italy	43/41	27±12/28±11	31 head/uncinate process/33 head/uncinate process	66/67	NA	Surgical pathology or clinical follow-up	6	NA
Fabbri C et al. 2011	Prospective	Italy	50/50	29±0.7	34 head; 8 uncinate process; 8 body	68.2±7.4	30/20	Surgical pathology or clinical follow-up	10.2 (6–27)	NA
Uehara H et al. 2011	Retrospective	Japan	54/66	NA	56 head; 42 body; 22 tail	63.31	72/43	Surgical pathology or clinical follow-up	NA	2 pancreatitis
Suzuki R et al. 2012	Prospective	Japan	20/20	27.6±21.1/27.6±12.2	15 body or tail/11 body or tail	67.9±8.5/67.5±8.7	11/9; 13/7	Surgical pathology or clinical follow-up	6	No
Lee JK et al. 2013	Prospective	Korea	94/94	33.2±1.5/37.7±1.9	31 head or uncinate process; 63 body or tail/53 head or uncinate process; 41 body or tail	58.5±11.8/61.3±11.1	54/40; 52/42	Surgical pathology or clinical follow-up	12	1 pancreatitis; 2 bleeding/6 pancreatitis; 4 bleeding
Vilmann P et al. 2013	Prospective	Denmark	28/31	30.9±14.46/28.4±12.1	NA	62±13.6/64±11.4	NA	Surgical pathology or clinical follow-up	6	No
Berzosa M et al. 2015	Retrospective	America	56/56	33	33 head; 5 uncinate process; 15 body; 2 tail; 6 peripancreatic lymph nodes	62±14.4	35/26	Surgical pathology or clinical follow-up	6	NA
Yang MJ et al. 2015	Retrospective	Korea	38/38	34.1±12.6/33.8±16.3	21 head or uncinate process; 17 body or tail/17 head or uncinate process; 21 body or tail	61.8±11.4/63.0±12.6	17/21; 18/20	Surgical pathology or clinical follow-up	8	No
Mavrogenis G et al. 2015	Prospective	America	19/19	39	NA	69	NA	Surgical pathology or clinical follow-up	7	No
Park SW et al. 2016	Prospective	Korea	28/28	35.3±17.1	24 head; 4 uncinate process; 18 body; 10 tail	65.8±9.5	35/21	Surgical pathology or clinical follow-up	6	No

NA – not available.

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Table 2. Quality assessment of included studies using QUADAS-2.

Author	Risk of bias				Applicability concerns		
	Patient selection	Index test	Reference standard	Flow & timing	Patient selection	Index test	Reference standard
Imazu H et al., 2009	LR	LR	LR	UR	HR	UR	LR
Lee JH et al., 2009	LR	LR	LR	LR	LR	LR	LR
Siddiqui UD et al., 2009	LR	LR	UR	LR	LR	LR	LR
Sakamoto H et al., 2009	LR	LR	LR	LR	LR	LR	LR
Yusuf TE et al., 2009	LR	LR	UR	LR	LR	LR	LR
Siddiqui AA et al., 2010	LR	LR	UR	LR	UR	LR	LR
Camellini L et al., 2011	LR	LR	LR	LR	HR	LR	LR
Fabbri C et al., 2011	LR	LR	LR	LR	LR	LR	LR
Uehara H et al., 2011	LR	LR	UR	LR	LR	LR	LR
Suzuki R et al., 2012	LR	LR	UR	LR	LR	LR	LR
Lee JK et al., 2013	LR	LR	UR	LR	LR	LR	LR
Vilmann P et al., 2013	LR	LR	LR	LR	LR	LR	LR
Berzosa M et al., 2015	LR	LR	UR	LR	LR	LR	LR
Yang MJ et al., 2015	LR	LR	LR	LR	LR	LR	LR
Mavrogenis G et al., 2015	LR	LR	LR	LR	LR	LR	LR
Park SW et al., 2016	LR	LR	LR	LR	LR	LR	LR

LR – low risk; HR – high risk; UR – unclear risk.

better outcomes [28]. The 2 needles both indicated strong diagnostic accuracy for ruling in pancreatic cancers (positive LRs beyond 10), but had less value for ruling out pancreatic cancers (positive LRs around 0.1).

