

Comparison of endoscopic ultrasound-guided tissue acquisition using 22 G versus 20 G procure needles in solid lesions: a pilot study

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Background and aim

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) allows tissue acquisition from solid lesions. The endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) needle was developed to improve diagnostic yield by acquisition of histological core. The impact of the needle type (FNA or FNB) on the diagnostic yield and the technical success needs to be further studied. Therefore, the aim of our study was to compare the diagnostic accuracy and technical success of the 22-G FNA needle with the 20-G procure FNB needle in solid lesions.

Patients and methods

The study was designed as a pilot study conducted on cases with solid mediastinal, pancreatic, and intra-abdominal lesions, and the patients involved were then randomized for tissue sampling using either the standard 22-G FNA needle or the new 20-G procure FNB needle.

Results

In this six-month study, 50 patients including 29 male individuals and 21 female individuals, with a mean age of 57.1±12.3 years (range: 15–80 years) were enrolled. No significant difference was detected between FNA 22 G and FNB 20 G as regards the diagnostic accuracy or the technical success rates. However, there was a significant difference in the number of passes needed to reach diagnosis. The success rate of first pass for FNA 22 G and FNB 20 G was 69 and 92.5%, respectively ($P=0.014$, 95%CI).

Conclusion

EUS-guided FNA and FNB have comparable diagnostic accuracy for solid lesions. The 20-G FNB needles are easy to handle in anatomically challenging locations and required fewer needle passes to reach diagnosis.

Keywords:

20 G procure needle, endoscopic ultrasound, endoscopic ultrasound-guided fine-needle aspiration, endoscopic ultrasound-guided fine-needle biopsy

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Introduction

Linear endoscopic ultrasound (EUS) creates real-time images of the gastrointestinal tract and adjacent organs, which allows identification of suspected malignancies [1]. Moreover, EUS-guided fine-needle aspiration (EUS-FNA) allows tissue acquisition from mediastinal, pancreatic, and intra-abdominal lesions under direct visualization [2]. However, the real efficacy of EUS-FNA in practice is affected by the site, size, and properties of the target lesion [3]. Despite its success, EUS-FNA still has several limitations. First, the diagnostic accuracy is affected by the availability of rapid onsite cytopathological examination (ROSE) [4]. Second, it is difficult to differentiate between well-differentiated tumors and regenerative inflammatory tissue only on the basis of cytological specimens. Third, accurate diagnosis of some tumors such as

lymphoma or neuroendocrine tumors may require histological assessment of tissue architecture or immunohistochemical staining [5]. Therefore, there is a clear need for alternative techniques to improve the diagnostic accuracy of EUS-guided tissue acquisition.

The endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) device using a core biopsy needle was developed to improve diagnostic yield by acquisition of both cytological aspirates and histological core samples. However, it is not feasible to use large-caliber needles in the torqued transduodenal approach, and some

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technical failures have been reported [6]. Recently, a new EUS needle has been launched: the 20-G procure needle (Cook medical, Bloomington, Indiana, USA). This EUS needle was designed to combine the best features of currently available needles: a large caliber for better histological tissue sampling and a flexibility approximating that of the 25-G needle, which allow easy manipulation in anatomically challenging locations.

The impact of the needle type (FNA or FNB) on the diagnostic yield and the technical success needs to be further studied. Therefore, the aim of our study is to compare the diagnostic accuracy and technical success of the standard 22-G FNA needle to the new 20-G procure FNB needle in solid lesions.

Patients and methods

Patients

A total of 50 patients with solid mediastinal, intra-abdominal, and pancreatic lesions over the 6-month study period spanning from January 2017 to July 2017 at the EUS Unit of the Department of Gastroenterology of Mansoura Specialized Medical Hospital, Mansoura University, Egypt, were included in the study. To avoid selection bias, no single patient with a solid lesion over the study period was excluded.

