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Performance of a new flexible 19 G EUS needle in pancreatic solid lesions located in the head and uncinate process: A prospective multicenter study

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ABSTRACT

Background and study aims The poor flexibility of large-bore EUS needles often leads to technical failure when sampling from the duodenum. The aim of this study was to evaluate the technical and diagnostic performances of a new Menghini tip 19G nitinol EUS needle for sampling pancreatic solid lesions in the head and uncinate process.

Patients and methods This was a European prospective multicenter single-arm study. A maximum of four passes were allowed. In case of failure, different needles were permitted.

Results We included 75 patients (51 % males) with lesions in the head (n = 68; 91 %) and uncinate process (n = 7; 9 %) (mean size: 33 ± 12 mm; number of passes: 1.8 ± 0.9). Technical success was seen in 71 of 75 (94.7 %). Diagnostic rates were 89.3 % (67/75) and 94.4 % (67/71) in the intention-to-treat (ITT) and per-protocol (PP) analysis, respectively. In the eight cases with failure, diagnosis was obtained with another needle (n = 4), from another lesion (n = 3) or with follow-up (n = 1). A histological sample was obtained in 64 patients (ITT 85.3 % and PP 90 %) and immunohistochemistry was successfully performed in 13 of 15 lesions in which it was required. No differences between rapid on-site evaluation (ROSE) and non-ROSE groups were observed regarding diagnostic success (87.5 % vs 91 %, $P = 0.582$) and diagnosis at the first pass (70 % vs 81 %, $P = 0.289$). Number of passes was lower in the ROSE group (1.4 + 0.9 vs 2.2 + 0.7, $P < 0.001$). One adverse event was recorded (1.3 %) consisting in a duodenal perforation after a single session EUS-ERCP.

Conclusions The new nitinol Menghini tip 19G EUS needle showed high technical diagnostic success in safely sampling solid lesions in the head and uncinate process of the pancreas.

Introduction

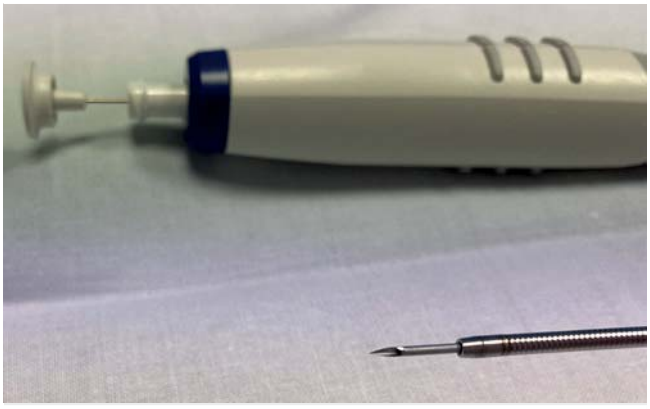
Endoscopic ultrasound (EUS)-guided tissue acquisition is useful and safe for assessing cytological or histological diagnosis of pancreatic solid tumors [1–5]. However, despite the availability of different needles, it remains technically challenging to sample tumors in the head/uncinate process of the pancreas using large bore EUS fine-needle biopsy (FNB) needles from the duodenum [6]. The need for large-bore needles depends on pathologist preference, unavailability of rapid on-site evaluation (ROSE), and/or when the preservation of tissue architecture and morphology is necessary for the diagnosis [7, 8]. Moreover, a good tissue core provides enough tissue for ancillary techniques such as immunohistochemistry [9].

Although the impact of ROSE in the accuracy of EUS fine-needle aspiration (EUS-FNA) is controversial [10–13], many centers, as suggested by guidelines, successfully use ROSE to improve diagnostic adequacy of EUS-FNA and reduce the number of needle passes [14–15]. The potential of ROSE to reduce the number of needle passes was also shown in two randomized studies [12, 13]. In this context, using EUS-FNB needles could overcome the problem by providing a core biopsy for analysis [16].

