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Comparative diagnostic accuracy of EUS needles in solid pancreatic masses: a network meta-analysis

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ABSTRACT

Background and study aims Endoscopic ultrasound (EUS)-guided tissue sampling is the standard of care for diagnosing solid pancreatic lesions. While many two-way comparisons between needle types have been made in randomized controlled trials (RCTs), it is unclear which size and type of needle offers the best probability of diagnosis. We therefore performed a network meta-analysis (NMA) to compare different sized and shaped needles to rank the diagnostic performance of each needle.

Methods We searched MEDLINE, EMBASE and Cochrane Library databases through August, 2020 for RCTs that compared the diagnostic accuracy of EUS fine-needle aspiration (FNA) and biopsy (FNB) needles in solid pancreatic masses. Using a random-effects NMA under the frequentist framework, RCTs were analyzed to identify the best needle type and sampling technique. Performance scores (P-scores) were used to rank the different needles based on pooled diagnostic accuracy. The NMA model was used to calculate pairwise relative risk (RR) with 95 % confidence intervals.

Results Review of 2577 studies yielded 29 RCTs for quantitative synthesis, comparing 13 different needle types. All

22G FNB needles had an RR > 1 compared to the reference 22G FNA (Cook) needle. The highest P-scores were seen with the 22G Medtronic FNB needle (0.9279), followed by the 22G Olympus FNB needle (0.8962) and the 22G Boston Scientific FNB needle (0.8739). Diagnostic accuracy was not significantly different between needles with or without suction.

Conclusions In comparison to FNA needles, FNB needles offer the highest diagnostic performance in sampling pancreatic masses, particularly with 22G FNB needles.

Introduction

Pancreatic cancer remains one of the most lethal malignancies, with a 5-year survival rate of 9 % and an estimated 57,600 new cases a year [1]. Obtaining an adequate tissue sample for an accurate diagnosis represents a first step in the management of this deadly disease. Endoscopic ultrasound (EUS)-guided tissue acquisition via fine needle aspiration (FNA) or fine needle biopsy (FNB) is the standard method for sampling and diagnosing solid pancreatic masses [2, 3]. Endosonographers face a variety of choices when performing EUS-guided tissue sampling of solid pancreatic masses. Recent years have seen the development of FNB needles, which feature alterations of the cutting tip or a side-slot in an attempt to preserve tissue architecture to allow for histologic examination [4, 5]. Despite these technological advances, studies have not demonstrated a clear superiority of FNB needles over FNA needles [6–8]. Furthermore, the various sizes available of both FNB and FNA needles, ranging from 19G to 25G, offer a wide selection to the endoscopist with studies failing to clearly demonstrate a superiority of one size over the other [9–11]. Adding procedural techniques such as fanning and suction to the decision-making process further demonstrates the variety of choices presented to the endosonographer during the evaluation of solid pancreatic masses.

With the growing number of commercially available EUS needles, a number of randomized trials have compared needle types and sizes of needles. As conducting a randomized trial comparing all the different needle types, however, would pose significant logistical and financial challenges, we performed a network meta-analysis (NMA) to compare the different needles with the primary aim of determining the comparative diagnostic operating characteristics in an effort to provide high-quality evidence to the practicing endoscopist in selecting a needle for sampling a solid pancreatic mass.

Methods

Literature search

We searched PUBMED, EMBASE and Cochrane Central Register of Controlled Trials using a combination of MESH terms, EMTREE terms and keywords that describe EUS-FNA and FNB needles in solid pancreatic masses (see **Supplementary Material**). We used the Cochrane Highly Sensitive Search Strategy and the RCT filter for EMBASE as recommended by the Cochrane Handbook to identify RCTs [12]. The search had no language restrictions and included the period since inception of each database to August 2020. We also manually searched the bibliographies of relevant systematic reviews to identify trials for inclusion [6, 8, 10, 13, 14].

Eligibility criteria

We included RCTs that enrolled patients undergoing EUS and that evaluated the diagnostic accuracy of sampling techniques, EUS-FNA and FNB needles in solid pancreatic masses. We excluded conference abstracts, as the information required for the assessment of study quality as well as details related to the needle and outcome could not be adequately obtained.