The inclusion criterion was as follows: patients who require EUS and EUS-guided tissue acquisition after an imaging study (computed tomography, MRI, and ultrasound) that shows either mediastinal, pancreatic, or intra-abdominal solid lesions (size >1 cm). The exclusion criteria were as follows: patients who did not accept to engage in the study, cystic lesions or lesions with predominant cystic areas, patients with a contraindication to interventional endoscopy, such as patients unfit for anesthesia or patients with coagulation disorders, and patients in whom the final diagnosis was not known. The study protocol was approved by our ethical committee, and informed consents were taken from all patients before the procedure.

Methods

The study was designed as a pilot study carried out on cases with solid mediastinal, pancreatic, and intra-abdominal lesions, and the patients involved were then randomized for tissue sampling using either the standard 22-G FNA needle (Cook medical) or the new 20-G procure FNB needle (Cook medical). On the day of the procedure; eligible patients were appointed to the endoscopy room for EUS examination under intravenous propofol sedation. EUS examination was

performed in all patients with a linear Echoendoscope Pentax EG3870UTK (PENTAX medical, Tokyo, Japan) attached to a Hitachi Avius ultrasound system (Hitachi Medical Systems, Tokyo, Japan). All examinations were performed by two experienced endosonographers.

Procedural technique

To avoid technical biases, the same technique was used for tissue sampling with both FNA and FNB needles. The echoendoscopist used color Doppler to identify the optimal position for puncture without intervening vessels between the needle and target lesion, and the needle was then inserted into the target tissue under EUS guidance. After the lesion was penetrated by the needle, the needle was moved to and fro 10–15 times in different directions while the stylet was slowly removed (slow pull technique). After each pass, tissue material was divided into two parts: the first one was smeared onto slides and fixed with 95% alcohol, and the second one was placed in a formalin tube, instantly name tagged and labeled. One pass was made using the FNA or FNB needle. If no adequate tissue sample in the first pass was obtained, another pass was performed with the same needle, but with the application of the 10 ml suction syringe during the to and fro movements within the lesion, and the suction was released before the needle removal. No pathologist was present in the room, and all samples were sent to the pathology department for evaluation.

Cytopathological analysis

All slides were stained with hematoxylin and eosin, and all tissue samples fixed in formalin were placed in paraffin, and stained with hematoxylin and eosin for evaluation for the presence of a histologic core. One cytopathologist with experience in gastrointestinal cytology and blinded to the type of the needle examined all prepared slides and tissue samples. The final cytological diagnosis was classified into four diagnostic categories: (a) positive for malignancy, (b) suspicious for malignancy (atypical), (c) negative for malignancy, and (d) nondiagnostic.

Final diagnosis standard reference

One of the following methods was used for final diagnosis: (a) surgical sample with definite diagnosis of malignancy, (b) EUS-FNA or EUS-FNB positive or suspicious for malignancy with imaging follow-up convenient with malignant disease, (c) EUS-FNA or EUS-FNB negative for malignancy and no malignant evidence in imaging for at least 6 months of follow-up.

Outcome parameters

The patients' medical records were revised for the standard data, which included patient demographics, indication of the procedure, complications of the procedure, cytopathological results and follow-up results. The primary outcome was diagnostic accuracy of FNA and FNB. The secondary outcomes were technical success, complications, and the number of passes required for diagnosis.

Sample size

Sample size was calculated using Power Analysis and Sample Size software program (PASS, kaysville, Utah, USA) version 11.0.4 for windows (2011) with the overall accuracy of the needle as the primary outcome of the study. To the best of our knowledge, no similar comparison between the 22 G FNA and the 20 G FNB is present in the literature; hence, this study was conducted as a pilot study. We based our calculations on the results of the comparison between 22 G FNA and 22 G FNB in the literature, assuming that the accuracy of the 20 G FNB will be comparable to that of the 22 G FNA. A case controlled study will require group sample sizes of 66 patients in each group (total of 132 patients) to achieve 80% power and detect a difference between the needles' accuracy of 9.7%. The test statistic used is the two-sided Likelihood Ratio test (χ^2 -test) with a significance of 0.05 ($\alpha=0.05$) and $\beta=0.2$. As a pilot study requires 10% or more of the calculated sample size, a total of 50 patients were recruited in this pilot study.