The technical difficulty of using 19 G needles with the torqued position of the echoendoscope when sampling the head or uncinated process of the pancreas from the duodenum is well known. In one randomized clinical trial (RCT) comparing 19 G and 22 G needles, the former provided better diagnostic accuracy but also a significantly higher technical failure rate in case of pancreatic head tumors [17]. In the same way, in a recent study of 548 patients who underwent EUS-FNA, the 25 G needle had superior technical performance over the 19 G and 22 G needles for sampling from the duodenum [10].

New nitinol-based needles have been developed with enhanced flexibility to improve the technical success of transduodenal sampling [18–20]. Nevertheless, a recent RCT comparing a flexible 19 G vs. a standard 22 G needle in pancreatic head lesions failed to show any advantage of using the larger needle at intention-to-treat analysis (diagnostic accuracy for malignancy 69.5 % vs 87.3 %, respectively; $P = 0.02$). Considering only the cases of technical success with the 19 G needle, the accuracy was noninferior to the 22 G (80.4 % vs 87.3 %; P = ns) [21].

The objective of this study was to assess the technical performance and diagnostic accuracy of a new nitinol 19 G needle (EZShot 3 Plus, Olympus, Tokyo, Japan) for sampling lesions in the pancreatic head and uncinate process. The new needle has a multilayer coil sheath and a tip with a Menghini design. Theoretically, it should be flexible enough even when the end of the scope is very angulated, thereby enabling easy access to difficult locations such as the pancreatic head and uncinate process from the duodenum.



▶ **Fig. 1** New nitinol 19 G needle with a multilayer coil sheath and a Menghini tip.

Patients and methods

Study design

This was a prospective, multicenter, single-arm study in four tertiary centers in Europe enrolling consecutive patients with solid pancreatic masses in the head or uncinate process of the pancreas referred for EUS-guided tissue sampling.

We used the following exclusion criteria: coagulation disorders (international normalized ratio > 1.5, platelets < 100,000), post-surgical anatomy (Roux-en-Y gastric bypass, esophagectomy, etc.) that prevented reaching the duodenum, pregnant women, age < 18 years and refusal to provide written consent. The study was approved by the Institutional Review Boards of all participating centers.

EUS-guided tissue sampling technique

EUS-guided tissue sampling was performed using a linear array echoendoscope and a 19 G EZShot 3 Plus needle (Olympus, Tokyo, Japan) (▶ **Fig. 1**). The procedure was performed under either conscious or deep sedation in all cases.

Once the needle tip was introduced into the target lesion, the stylet was removed, and 5-mL suction was applied with a 10-mL syringe while the needle was moved back and forth eight to 10 times within the lesion (fanning technique). When ROSE was available, it was performed according to the local protocols. A maximum of four passes were allowed. In case of technical failure or inadequate sample for diagnosis, a standard 22 G or 25 G needle was used at the discretion of the endoscopists and specimens were separately analyzed.

The patients were kept under observation for 4 to 8 hours after the procedure. Data concerning postprocedural abdominal pain, bleeding, fever or any other symptoms were recorded to assess the rate and type of possible early adverse events (AEs). AE was defined, following the lexicon of American Society of Gastrointestinal Endoscopy Workshop, as an event that prevents completion of the EUS-guided tissue sampling and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (needing sedation/anesthesia), or subsequent medical consultation [22]. Late AEs were assessed by phone call 7 and 21 days after the procedure.

The final diagnosis was based on surgical pathology from the resected specimen when available or on malignant histology or cytology in patients managed without surgery. A benign diagnosis had to be supported by other imaging techniques, negative tumoral markers, and a 6-month uneventful follow-up.

Sample processing

In centers where ROSE was available, some of the slides were stained with a quick panoptic stain for immediate review and verification of the adequacy of the specimen. The rest of the slides were fixed in alcohol and processed in the laboratory. If any tissue fragment was obtained, it was carefully separated from the slide and fixed in formalin, embedded in paraffin, and stained with hematoxylin and eosin for histopathological evaluation (▶ **Fig. 2**). When on-site evaluation was not possible, the slides were fixed in alcohol and sent to the laboratory for further manipulation and analysis. The first pass with the study needle was analyzed separately, whereas subsequent passes with the same needle were analyzed cumulatively.