Article review and data abstraction

We employed a systematic approach for reviewing the search results in accordance with the Cochrane guidelines [15] and Agency for Healthcare Research and Quality Methods Guide [16]. Four reviewers (SH, OA, AK, PH) independently reviewed titles, abstracts and full texts. In the title review stage, any study having a title potentially related to EUS was included. In the abstract review stage, any study evaluating FNA or FNB in pancreatic masses was included. During the full-text review, RCTs that compared EUS FNA and/or FNB needles were eligible for data abstraction. During the abstract and full-text review stages, we resolved conflicts by consensus. We consulted with an epidemiologist, biostatistician and an endoscopist when necessary during the review process. One reviewer abstracted data that were verified by a second reviewer, using pilot-tested data extraction forms containing all the variables of interest, including study design, population and agent characteristics, as well as the diagnostic accuracy. We assessed study quality using the Cochrane Collaboration's tool for assessing risk of bias in RCTs [17].

Outcome of interest

Diagnostic accuracy was the primary outcome of interest. The effect of the use of suction was the secondary outcome of interest.

Statistical analysis

To combine direct and indirect evidence for FNA and FNB needle performance, an NMA was conducted in R (3.6.2, R Foundation, Vienna, Austria) using a frequentist method based on a graph-theoretical approach according to the electrical network theory [18]. In the primary analysis, needles regardless of sampling technique were compared with each other. In the secondary analysis, needles were compared with each other with regards to the use of suction. We estimated summary relative risks (RRs) for dichotomous outcomes. We ranked the various treatments for the efficacy outcomes using performance (P)

scores [19]. The P scores are values between 0 and 1 and have an interpretation analogous to the surface under the cumulative ranking curve values (SUCRA) [20] and measure the extent of certainty that a treatment is better than another treatment, averaged over all competing treatments. P scores induce a ranking of all treatments that mostly follows that of the point estimates and thus reflects pooled diagnostic accuracy but takes precision into account [21]. Statistical significance was defined at a 2-sided α level of less than 0.05. We assumed that the between-study heterogeneity was the same for all treatment comparisons in the NMAs. Heterogeneity was quantified using the (within-design) Q statistic [22], the between-study variance τ^2, and the heterogeneity statistic I^2 [23]. There is a lack of a concrete methodology of assessing across-studies bias (publication bias) in NMA. Therefore, a comparison-adjusted funnel plot with accompanying Egger test for asymmetry was conducted [24]. The certainty of evidence in network estimates was assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) ratings [25, 26].