In our results, some explanations should be considered for the higher accuracy of 25-gauge FNA needle in sampling pancreatic lesions. In these studies, most lesions were located in the head and uncinate process of the pancreas. Although the 22-gauge FNA needle could be useful for diagnosis with the pancreatic uncinate and head masses, its application in this scenario is limited. In this study, the selection bias might result in the underestimation of the true diagnostic performance for 22-gauge EUS-FNA. It has been reported that the 25-gauge needle had higher diagnostic accuracy for pancreatic tumors compared to that of the 22-gauge needle (91.7% *vs.* 75%) [11], and the 25-gauge EUS-FNA was also reported to be superior to 22-gauge EUS-FNA in technical success rate because of its flexibility with thinner caliber [29], especially for hard lesions needing extreme scope bending, and less complications.

To explain the results appropriately, several limitations should be noted in future research. First, the main source of bias within studies was associated with reporting of the reference standard and patient selection. Many studies used 2 approaches (surgical pathology or clinical follow-up) to confirm pancreatic cancer, which could affect the diagnostic accuracy. Second, blinding to the reference standard was not explicitly stated in some studies, which might lead to a risk of bias for results interpretation in these studies. Third, the length of follow-up in the included studies was not long, and it this might increase the risk of false-negative cases. Fourth, existing publication bias might also lead the physician to overestimate the availability of both these needles.

Despite the aforementioned limitations, we carefully conducted a systematic literature search using a predefined protocol, and tried to minimize the risk of publication bias by reading all potential studies from the citations in other literatures. The risk of bias was seriously evaluated using QUADAS-2. Data extracting was analyzed through a bivariate mixed-effects regression model.