Definitions

Technical success was defined as successful completion of all steps from needle insertion into the echoendoscope accessory channel to tissue procurement. Inability to complete any step above was defined as a technical failure.

Technical feasibility was defined as the ability to reach the lesion with the needle was evaluated with a subjective scale ranging from 1 to 5: 1. Very easy; 2. Easy; 3: Average; 4. Difficult; 5. Very difficult.

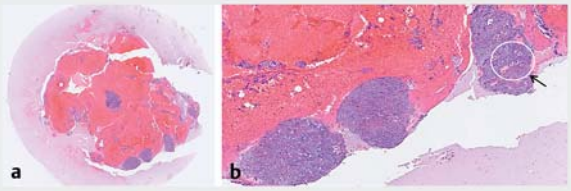
Endpoints

The primary endpoint was assessment of the technical success of sampling pancreatic solid lesions in the head/uncinate process through the duodenum with the study needle. The secondary endpoints were evaluation of the yield of the first pass with the study needle and assessment of the rate and type of AEs.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation. The rate of technical success of the needle, the adequacy of the sample for both cytological and histological diagnosis, macroscopic evaluation of the sample and ancillary techniques as well as the rate and type of AEs were expressed as a percentage.

Calculations were performed for an intention-to-treat (ITT) and per protocol analysis (PP). The study population for the ITT analysis included all patients who were included in the study whereas the PP analysis included only the cases with technical success of the needle. Sample size calculation was performed assuming from previous data [19] that the rate of technical success of the standard 19G needle is 75 % and with the new needle would be 95 %. In order to obtain a precision of 5 % in the estimation of the success proportion by a two-sided 95 % confidence interval, it was necessary to include 73 patients in the study [23]. $P<0.05$ was considered statistically significant.



▶ **Fig. 2** **a** Cell block of a sample obtained by a 19 G EZ Shot 3 Plus needle showing biopsy cores (HE × 40). **b** Three biopsy cores that show stromal desmoplasia and infiltrating cells of adenocarcinoma (arrow) (HE × 100).

Results

Between March 2018 and February 2019, 85 patients were eligible for the study. After excluding 10 (coagulation disorders n = 2, post-surgical anatomy alteration n = 4 and refusal to provide written informed consent n = 4), 75 patients were included. Most of the lesions were located in the head of the pancreas (n = 68; 91 % vs. n = 7; 9 % in the uncinate process). Main characteristics of the patient population are described in ▶ **Table 1**.

Technical success was achieved in 71 patients (94.6 %). The reasons for the four technical failures were a very difficult position (n = 2), duodenal stenosis (n = 1) and the presence of periduodenal varices (n = 1) that prevented a correct insertion of the needle. A diagnosis was reached in 67 patients, resulting in a PP diagnostic yield of 94.4 % and an ITT diagnostic yield of 89.3 %.

Macroscopic evaluation of the samples and other details of EUS-guided tissue sampling are described in ▶ **Table 2**. ROSE was performed in 40 cases (53 %) with no differences between ROSE and non-ROSE groups regarding diagnostic success (87.5 % vs 91 %; $P = 0.582$). The number of needle passes was lower with ROSE than without (1.4 ± 0.9 vs 2.2 ± 0.7; $P<0.001$ (▶ **Table 2**). First pass was evaluated separately in 67 cases, either in the endoscopy room when ROSE was available (n = 40) or in the pathology lab (n = 27). Diagnosis at the first pass was reached in 50 of 67 (75 %). Tissue for histology was obtained in 64 patients (ITT: 85.3 %, PP: 90 %). In the 15 cases in which immunohistochemistry was deemed to be necessary, it could be obtained in all but two. A summary of the performance of the study needle is shown in ▶ **Table 3**.

Concerning technical feasibility, the access of the needle into the lesion was considered satisfactory by the endosonographer in all cases, with 80 % of cases being better than or within average.

In seven of eight patients in whom the study needle failed, an alternative needle was used in the same lesion, whereas in the remaining case, a different lesion was targeted. Details related to the workup for diagnosis in these patients are shown in ▶ **Fig. 3** and ▶ **Table 4**.