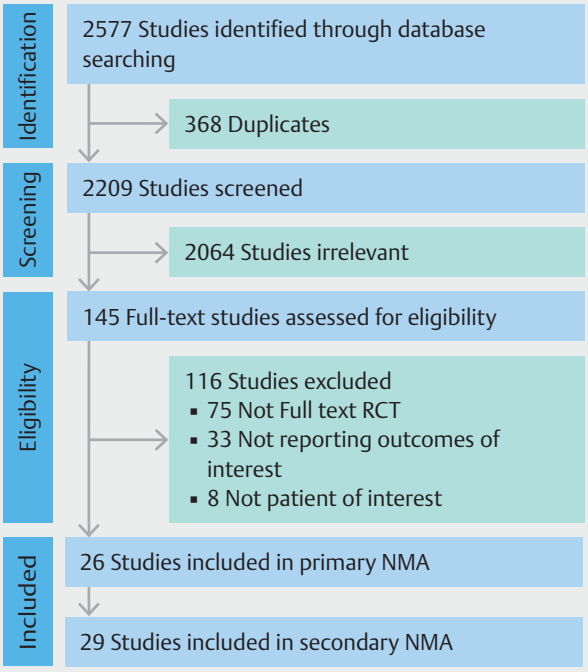
Results

Included studies

A total of 2577 studies were identified, of which 2209 were screened after removing duplicates (▶ **Fig. 1**). After full-text review of 145 studies, a total of 26 studies with 3398 subjects were included in the primary network meta-analysis. The network of randomized trials centered around comparison with the 22G EchoTip FNA needle (Cook, Bloomington, IN) is depicted in ▶ **Fig. 2** [27–50]. Comparison of the 22G FNA (Cook) and FNB (Cook) needles contained the largest number of studies (n = 5) followed by comparison (n = 3) between the 22G FNA (Cook) needle and the 25G FNA (Cook) needle. Other needles of investigations included 22G and 25G Boston Scientific FNA (Expect)/FNB (Acquire) needles (Marlborough, MA) [51–56], the 22G Olympus FNA/FNB needle (EZ Shot 3, Olympus America, Center Valley, PA) [57–59], the 22G Medtronic FNB needle (SharkCore, Dublin, Ireland) [51], the 25G Cook FNA needle [60], the 21G Hakko FNB needle (EUS Sonopsy CY, Tokyo, Japan) [61], and the 20G, 22G, and 25G Cook ProCore FNB needles [58, 62–64]. The baseline characteristics of the included randomized trials are depicted in ▶ **Table 1**. All studies came from Europe, Asia, and North America.

Diagnostic accuracy

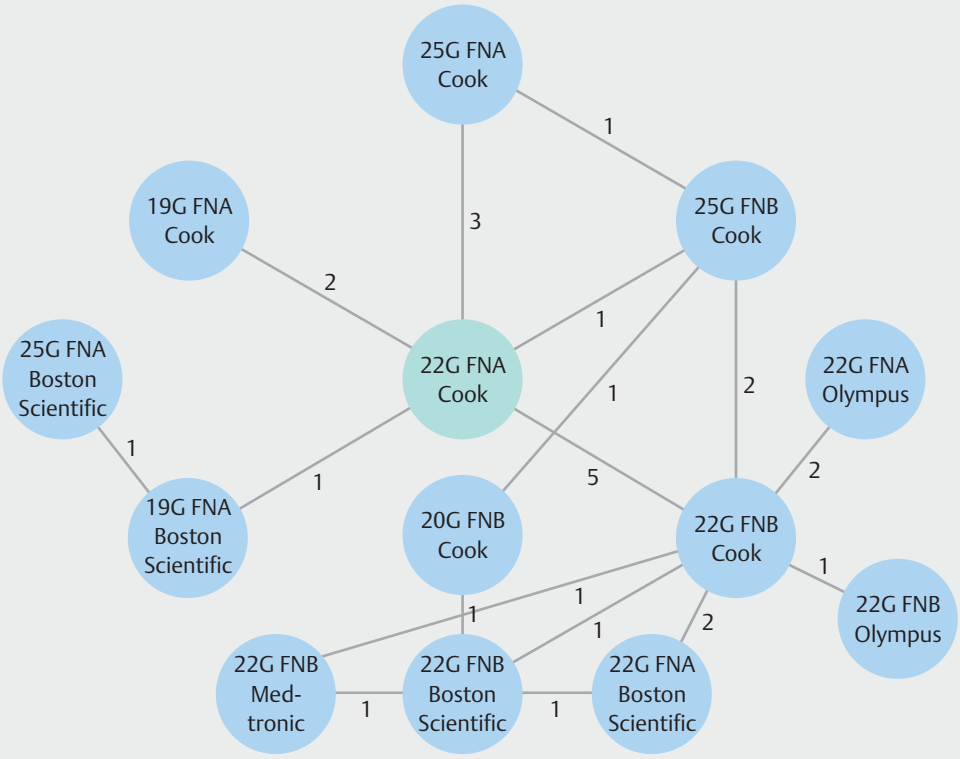
In terms of pooled diagnostic accuracy, the greatest performance score (0.9279, RR: 1.27, 95 % CI: 1.12–1.44) was seen in the 22 G SharkCore FNB needle (Medtronic) followed by the 22G EZ Shot 3 FNB needle (Olympus) with a performance score of 0.8962 (RR: 1.26, 95 % CI: 1.11–1.43) and the 22G Acquire FNB needle (Boston Scientific) with a performance score of 0.8739 (RR: 1.25, 95 % CI: 1.11–1.41) in comparison to the 22G FNA EchoTip (Cook) Needle (▶ **Fig. 3**). Concordantly, these are also reflected in the pairwise comparisons shown in **Supplementary Table 1** where these three 22G FNB needles (SharkCore, EZ Shot 3, and Acquire) had a significantly higher diagnostic performance than the 22G FNA and FNB Cook needles. In addition to the 3 aforementioned needles, the 22G Expect FNA needle (Boston Scientific) also had a significantly greater diagnostic accuracy (performance score 0.7963, RR: 1.19, 95 % CI: 1.07–1.33) than the 22G FNA needle (Cook). The 19G and 25G Expect FNA needles (Boston Scientific) had significantly lower diagnostic accuracy (25G performance score 0.0270, RR: 0.76, 95 % CI: 0.61–0.95; 19G performance score 0.0778, RR: 0.80, 95 % CI: 0.66–0.97) compared to the 22G FNA needle (Cook). The majority of FNB needles with the exception of the 21G FNB needle (Hakko) and 25G FNB needle (Cook) had a RR > 1 and corresponding performance scores greater than that of the reference 22G FNA needle. Relative risks of comparisons between specific needle types are shown in **Supplementary Table 1** with notable findings including the lack of any significant difference between the three top-performing FNB needles (22G SharkCore, EZ Shot 3, and Acquire). There was no significant heterogeneity within the study designs (Q statistic 13.17, $P = 0.15$) and no significant inconsistency between study designs (Q statistic 1.16, $P = 0.56$). The between-study variance τ^2 was 0.14, and the heterogeneity statistic I^2 was 23.2 %, corresponding to small amount of heterogeneity overall (< 25 %).