Statistical analysis

IBM's SPSS statistics (statistical package for the social sciences) for windows (version 24; SPSS Inc., Chicago,

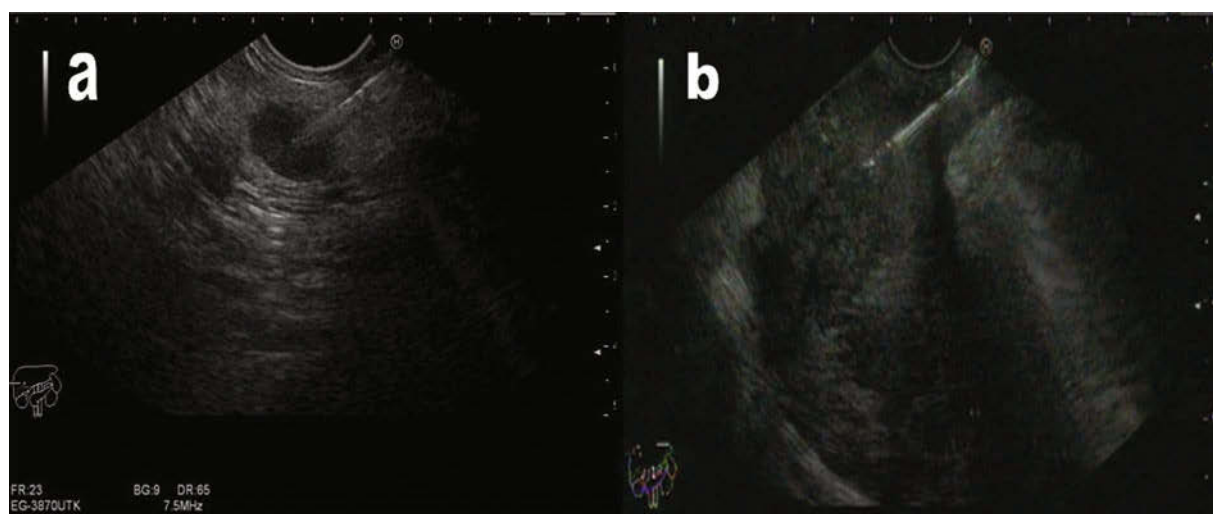
Illinois, USA) was used for statistical analysis of the collected data. Shapiro–Wilk test was used to check the normality of the data distribution. Normally distributed continuous variables were expressed as mean \pm SD, whereas categorical variables and the abnormally distributed continuous ones were expressed as median or number and percentage (as appropriate). Student's *t*-test and Mann–Whitney test were used for normally and abnormally distributed continuous data, respectively. χ^2 -Test was used for categorical data. All tests were conducted with 95% confidence interval. Accuracy, sensitivity, specificity, positive predictive value and negative predictive value were calculated by 'crosstabs' function. *P* (probability) value less than 0.05 was considered statistically significant.

Results

In this 6-month study, 50 patients including 29 male individuals and 21 female individuals with a median age of 57.1 \pm 12.3 years (range: 15–80 years) were enrolled. They were randomized to either FNA 22 G (29 patients) or FNB 20 G (21 patients) (Figs 1 and 2). No patient experienced technical difficulties with either needle malfunction or difficult procedure. Only one case among the FNA 22 G patients was complicated by bleeding from esophageal varices following transesophageal mediastinal lesion sampling. The bleeding was immediately controlled by band ligation with no further complications.