Patients were followed up for AEs a mean of 16 ± 9.4 days (range 0–37). A total of 38 patients (50.6 %) could not complete the follow-up because they underwent either surgery (n = 12, 16 %) or ERCP (n = 26, 35 %) earlier than 21 days after EUS. How-

▶ **Table 1** Main characteristics of the patient population.

	N = 75
Sex	
▪ Male	38 (51 %)
▪ Female	37 (49 %)
Age, years (mean ± SD, range)	65 ± 13 (32–88)
Symptoms (jaundice, pain, weight loss)	59 (78.7 %)
Anticoagulants or antiplatelets	9 (12 %)
Location	
▪ Head	68 (91 %)
▪ Uncinated process	7 (9 %)
Size, mm (mean ± SD, range)	33 ± 12 (12–80)
Final diagnosis	
▪ Adenocarcinoma	59 (78.7 %)
▪ NET	5 (6.7 %)
▪ Metastases	2 (2.7 %)
▪ Lymphoma	2 (2.7 %)
▪ Chronic pancreatitis	2 (2.7 %)
▪ Metastatic lymph node	1 (1.3 %)
▪ Sarcoma	1 (1.3 %)
▪ Serous cystoadenoma	1 (1.3 %)
▪ GIST	1 (1.3 %)
▪ Undifferentiated carcinoma	1 (1.3 %)

NET, neuroendocrine tumor; GIST, gastrointestinal stromal tumor.

▶ **Table 2** Details of EUS-guided tissue sampling.

	N = 75
ROSE	40 (53 %)
Adequate sample	30/40 (75 %)
Number of passes	1.8 ± 0.9 (1–4)
Difficulty[1]	
▪ Very easy	21 (28 %)
▪ Easy	22 (29 %)
▪ Average	17 (23 %)
▪ Difficult	10 (13 %)
▪ Very difficult	5 (7 %)
Macroscopic evaluation	
▪ Non-bloody fragment	33 (44 %)
▪ Bloody fragment	28 (37.3 %)
▪ Non-bloody cytological specimen	6 (8 %)
▪ Bloody cytological specimen	7 (9.3 %)
▪ No sample	1 (1.3 %)
Use of an alternative needle	7 (9 %)
▪ 22G	5
▪ 25G	2

EUS, endoscopic ultrasound; ROSE, rapid on-site evaluation.
[1] Reasons for difficulty: angulation, stiffness of duodenum, hardness of the lesion, stent, and collateral vessels.

ever, all of them were fine at that time. Only one AE was recorded (1.3 %) consisting in a duodenal perforation after ERCP performed in the same session after the EUS-guided sampling.

Regarding the three patients with a diagnosis of benignity, one of them was diagnosed of a pancreatic cancer in the follow-up and the remaining two (one chronic pancreatitis and one serous cystadenoma) were alive and in good condition after 6 months of follow-up.

Discussion

This European multicenter, prospective and single-arm study demonstrates that a novel nitinol 19 G EUS needle has a high technical success and diagnostic yield in solid lesions in the head and uncinate process of the pancreas, irrespective of the presence of on-site cytopathologist. Moreover, despite previous results showing that large bore needles are not flexible enough and might fail to procure tissue in difficult positions, our results show an acceptable perception of difficulty among the endosonographers.