▶ **Fig. 1** Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flow diagram showing the inclusion of studies from literature review through network meta-analysis.

Secondary outcome

Supplementary Fig. 1 depicts a network Forest plot comparing needle size and type (regardless of manufacturer) by use of suction (**Supplementary Table 2**). In comparison to use of a 22G FNA needle with suction, diagnostic accuracy was not significantly different between any of the needles with or without



▶ **Fig. 2** Network of randomized controlled trials (RCT) comparing each of the EUS FNA needle against 22G FNA needle (Cook). The number adjacent to the lines connecting agents indicate the number of RCTs and number of patients randomized. FNA, fine needle aspiration; FNB, fine needle biopsy.

suction (22G FNB with suction performance score 0.6841, RR: 1.03, 95% CI: 0.98–1.08) with the exception of the 20G FNB needle with suction which performed significantly worse than the 22G FNA needle with suction (performance score 0.0504, RR: 0.79, 95% CI: 0.64–0.97). Relative risks comparing needle types with and without suction are shown in **Supplementary Table 3** and ▶ **Fig. 4**.

Quality of evidence

In examining the quality of the randomized studies included, we found that performance bias was potentially high due to the unblinded nature of the trials (**Supplementary Fig. 2**). Reporting bias was also of concern due to the selective reporting of diagnostic operative characteristics within studies in addition to inconsistent definitions. A funnel plot with Egger's test of the included studies did not find any significant publication bias ($P = 0.97$) (**Supplementary Fig. 3**). The certainty of evidence for the network estimates (CINeMA) in line with GRADE recommendations is reported in the **Supplementary Material**. The CINeMA framework gives moderate-high confidence rating to the top performing EUS needles suggesting credibility for translating the NMA results to practice.

Discussion

The results of this network meta-analysis provide a higher level of evidence for the greater diagnostic accuracy of FNB needles in comparison to FNA needles in the evaluation of pancreatic solid masses. Specifically, 22G FNB needles from Medtronic (SharkCore), Olympus (EZ Shot 3 Plus) and Boston Scientific (Acquire), respectively, had the three highest rates of obtaining the correct diagnosis compared to other needle types and gauges.