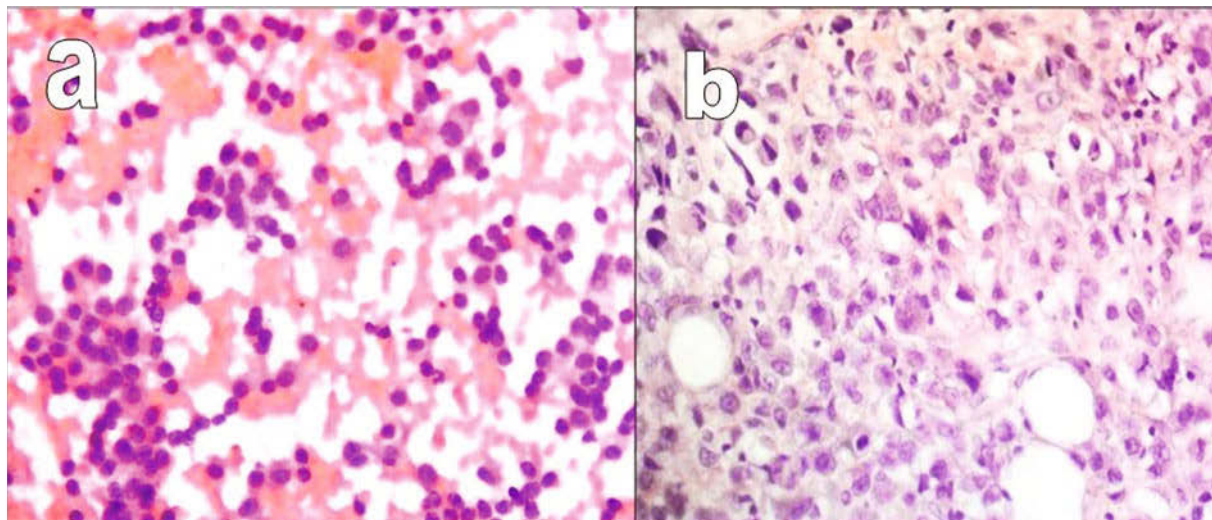
No significant statistical difference was detected between the two groups as regards age, sex, lesion's size, site, or diagnosis (Table 1). Results of the EUS-guided sampling and final diagnosis according to

Figure 1



EUS-FNA of pancreatic body mass by 22 G needle (a), EUS-FNB of pancreatic uncinata mass by 20 G needle (b). EUS-FNA, endoscopic ultrasound-guided fine-needle aspiration; EUS-FNB, endoscopic ultrasound-guided fine-needle biopsy.

Figure 2



Cytopathological examination of the pancreatic body mass showing loosely cohesive aggregates of rounded cells with rounded nuclei, granular chromatin and little amount of cytoplasm (hemotoxylin and eosin, 400 \times), consistent with neuroendocrine tumor (a), and of the pancreatic uncinate mass showing sheets of atypical epithelial cells with marked pleomorphism, large hyperchromatic nuclei and little amount of cytoplasm (hemotoxylin and eosin, 400 \times), consistent with adenocarcinoma (b).

Table 1 Demographic details and lesions' nature of 50 patients included in the study

Needle	FNA 22 G ($n=29$) [n (%)]	FNB 20 G ($n=21$) [n (%)]	<i>P</i> value
Age	60.4 \pm 10.2	54.7 \pm 13.3	0.1
Sex			
Male	15 (52)	14 (67)	0.29
Female	14 (48)	7 (33)	
Size	4.1 \pm 2.0	4.5 \pm 1.5	0.24
Nature (final diagnosis)			
Benign	3 (10)	2 (10)	0.92
Malignant	26 (90)	19 (90)	

FNA, fine-needle aspiration; FNB, fine-needle biopsy.

lesion sites are shown in Tables 2 and 3. A total of five biopsies were nondiagnostic (three in FNA 22 G and two in FNB 20 G). Final diagnosis in these cases was linitis plastica ($n=2$) in gastric lesions, adenocarcinoma ($n=1$) in esophageal lesion, lymphoma ($n=1$) in mediastinum and GIST ($n=1$) in gastric lesion.

No significant difference was detected between FNA 22 G and FNB 20 G as regards the diagnostic accuracy or the technical success rates. However, there was a significant difference in the number of passes needed to reach diagnosis; FNA 22 G (nine cases of 29) and FNB 20 G (one case of 21) needed more than one pass. The success rate of first pass for FNA 22 G and FNB 20 G was 69 and 92.5%, respectively ($P=0.014$, 95%CI). Specificity, sensitivity, positive predictive value and negative predictive value of both needles were calculated on the basis of the final diagnosis (Table 4).