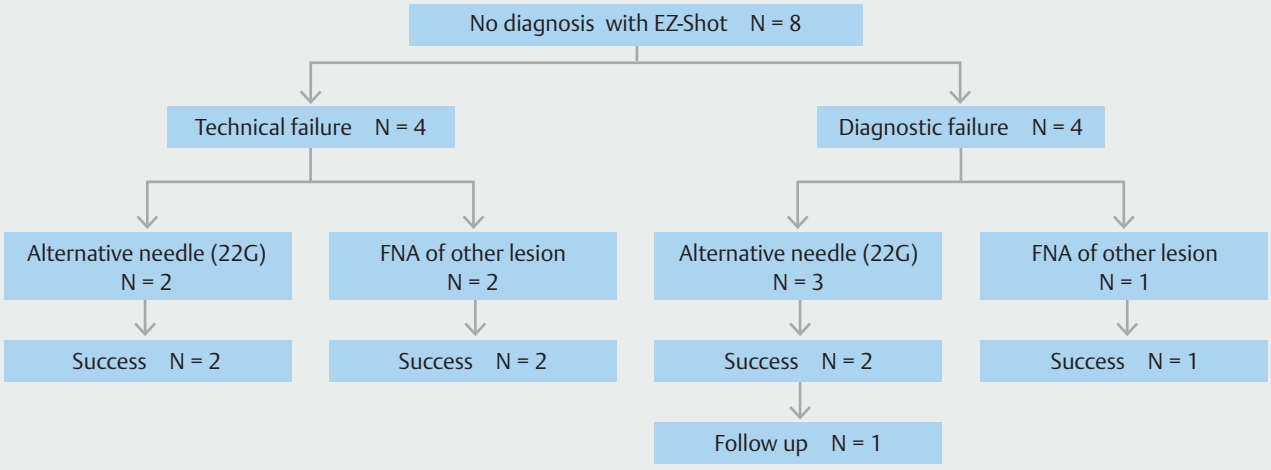
Conventional 19 G needles are recommended to procure samples with preserved tissue architecture for histologic evaluation that may be crucial in a subgroup of diseases such as autoimmune pancreatitis or lymphoma, or when immunohistochemical analysis is mandatory [3, 16]. In addition, obtaining a core biopsy could make ROSE unnecessary [17, 18]. Transduodenal EUS-guided sampling using conventional 19 G needles is usually challenging due to their stiffness, technical failure rates being higher than with 22 G or 25 G needles [8]. The only RCT [20] comparing 22 G vs. 19 G standard needles in solid pancreatic masses found significantly higher accuracy for the 19 G needle in the per-protocol analysis. However, in the intention-to-treat analysis, no significant difference in accuracy was demonstrated due to a higher technical failure rate of the 19 G needle when the lesions were in the pancreatic head.

Flexible 19 G needles made of nitinol have been developed to overcome this technical challenge. Itoi et al. [18] evaluated the functional characteristics of different 19 G needles, including standard, nitinol-made, and reverse-bevel needles, by bench simulation for angulation and for resistance to passage under various conditions. The nitinol-made needle showed less resistance to passage in various conditions compared to the other 19 G needles. Varadarajulu et al. [21] demonstrated a technical and diagnostic success of 100 % with a 19 G nitinol needle in a prospective cohort study that included 32 pancreatic head or uncinate masses. In addition, adequate tissue core

▶ **Table 3** Summary of performance of the study needle.

	Total N = 75	ROSE N = 40	No ROSE N = 35	*P*
Technical success	71 (94.7 %)			
Diagnostic success	ITT: 67/75 (89.3 %)	35/40 (87.5 %)	32/35 (91.4 %)	0.582
	PP: 67/71 (94.4 %)	35/38 (92.1 %)	32/33 (97 %)	
Diagnostic success at first pass	50/67 (75 %)			
Histological sample	ITT: 64/75 (85.3 %)			
	PP: 64/71 (90.1 %)			
Feasibility of ancillary techniques when needed	13/15 (86.6 %)			
Adverse events	1 (1.3 %)			

ROSE, rapid on-site evaluation.



▶ **Fig. 3** Flowchart showing the management of patients in whom the study needle failed.

for histologic examination was obtained in 94 % of patients. However, a recently published multicenter RCT conducted by Laquière et al. [20] compared a 19 G nitinol needle with a standard 22 G needle for transduodenal sampling of pancreatic solid lesions and did not confirm the previous excellent results. With 122 patients included, the diagnostic accuracy of the 19 G and 22 G needles was 69 % and 87 %, respectively ($P = 0.02$). Even after exclusion of eight technical failures with the 19 G needle in the per-protocol analysis, there was no diagnostic advantage for the 19 G over the 22 G needle in terms of diagnostic accuracy (80 % vs 87 %, $P = 0.12$). In addition, remarkable technical difficulties were observed in 29 % of patients in whom the 19 G needle was used, as compared with 11 % of patients with the 22 G needle.