The SharkCore (Medtronic) is a fork-tip needle with six distal cutting-edge surfaces in an asymmetric design while the EZ Shot 3 Plus (Olympus) is a nitinol needle with a Menghini tip and the Acquire (Boston Scientific) has a crown-tip with three symmetrical surfaces containing three cutting edges. These needles were designed to not only acquire histologically intact tissue samples for indications such as subtyping of suspected lymphoma, autoimmune pancreatitis and neuroendocrine tumor, but also offer higher diagnostic accuracy. These needles were evaluated in a head to head fashion in a recent randomized trial by Bang et al [49]. They directly compared four different types of 22G FNB needles and similar to our results, found that the SharkCore (Medtronic) and the Acquire (Boston Scientific) performed best with diagnostic accuracies >90%, although with the application of suction, the EZ Shot 3 Plus (Olympus) had a comparable diagnostic accuracy of 87.9%

▶ **Table1** Characteristics of included randomized trials in the primary analysis comparing EUS needles.

Author, year	Country	Mean age ± SD	Female n (%)	Location of mass head/ uncinate n (%)	EUS needle evaluated	Number of patients or samples included/ analyzed	Positive diagnosis n (%) (accuracy)
Alatawi et al 2015 [28]	France	68 ± 11.2	15 (30)	38 (76)	22G FNA Cook	50	45 (90)
		67.8 ± 13.1	22 (44)	34 (68)	22G FNB Cook	50	50 (100)
Asokkumar et al 2019 [29]	Singapore	63.5 ± 11.4	16 (44)	NR	22G FNA Boston Scientific	20	18 (90)
				NR	22G FNB Boston Scientific	20	18 (90)
Bang et al 2012 [52]	USA	65.4 ± 11	12 (42.9)	20 (71.4)	22G FNA Boston Scientific	28	28 (100)
		65 ± 15.4	13 (46.4)	20 (71.4)	22G FNB Cook	28	25 (89)
Bang et al 2018 [51]	USA	71.3 ± 11	22 (44)	29 (58)	22G FNB Boston Scientific	50	47 (94)
					22G FNB Medtronic	50	49 (98)
Bang et al 2020 [49]	USA	71.9 ± 10.6	16 (48.5)	25 (75.8)	22G FNB Cook	33	28 (85)
		67.9 ± 13.8	13 (39.4)	27 (81.8)	22G FNB Olympus	33	33 (100)
		69.8 ± 9.9	18 (56.3)	24 (75)	22G FNB Boston Scientific	32	32 (100)
		63.8 ± 15.5	14 (45.2)	23 (74.2)	22G FNB Medtronic	31	31 (100)
Cheng et al 2018 [30]	China	58.3 ± 12.2	51 (40.7)	NR	22G FNA Cook	126	107 (85)
		58.3 ± 11.1	45 (36.4)	NR	22G FNB Cook	123	110 (89)
Cho et al 2020 [61]	Korea	69	23 (51.1)	24 (53.3)	20G FNB Cook	45	40 (89)
		64	17 (39.5)	23 (53.5)	25G FNB Cook	43	34 (79)
Fabbri et al 2011 [31]	Italy	68.2 ± 7.4	20 (40)	42 (84)	22G FNA Cook	50	43 (86)
					25G FNA Cook	50	47 (94)
Gimeno-García et al 2014 [32]	Canada	65.6 ± 11.3	61 (50.8)	43 (34.1)	22G FNA Cook	78	65 (83)
					25G FNA Cook	78	70 (90)
Hedenstrom et al 2018 [53]	Sweden	67	36 (53)	35 (51)	22G FNA Boston Scientific	68	53 (78)
					22G FNB Cook	68	47 (69)
Hucl et al 2013 [33]	India	51.7 ± 13.6	32 (46)	37 (54)	22G FNA Cook	69	51 (74)
					22G FNB Cook	69	59 (86)
Igarashi et al 2019 [61]	Japan	74.4 ± 9.0	19 (63.3)	13 (43.3)	22G FNB Cook	30	24 (80)
					21G FNB Hakko	30	22 (73)
Kamata et al 2016 [68]	Japan	68	53 (50)	NR	25G FNB Cook	106	84 (79)
		67	49 (45)	NR	25G FNA Cook	108	82 (76)
Karsenti et al 2020 [50]	France	Median (IQR): 69 (63–74)	22 (37)	32 (53)	20G FNB Cook	60	40 (67)
					22G FNB Boston Scientific	60	52 (87)
Laquière et al 2019 [34]	France	73	26 (41)	NR	22G FNA Cook	63	55 (87)
		70	22 (37)	NR	19G FNA Boston Scientific	59	41 (69)

