

Initial experience with a novel EUS-guided core biopsy needle (SharkCore): results of a large North American multicenter study

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Institutions are listed at the end of article.

submitted

14. December 2015

accepted after revision

5. July 2016

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DOI <http://dx.doi.org/10.1055/s-0042-112581>
Published online: 30.8.2016
Endoscopy International Open 2016; 04: E974–E979
© Georg Thieme Verlag KG
Stuttgart · New York
E-ISSN 2196-9736

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Background and aims: The ability to safely and effectively obtain sufficient tissue for pathologic evaluation by using endoscopic ultrasound (EUS) guidance remains a challenge. Novel designs in EUS needles may provide for improved ability to obtain such core biopsies. The aim of this study was to evaluate the diagnostic yield of core biopsy specimens obtained using a novel EUS needle specifically designed to obtain core biopsies.

Patients and methods: Multicenter retrospective review of all EUS-guided fine-needle biopsies obtained using a novel biopsy needle (SharkCore FNB needle, Medtronic, Dublin, Ireland). Data regarding patient demographics, lesion type/location, technical parameters, and diagnostic yield was obtained.

Results: A total of 250 lesions were biopsied in 226 patients (Median age 66 years; 113 (50%) male). Median size of all lesions (mm): 26 (2–

150). Overall, a cytologic diagnosis was rendered in 81% specimens with a median number of 3 passes. When rapid onsite cytologic evaluation (ROSE) was used, cytologic diagnostic yield was 126/149 (85%) with a median number of 3 passes; without ROSE, cytologic diagnostic yield was 31/45 (69%, $P=0.03$) with a median number of 3 passes. Overall, a pathologic diagnosis was rendered in 130/147 (88%) specimens with a median number of 2 passes. Pathologic diagnostic yield for specific lesion types: pancreas 70/81 (86%), subepithelial lesion 13/15 (87%), lymph node 26/28 (93%). Ten patients (10/226, 4%) experienced adverse events: 4 acute pancreatitis, 5 pain, 1 fever/cholangitis.

Conclusions: Initial experience with a novel EUS core biopsy needle demonstrates excellent pathologic diagnostic yield with a minimum number of passes.

Introduction

EUS-guided tissue acquisition (EUS-TA) can be performed by way of fine-needle aspiration (EUS-FNA) or fine-needle biopsy (EUS-FNB), otherwise known as core biopsy. The most critical issue in performing EUS-FNA is that of the non-diagnostic procedure. This not only results in higher costs related to repeat procedures and/or attempts at alternative biopsy methods, but also patient angst related to delayed diagnosis of a potentially malignant lesion. EUS-FNB is commonly utilized as a salvage technique in cases where EUS-FNA fails to procure adequate tissue. In addition, these core biopsy specimens are critical in making an accurate diagnosis in certain disease states, such as lymphoma and autoimmune pancreatitis.

Interest in EUS-FNB is growing. From a clinical practice standpoint, the ability to reliably obtain adequate diagnostic tissue with minimal effort and without the need for rapid on-site evaluation

of the specimen would allow for more efficient and less costly procedures. In addition, there is a movement toward use of EUS-guided core biopsy specimens to perform molecular and genetic studies to aid in both diagnosis and guide therapy of pancreatic neoplasms [1, 2].

Currently, there is no standard or preferred needle type, size, or FNB technique that can serve this function. Novel designs in needles may provide an advantage in allowing for the acquisition of diagnostic tissue with minimal needle passes, thus making on-site cytologic analysis obsolete. In this study, we report the initial North American experience of using a novel core biopsy needle in EUS-TA.

Patients and methods

This study is a multicenter retrospective review of all patients who underwent EUS-TA performed by using a novel core biopsy needle (SharkCore FNB

License terms





Fig. 1 SharkCore FNB Needle with opposing bevel design (photo provided by Medtronic).

needle, Medtronic, Dublin, Ireland). The needle tip is designed with 6 cutting-edge surfaces and an opposing bevel designed to catch tissue as it is sheared off (► **Fig. 1**). A total of 18 centers participated, consisting of academic tertiary referral centers and high-volume community-based medical centers. Institutional Review Board approval was obtained from all participating centers prior to data collection and analysis.

The study time frame was between October 2014 and March 2015. The study involved patients referred for EUS-TA of a lymph node, solid mass lesion involving the gastrointestinal lumen, pancreas, liver, or biliary system, or any other extraluminal masses suitable for EUS-TA. Use of FNA, FNB, or both for any particular lesion was left to the discretion of each individual endoscopist at each center.