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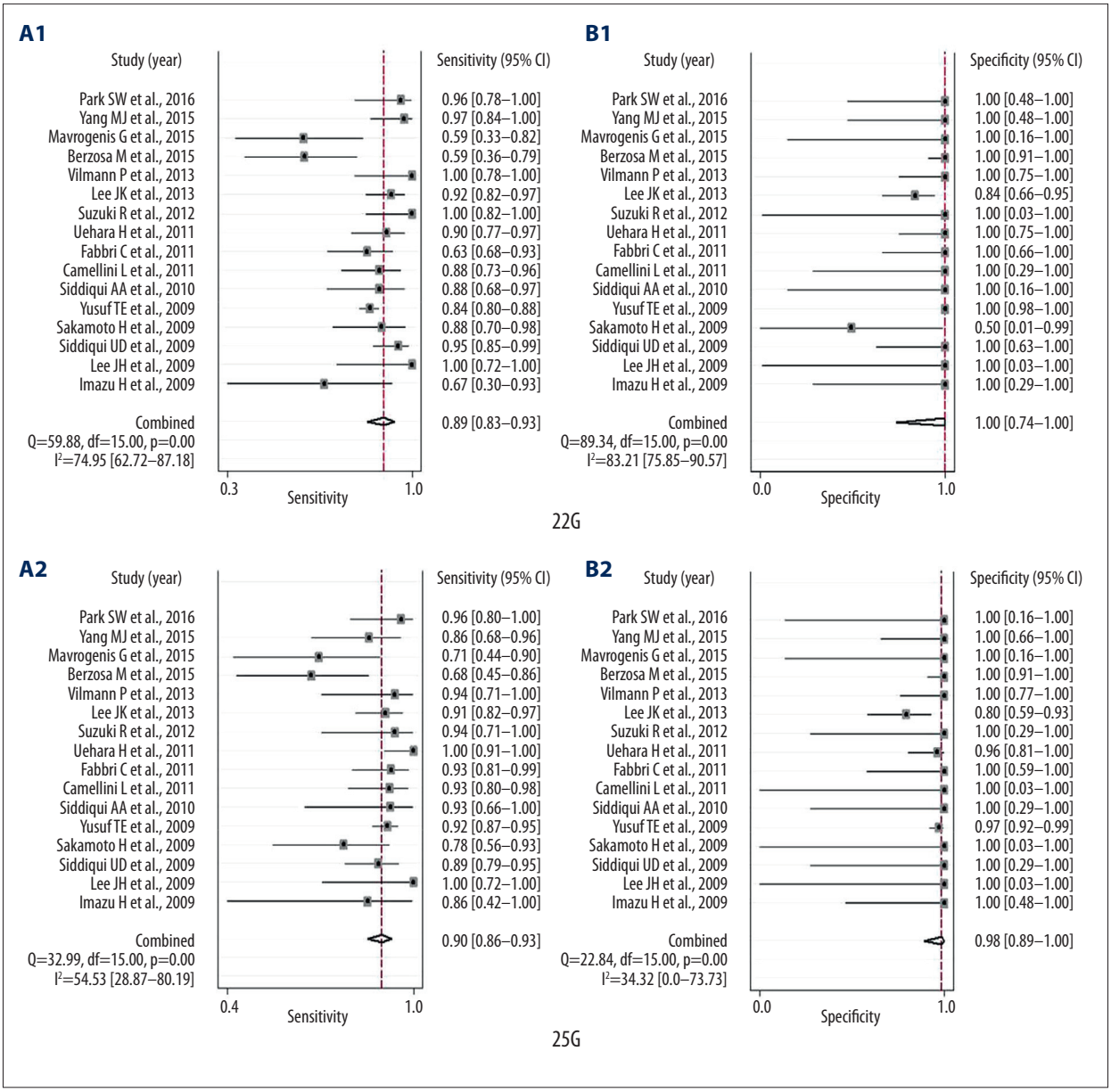

Figure 2. Forest plots showing sensitivity (**A1, A2**) and specificity (**B1, B2**) of all studies diagnosing pancreatic cancers by 22-gauge and 25-gauge endoscopic ultrasound-guided fine-needle aspiration.

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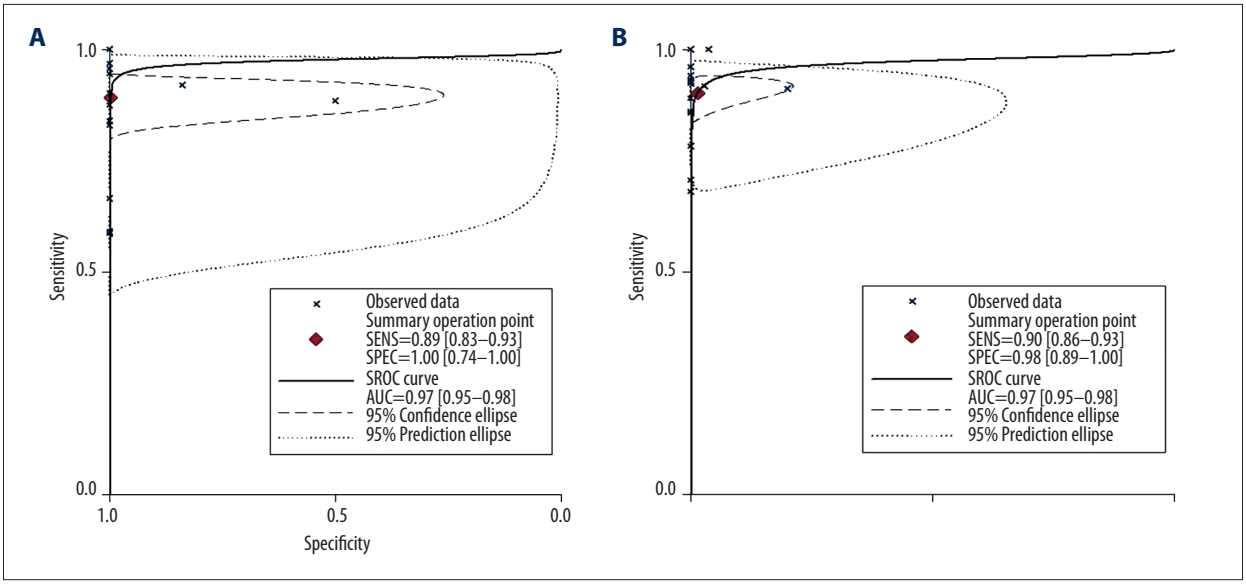