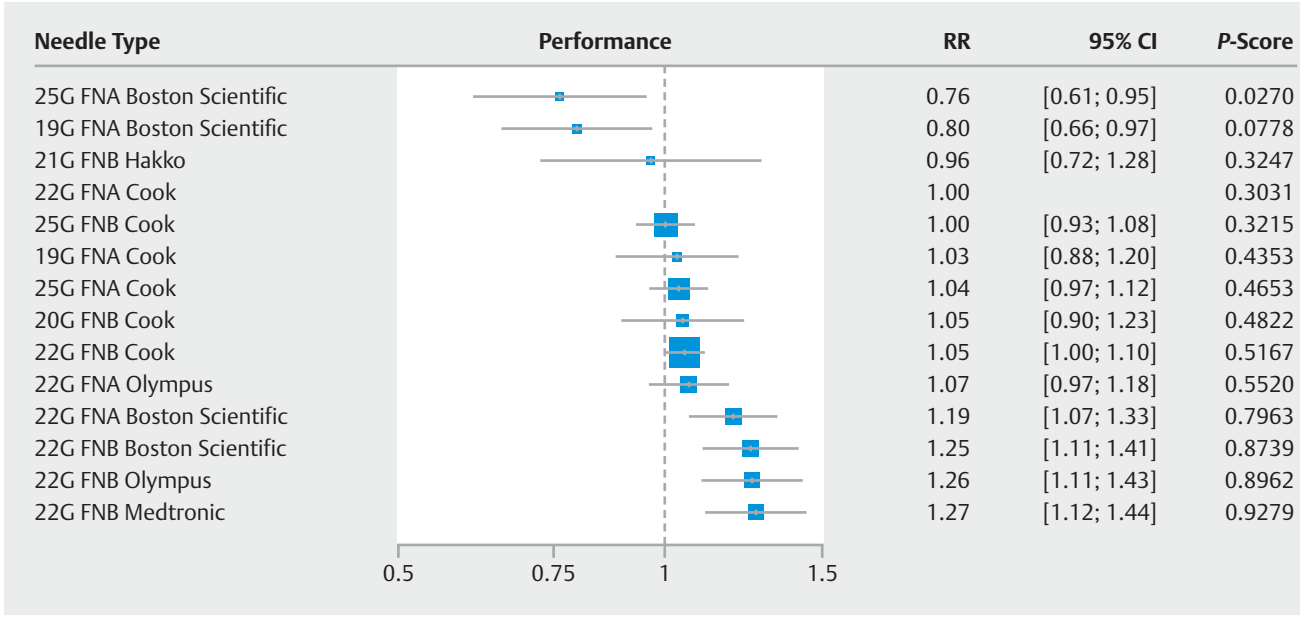
▶ **Table1** (Continuation)