Our study shows a 94 % technical success rate with a new nitinol 19 G needle, which is higher than previously reported [24]. This could be related to the innovative design of the needle, featuring a multilayer coil sheath and a Menghini tip that provides a high flexibility even when the end of the scope is very angulated. Our results also show an acceptable perception of technical feasibility since only 20 % of the cases were considered difficult by the endosonographers.

As stated before, advantages of 19 G needles include obtaining tissue core for analysis. In our study, a histological sample was obtained in 64 patients (ITT 85.3 %, PP 90 %) and immunohistochemistry was successful in 13/15 (86 %) lesions in which it was required. This performance is similar to that of other EUS histology needles [9, 25, 26] and superior to the rate reported with the 22 G and 25 G reverse bevel needles (69 %-83 % and 32 %-88 %, respectively) [27–29].

Although the impact of ROSE on EUS-guided-tissue acquisition in solid pancreatic masses is still controversial [10, 14, 15, 29], this new 19 G needle might provide samples that could obviate the need for ROSE. The results of our study reinforce this assumption because diagnostic accuracy and diagnosis at the first pass did not significantly differ with or without ROSE (91 % vs 87.5 % and 81 % vs 70 %, respectively).

▶ **Table 4** Details about patient diagnostic workup.

#	EZ-shot passes	ROSE	Alternative needle	Dx with alternative needle	Method for final Dx	Final Dx	Comments
1	2	No cells	No	–	FNA another lesion (LN)	NSCLC	Diagnostic failure. Easy performance
2	1	No cells	25G	No dx	FNA another lesion (pancreatic body)	NET	Technical failure. Very difficult
3	4	No cells	22G	ADK	Alternative needle	PDAC	Diagnostic failure. Easy performance
4	4	No cells	22G	ADK	Alternative needle	PDAC	Diagnostic failure. Easy performance
5	1	No cells	22G	ADK	Alternative needle	PDAC	Technical failure. Very difficult
6	1	–	25G	ADK	Alternative needle	PDAC	Technical failure. Very difficult
7	3	–	22G	Chronic pancreatitis	Follow up	PDAC	Diagnostic failure. Easy performance
8	2	–	22G	No dx	FNA another lesion (LN)	PDAC	Technical failure. Very difficult

No dx, no diagnosis; LN, lymph node; ROSE, rapid on-site evaluation; NSCLC, non-small cell lung cancer; NET, neuroendocrine tumor; PDAC, pancreatic ductal adenocarcinoma.

There might be concern about incurring more AEs by using 19 G EUS needles as opposed to thinner needles. However, the use of a nitinol 19 G EUS needle through the duodenum in our study proved to be safe. One patient experienced retroperitoneal perforation during ERCP performed in a single session after EUS. Therefore, we assume that this AE cannot be primarily attributed to the use of the study needle.

The high number of patients included in this multicenter investigation strengths the validity of the results. Moreover, AEs can be correctly assessed only in a prospective fashion such as done in the present study.

Our study presents some limitations. First, because it was the first study with this new nitinol Menghini tip 19 G needle, we did not perform a randomized trial with other EUS needles. Consequently, direct comparisons in terms of technical success and diagnostic accuracy cannot be drawn. Second, only highly experienced endosonographers were involved, limiting its generalizability to centers with less experience. Last, the lack of a centralized cytopathological evaluation that could be considered a limitation of the study did not have a negative impact on the results, considering the high diagnostic yield achieved.

Conclusions

In conclusion, our data indicate that EUS-guided tissue acquisition of pancreatic solid lesions in the head/uncinate process using a new nitinol Menghini tip 19 G needle is technically feasible and safe with a high percentage of diagnoses at the first pass. Randomized comparative trials are warranted to assess the actual advantages of this new nitinol needle over other EUS needles.

Competing interests

Dr. Fernández-Esparrach has received fees for organizing courses for Norgine Iberia and Olympus Spain in the last 2 years and has been a consultant for trial design for CDx Diagnostics. Dr. Ginès has been a consultant for Cook Medical and Olympus Europe.

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