Figure 3. Summary SROC plot of studies diagnosing pancreatic cancers by 22-gauge (**A**) and 25-gauge (**B**) endoscopic ultrasound-guided fine-needle aspiration.

Conclusions

The meta-analysis suggested that 22-gauge and 25-gauge EUS-FNA for diagnosing pancreatic lesions had favorable results with a low risk of complications, but 25-gauge EUS-FNA might have a higher sensitivity for pancreatic tumor detection with good sensitivity. However, future well-designed prospective studies are required to identify the feasibility of different EUS-FNA needles for pancreatic lesions and address knowledge gaps.

Conflict of interest

None.

Supplementary Materials

Supplementary Text 1. Search strategy.

Search strategy:

Pubmed

1. 'endoscopic ultrasonography' OR EUS OR 'ultrasonic endoscope'
2. 22 AND 25 AND pancrea*
3. neoplasm OR cancer OR tumor OR tumour OR carcinoma OR oncology OR oncologic
4. #1 AND #2 AND #3
5. 'endoscopic ultrasonography'[Mesh]
6. 'pancrea' [Mesh]
7. 'cancer' [Mesh]
8. #5 AND #6 AND #7
9. #4 OR #8

Embase

1. 'EUS': ab,ti
2. 'endoscopic ultrasonography': ab,ti
3. 'ultrasonic endoscope': ab,ti
4. #1 OR #2 OR #3
5. '22': ab,ti
6. '25': ab,ti
7. 'pancrea': ab,ti
8. #5 OR #6 OR #7
9. 'neoplasm': ab,ti
10. 'cancer': ab,ti
11. 'tumor': ab,ti
12. 'tumour': ab,ti
13. 'carcinoma': ab,ti
14. 'oncology': ab,ti
15. 'oncologic': ab,ti
16. #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
17. #4 AND #8 AND #16

Scoups

1. TITLE-ABS-KEY ('EUS')
2. TITLE-ABS-KEY ('endoscopic ultrasonography')
3. TITLE-ABS-KEY ('ultrasonic endoscope')
4. #1 OR #2 OR #3
5. TITLE-ABS-KEY ('22')
6. TITLE-ABS-KEY ('25')
7. TITLE-ABS-KEY ('pancrea')