Author, year	Country	Mean age ± SD	Female n (%)	Location of mass head/ uncinate n (%)	EUS needle evaluated	Number of patients or samples included/ analyzed	Positive diagnosis n (%) (accuracy)
Lee et al 2009 [35]	USA	NR	NR	7 (58)	22G FNA Cook	12	12 (100)
					25G FNA Cook	12	12 (100)
Mavrogenis et al 2015 [41]	Belgium	Median: 69	18 (67)	NR	22G FNA Cook	19	16 (84)
					25G FNB Cook	19	16 (84)
Noh et al 2018 [58]	Korea	61.6 ± 10	25 (41.7)	23 (38)	22G FNA Olympus	60	57 (95)
					22G FNB Cook	60	56 (93)
Park et al 2016 [63]	Korea	65.8 ± 9.5	21 (38)	28 (50)	22G FNB Cook	56	34 (61)
					25G FNB Cook	56	37 (66)
Ramesh et al 2015 [54]	USA	68.1 ± 11	19 (38)	30 (60)	19G FNA Boston Scientific	50	48 (96)
		68.8 ± 11	20 (40)	31 (62)	25G FNA Boston Scientific	50	46 (92)
Sakamoto et al 2009 [44]	Japan	NR	NR	12 (50)	19G FNA Cook	24	13 (54)
					22G FNA Cook	24	19 (79)
Song et al 2010 [48]	Korea	56.77 ± 12.13	26 (43)	26 (43)	19G FNA Cook	60	52 (87)
		58.63 ± 11.74	29 (51)	29 (51)	22G FNA Cook	57	45 (79)
Sterlacci et al 2016 [45]	Germany	68 ± 12	27 (48.2)	NR	22G FNA Cook	37	33 (89)
					22G FNB Cook	34	32 (94)
Tian et al 2018 [59]	China	61.4 ± 6.9	6 (33.3)	8 (44.4)	22G FNA Olympus	18	15 (83)
		61.2 ± 9.3	7 (38.9)	8 (44.4)	22G FNB Cook	18	15 (83)
Vanbiervliet et al 2014 [46]	France	67.1 ± 11.1	31 (39)	50 (62.5)	22G FNA Cook	80	74 (93)
					22G FNB Cook	80	72 (90)
Woo et al 2017 [64]	Korea	61.2 ± 12.8	41 (40)	41 (40)	22G FNB Cook	103	100 (97)
		61.3 ± 11.6	37 (36)	48 (47)	25G FNB Cook	103	94 (91)

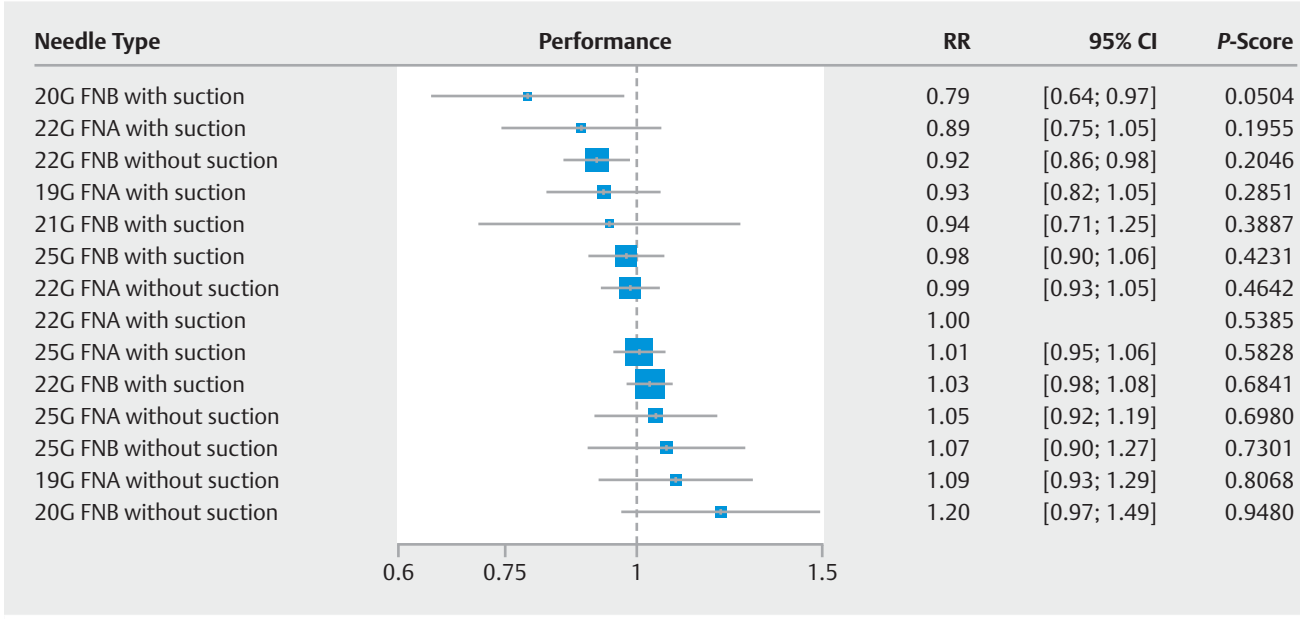
[49]. In contrast, Faciorusso et al. recently published a NMA that indicated no difference between FNA and FNB needles in the diagnostic accuracy of EUS-guided sampling of solid pancreatic masses [8]. Several factors may explain the differences in our results with Facciorusso et al. We were able to include data from several recent trials such as the aforementioned study by Bang et al, which were not yet available at the time of Facciorusso et al's date of search and support the high diagnostic accuracy of FNB needles. We also excluded conference papers not yet published in manuscript form to ensure a strict transitivity in our NMA. Furthermore, as seen in our network geometry, we delineated the needle types by brand of needle, using the most commonly studied needle (22G FNA Cook) as our reference needle. By doing so, we demonstrated a clear superiority of 22G FNB needles in this analysis with all the different types of 22G FNB needles having RRs greater than 1 in comparison to the reference needle. This supports the anecdotal thinking and leaning over the past several years since the mainstream introduction of the FNB needle as more and more endosonographers have increasingly utilized FNB needles over FNA needles in targeting solid lesions [30, 65].