Discussion

The role of EUS-FNA in obtaining cytological materials is well established [7]. However, some studies suggested that the false-positive rate of FNA cytology is 5–7%, which is higher than the originally reported rates of 0–1% [8,9]. Moreover, a growing interest in histological tissue sampling exists because of the advantage in diagnosing certain suspected tumor types that need immunohistochemical staining, such as neuroendocrine tumors and lymphomas [10]. A number of measures have been proposed to improve diagnostic accuracy and tissue sampling [11]. ROSE has been reported to increase the diagnostic yield of tissue sampling by 10–15% [12]. Nevertheless, ROSE is not available in all facilities due to the high cost and a longer procedure duration. With the growing interest in the development of EUS-guided sampling, the 19 G FNA needle and the Trucut needle appeared [13,14], but all of these needles did not increase the diagnostic

Table 2 Lesion sites and final diagnosis

Site	FNA 22 G (n=29)		FNB 20 G (n=21)	
	n (%)	Diagnosis	n (%)	Diagnosis
Pancreas				
Head	3 (10)	Adenocarcinoma (1) Undifferentiated (1) NET (1)	4 (19)	Adenocarcinoma (4)
Body	7 (24)	Adenocarcinoma (3) NET (2) SPN (2)	4 (19)	Adenocarcinoma (4)
Uncinate	7 (24)	Adenocarcinoma (7)	2 (10)	Adenocarcinoma (2)
GIT				
Esophagus	–		1 (5)	Adenocarcinoma (1)
Stomach	4 (14)	GIST (2) Linitis plastica (2)	2 (10)	Adenocarcinoma (1) GIST (1)
Duodenal	1 (3)	GIST (1)	–	
CBD	1 (3)	Inflammatory (1)	–	
Lymph nodes				
Paraesophageal	1 (3)	Inflammatory (1)	–	
Mediastinal	2 (7)	Lymphoma (1) Thymoma (1)	7 (33)	Undifferentiated (2) Lymphoma (3) Inflammatory (1) Sarcoidosis (1)
Para-aortic	2 (7)	Undifferentiated (1) Lymphoma (1)	1 (5)	Lymphoma (1)
Portahepatis	1 (3)	Undifferentiated (1)	–	

CBD, common bile duct; FNA, fine-needle aspiration; FNB, fine-needle biopsy; GIT, gastrointestinal tract; NET, neuroendocrine tumor; SPN, solid pseudopapillary neoplasm.

Table 3 Results of pathological and final diagnosis for both groups

	FNA 22 G diagnosis (n=29) [n (%)]	Final diagnosis	FNB 20 G diagnosis (n=21) [n (%)]	Final diagnosis
Positive for malignancy				
Adenocarcinoma	9 (31)	11 (38)	11 (52)	12 (57)
Undifferentiated carcinoma	3 (10)	3 (10)	2 (10)	2 (10)
Lymphoma	2 (7)	2 (7)	3 (14)	4 (19)
Neuroendocrine tumor	3 (10)	3 (10)	–	–
Solid pseudopapillary neoplasm	2 (7)	2 (7)	–	–
neoplasm				
GIST	2 (7)	3 (10)	1 (5)	1 (5)
Linitis plastica	–	2 (7)		
Negative for malignancy				
Inflammatory	2 (7)	2 (7)	1 (5)	1 (5)
Thymoma	1 (3)	1 (3)	–	–
Sarcoidosis	–		1 (5)	1 (5)
Suspicious (atypical)	2 (7)	–	–	–
Nondiagnostic	3 (10)	–	2 (10)	–

FNA, fine-needle aspiration; FNB, fine-needle biopsy; GIST, gastrointestinal tract.

yield and showed some technical difficulties, especially in the transduodenal position. In recent years, the 20-G procore needle (Cook medical) has been designed to combine the best features of currently available needles: a large caliber for better histological tissue sampling and a flexibility approximating that of the 25-G needle, which allow easy manipulation in anatomically challenging locations.