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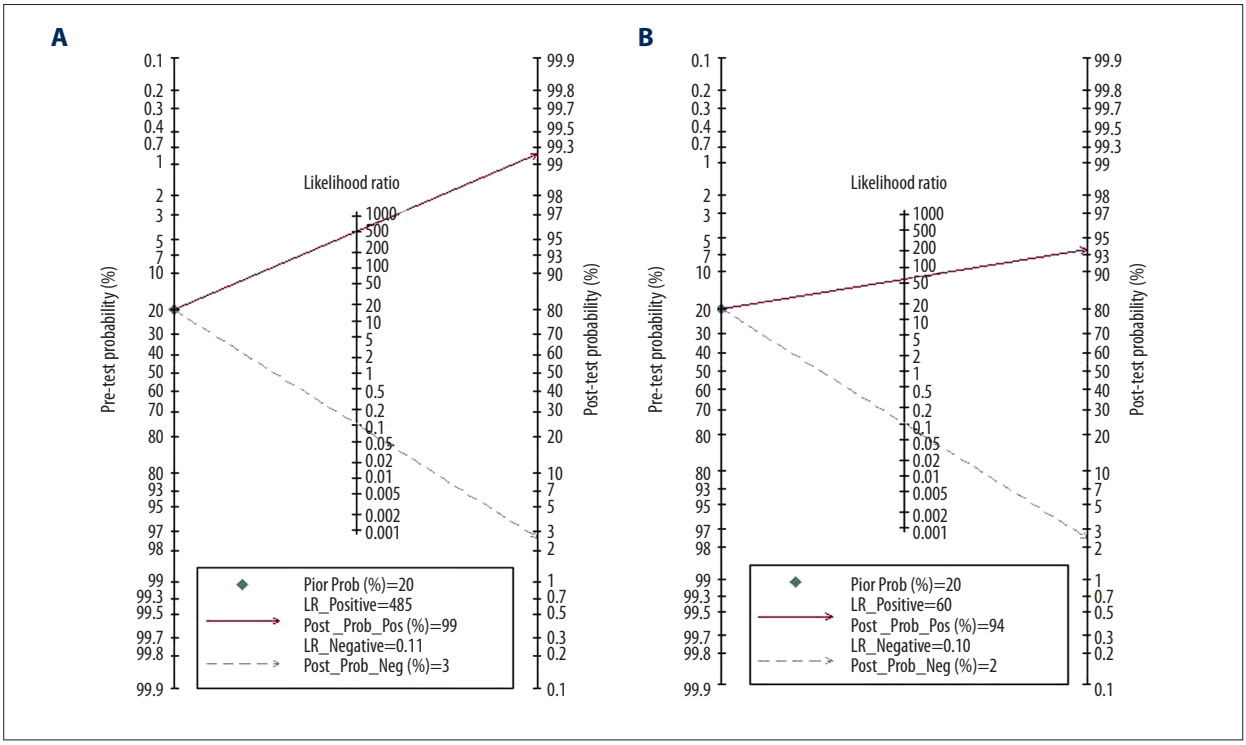
8. #5 OR #6 OR #7
9. TITLE-ABS-KEY ('neoplasm')
10. TITLE-ABS-KEY ('cancer')
11. TITLE-ABS-KEY ('tumor')
12. TITLE-ABS-KEY ('tumour')
13. TITLE-ABS-KEY ('carcinoma')
14. TITLE-ABS-KEY ('oncology')
15. TITLE-ABS-KEY ('oncologic')
16. #9 OR #10 OR #11 OR #12 OR #13 #OR #14 OR #15
17. #4 AND #8 AND #16

Web of science

1. TS=(endoscopic ultrasonography)
2. TS=(fine needle)
3. TS=(pancreatic)
4. TS=(cancer)
5. #1 AND #2 AND #3 AND #4
6. TI=(EUS)
7. TI=(endoscopic ultrasonography)
8. TI=(ultrasonic endoscope)
9. #6 OR #7 OR #8
10. TI=(22)
11. TI=(25)
12. TI=(pancrea*)
13. #10 AND #11 AND #12
14. neoplasm
15. cancer
16. tumor
17. tumour
18. carcinoma
19. oncology
20. oncologic
21. #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20
22. #9 AND #13 AND #21
23. #5 OR #22

Cochrane library

1. 'endoscopic ultrasonography' OR EUS OR 'ultrasonic endoscope'
2. pancrea*
3. neoplasm OR cancer OR tumor OR tumour OR carcinoma OR oncology OR oncologic
4. #1 and #2 and #3
5. MeSH descriptor: [Endosonography] explode all trees
6. MeSH descriptor: [Pancreatic Neoplasms] explode all trees
7. #5 and #6
8. #4 OR #7



Supplementary Figure 1. Fagan nomogram for pancreatic cancers using 22-gague (**A**) and 25-gauge (**B**) endoscopic ultrasound-guided fine-needle aspiration.

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