Our results have immediate clinical practice implications. Given the availability of different needle shapes and sizes from different manufacturers, there are over 14 different needles available on the market. This wide array of options pose difficulties for practices to determine which needle is the best performing. Exploiting the ability of network meta-analysis, we were able to rank the needles from 1 to 14 with associated comparative risk ratios and performance scores. The presentation of our results potentially makes it easier for endosonographers to immediately assess the comparative performances of each needle.

In our secondary analysis, addition of suction did not appear to provide incremental improvement in diagnostic accuracy.



▶ **Fig. 3** Performance scores and relative risk (RR) of diagnostic accuracy in comparison to 22G FNA Cook Needle. FNA, fine needle aspiration.



▶ **Fig. 4** A network Forest plot comparing each of the EUS needles against a 22G Cook FNA needle including relative risk (RR) and 95 % confidence intervals (CI). A rank based on cumulative direct and indirect evidence using performance score from the network meta-analysis is included.

Several studies have supported the use of suction in tissue sampling with two randomized controlled trials demonstrating greater diagnostic accuracy in EUS-FNA of solid pancreatic masses [37, 56]. Studies comparing suction to no suction in FNB studies, however, are lacking. As a result, our NMA likely lacked the power to detect a meaningful difference between suction and no-susction method. Our findings suggest that application of suction to the FNB needle does not add incremental value to diagnostic accuracy during tissue acquisition but additional randomized clinical trials are warranted.

The main strength of this study was the use of a NMA to analyze multiple RCTs using rigorous methodology. In addition, we utilized the GRADE ratings to assess the certainty of evidence to make the data clinically applicable. Several limitations of the study, however, warrant further discussion. As with all network meta-analyses, there exists limited network connectivity as demonstrated in ▶ **Fig. 1** where there are a limited number of

head-to-head comparisons for several needle types. In addition, indirect evidence, while useful in situations with limited studies, must always be interpreted with caution, particularly given how diagnostic accuracies offer an estimate and not an exact probability of performance. None of the randomized studies were blinded, which introduces performance bias. Further, several factors associated with tissue sampling, i. e. fanning, ROSE, number of passes, could not be accounted for due to either unavailability of data or non-standardized nature of these variables in the included studies. Number of passes, which is a variable that affects sensitivity of EUS-guided tissue acquisition [42], was not recorded in most studies and may have affected our results. Lastly, we did not account for the cost of these needles. More studies are needed to assess the cost-effectiveness of the needles to not only guide individual endoscopists but endoscopy units as a whole given the financial reality of cost limitations and restraints with industry-institution contracts.

Conclusions

In summary, this network meta-analysis suggests that 22G FNB needles offer greater diagnostic performance in the sampling of solid pancreatic masses in comparison to FNA needles. These results may help guide endoscopists in the important decision of choosing which needle to use for pancreatic mass tissue sampling. Choosing a needle with a high diagnostic accuracy can help endoscopists meet the quality indicator threshold as advocated by the US and European societies of having a sensitivity ≥ 85 % in pancreatic masses and most importantly, deliver the highest-quality care to each patient [66, 67].

Competing interests

The authors declare that they have no conflict of interest.

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CORRECTION

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In the above mentioned article the name of a co-author was misspelled. Correct is: Papachristou