In our study, we compared FNA and FNB in two aspects. As regards the diagnostic accuracy, we found no significant difference between FNA 22 G and FNB 20 G. The current literature comparing FNA and FNB

needles did not provide definitive results [1,15]. In a recent meta-analysis, there was no significant difference between the standard FNA needle and one FNB needle (ProCore; Cook Endoscopy) with regard to diagnostic yield, adequacy of the sample, or acquisition of a core tissue; however, the FNB needle needed fewer passes to reach the diagnosis [16]. This was similar to our study, wherein the success rate of first pass for FNB 20 G was significantly higher than FNA (92.5 and 69%, respectively; $P=0.014$, 95%CI). In contrast to our study, another study showed that the diagnostic accuracy and sample adequacy of FNB needles was significantly higher than that of FNA

Table 4 Technical characteristics and outcomes for both groups

	FNA 22 G (n=29) [n (%)]	FNB 20 G (n=21) [n (%)]	P value
Technical success	29 (100)	21 (100)	1.0
First-pass success	20 (69)	20 (92.5)	0.014
Accuracy	26 (89.7)	19 (90.5)	0.92
Sensitivity (%)	90	91	–
Specificity (%)	100	100	–
PPV (%)	100	100	–
NPV (%)	58	42	–

FNA, fine-needle aspiration; FNB, fine-needle biopsy; NPV, negative predictive value; PPV, positive predictive value.

needles for all sampled solid mass lesions. The authors also recognized that there were significant implications on the cost associated with the needle choice. They found that routine use of FNB needles could provide diagnostic accuracy high enough to eliminate the need for ROSE, which would not only reduce the direct costs but also would significantly reduce the indirect costs (costs associated with the time lost waiting for the feedback of cytological evaluation) [17].

With regard to the technical performance, Iglesias-Garcia *et al.* [6] evaluated the performance of the 19 G FNB needles in 114 lesions; two technical failures (5.7%) occurred with the scope in the duodenum. Furthermore, there was difficulty in needle insertion into the endoscope in 18% of cases and also greater difficulty in 1% of cases. This difficulty was explained by the curved position of the echoendoscope in the duodenum [6]. In contrast, we experienced no technical failures or technical difficulties when performing sampling with our 20 G FNB needle. In all our cases, the needle was inserted easily into the endoscope, irrespective of the endoscope location or curved position.

Our study had many limitations that might affect our final conclusions. First, all procedures were carried out at a single center to minimize variables; therefore, these conclusions should be verified by additional centers before being generalized for all echoendoscopists. Second, the sample size was relatively small; therefore, a larger sample size is needed to confirm our results. Third, the endoscopists were not blinded to the needle type used during tissue sampling, but it should not be considered as a major limitation, as the pathologists were blinded to the needle type used for tissue sampling.

In conclusion, EUS-guided FNA and FNB are safe, appropriate procedures that have comparable

diagnostic accuracy for solid lesions within the gastrointestinal tract and nearby organs. The 20-G FNB needles are easy handling in anatomically challenging locations and required fewer needle passes to reach diagnosis; which could eliminate the need for ROSE.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

- Strand DS, Jeffus SK, Sauer BG, Wang AY, Stelow EB, Shami VM. EUS-guided 22-gauge fine-needle aspiration versus core biopsy needle in the evaluation of solid pancreatic neoplasms. *Diagn Cytopathol* 2014; 42:751–758.
- Weston BR, Bhutani MS. Optimizing diagnostic yield for eus-guided sampling of solid pancreatic lesions: a technical review. *Gastroenterol Hepatol* 2013; 9:352–363.
- Ieni A, Todaro P, Crino SF, Barresi V, Tuccari G. Endoscopic ultrasound-guided fine-needle aspiration cytology in pancreaticobiliary carcinomas: diagnostic efficacy of cell-block immunocytochemistry. *Hepatobiliary Pancreat Dis Int* 2015; 14:305–312.
- Song TJ, Kim JH, Lee SS, Eum JB, Moon SH, Park do H, *et al.* The prospective randomized, controlled trial of endoscopic ultrasound-guided fine-needle aspiration using 22G and 19G aspiration needles for solid pancreatic or peripancreatic masses. *Am J Gastroenterol* 2010; 105:1739–1745.
- Mesa H, Stelow EB, Stanley MW, Mallery S, Lai R, Bardales RH. Diagnosis of nonprimary pancreatic neoplasms by endoscopic ultrasound-guided fine-needle aspiration. *Diagn Cytopathol* 2004; 31:313–318.
- Iglesias-Garcia J, Poley JW, Larghi A, Giovannini M, Petrone MC, Abdulkader I, *et al.* Feasibility and yield of a new EUS histology needle: results from a multicenter, pooled, cohort study. *Gastrointest Endosc* 2011; 73: 1189–1196.
- Dwyer J, Pantanowitz L, Ohori NP, Pai RK, Vrbic C, Brand RE, Monaco SE. Endoscopic ultrasound-guided FNA and ProCore biopsy in sampling pancreatic and intra-abdominal masses. *Cancer Cytopathol* 2016; 124:110–121.
- Gleeson FC, Kipp BR, Caudill JL, Clain JE, Clayton AC, Halling KC, *et al.* False positive endoscopic ultrasound fine needle aspiration cytology: incidence and risk factors. *Gut* 2010; 59:586–593.
- Hawes RH. The evolution of endoscopic ultrasound: improved imaging, higher accuracy for fine needle aspiration and the reality of endoscopic ultrasound-guided interventions. *Curr Opin Gastroenterol* 2011; 26:1.
- Navina S, McGrath K, Chennat J, Singh V, Pal T, Zeh H, *et al.* Adequacy assessment of endoscopic ultrasound-guided, fine-needle aspirations of pancreatic masses for theranostic studies: optimization of current practices is warranted. *Arch Pathol Lab Med* 2014; 138:923–928.
- Polkowski M, Larghi A, Weynand B, Boustiere C, Giovannini M, Pujol B, Dumonceau JM. Learning, techniques, and complications of endoscopic ultrasound (EUS)-guided sampling in gastroenterology: European Society of Gastrointestinal Endoscopy (ESGE) Technical Guideline. *Endoscopy* 2012; 44:190–206.
- Iglesias-Garcia J, Dominguez-Munoz JE, Abdulkader I, Larino-Noia J, Eugenyeva E, Lozano-Leon A, Forteza-Vila J. Influence of on-site cytopathology evaluation on the diagnostic accuracy of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) of solid pancreatic masses. *Am J Gastroenterol* 2011; 106:1705–1710.
- Thomas T, Kaye PV, Ragunath K, Aithal G. Efficacy, safety, and predictive factors for a positive yield of EUS-guided Trucut biopsy: a large tertiary referral center experience. *Am J Gastroenterol* 2009; 104:584–591.
- Larghi A, Verna EC, Ricci R, Seerden TC, Galasso D, Carnuccio A, *et al.* EUS-guided fine needle tissue acquisition by using a 19-gauge needle in a

- selected patient population: a prospective study. *Gastrointest Endosc* 2011; 74:504–510.
- 15 Vanbiervliet G, Napoléon B, Saint Paul MC, Sakarovitch C, Wangermez M, Bichard P, *et al.* Core needle versus standard needle for endoscopic ultrasound-guided biopsy of solid pancreatic masses: a randomized crossover study. *Endoscopy* 2014; 46:1063–1070.
- 16 Bang JY, Hawes R, Varadarajulu S. A meta-analysis comparing ProCore and standard fine-needle aspiration needles for endoscopic ultrasound-guided tissue acquisition. *Endoscopy* 2016; 48:339–349.
- 17 Aadam AA, Wani S, Amick A, Shah JN, Bhat YM, Hamerski CM, *et al.* A randomized controlled cross-over trial and cost analysis comparing endoscopic ultrasound fine needle aspiration and fine needle biopsy. *Endosc Int Open* 2016; 4:E497–E505.