Data regarding patient demographics, target lesion type and location, technical parameters, diagnostic yield, and adverse events were obtained.

Equipment and technique

The SharkCore FNB needle was utilized for all tissue acquisition in this study. In this study, EUS-guided biopsy was performed using a 25-gauge needle and/or a 22-gauge needle. The needle size used for each patient was left to the discretion of the endoscopist.

All procedures were performed with the stylet in place within the needle. Upon advancing the needle out of the scope channel and sheath, the stylet was retracted a few millimeter's prior to puncturing the target lesion. Care was taken to avoid retracting the stylet prior to needle advancement out of the sheath so as to avoid inadvertent "catching" and puncture of the needle sheath with the needle tip. The needle was then used to puncture the target lesion in a standard fashion. The stylet was maximally advanced inside the needle to remove any possible tissue plugs. Following that, the stylet was either removed entirely from the needle and 10 mL of suction was applied, or the stylet was retracted in a "slow pull" manner, all while performing multiple to-and-fro motions of the needle within the target lesion. Use of standard stylet technique or the slow-pull technique was left to the discretion of the endoscopist.

Specimen preparation and evaluation

Fine-needle aspiration (FNA) was defined as the performance of any single needle pass in which the acquired tissue was prepared for cytologic analysis. Methods used for cytologic analysis included Diff-Quik analysis and/or the creation of a cell block analyzed by hematoxylin and eosin staining, and relevant immunohistochemical staining when appropriate. At the discretion of the endoscopist, rapid on-site evaluation (ROSE) of specimens was utilized to determine whether adequate specimen was obtained.

Table 1 Patient demographics and lesion characteristics.

Patients	n = 226
Median age, years	66 (18–92)
Gender	Male 113 (50%)
Lesion location	n = 250
Subepithelial tumor	28
Esophagus	2
Stomach	22
Rectum	3
Ascending colon	1
Pancreas	136
Head	64
Uncinate	14
Genu	8
Body	25
Tail	25
Bile duct	5
Liver	19
Lymph node	51
Other	11
Median size (mm)	26 (2–150)

Fine-needle biopsy (FNB) was defined as the performance of any single needle pass in which the acquired tissue was prepared for pathologic analysis. The goal of an FNB was to obtain intact tissue (i.e. a core biopsy) for histopathologic analysis. These core biopsy specimens were placed directly into formalin, embedded into paraffin, and sectioned for standard hematoxylin and eosin staining as per standard pathology protocol. Relevant immunohistochemical staining was performed as appropriate (e.g. c-kit and/or dog-1 stain for suspected gastrointestinal stromal tumor). Final analysis of specimens sent for cytology and/or pathology was given one of the following designations: non-diagnostic, benign, atypical, suspicious, or malignant. Both cytologic yield and pathologic yield were determined by calculating the percentage of cases receiving either a benign or malignant diagnosis; designations of atypical or suspicious were considered to be non-diagnostic in this context.

Statistical analysis

A two-sided Fisher's exact test was used to compare categorical variables. A *P* value < 0.05 was considered statistically significant.

Results

Patient and lesion characteristics

A total of 250 lesions underwent EUS-TA in 226 patients. Patient demographics and lesion characteristics are detailed in ► **Table 1**.

Technical aspects

A 25-gauge needle was used in 29% cases, a 22-gauge needle was used in 65% cases, and both were used in 6% cases.

Overall diagnostic yield

A total of 194 cases had specimen sent for cytologic analysis; the median number of passes used was 3 [1–7]. The overall cytologic diagnostic yield was 157/194 (81%). Final cytologic diagnoses were as follows: Non-diagnostic 15 (8%), benign 42 (22%), atypical 10 (5%), suspicious 12 (6%), malignant 115 (59%). ROSE was utilized in 149 cases. Adequate specimen as deemed by ROSE

Table 2 Diagnostic yield by lesion type.

Lesion type	n	Median size, mm (range)	Median number passes for cytology (range)	Diagnostic yield cytology (range)	Median number of passes for pathology (range)	Diagnostic yield, pathology (n, %)	Adverse events (n)
Pancreas	136	28 (4–150)	3 (1–7)	85/106 (80)	2 (1–10)	70/81 (86)	5 (2 pancreatitis, 3 pain)
Subepithelial mass	28	29 (9–54)	3 (1–7)	19/28 (68)	2 (1–5)	13/15 (87)	
Lymph node	51	20 (2–53)	3 (1–7)	21/42 (50)	2 (1–4)	26/28 (93)*	2 (pain)

* $P < 0.05$, lymph node pathology yield vs lymph node cytology yield

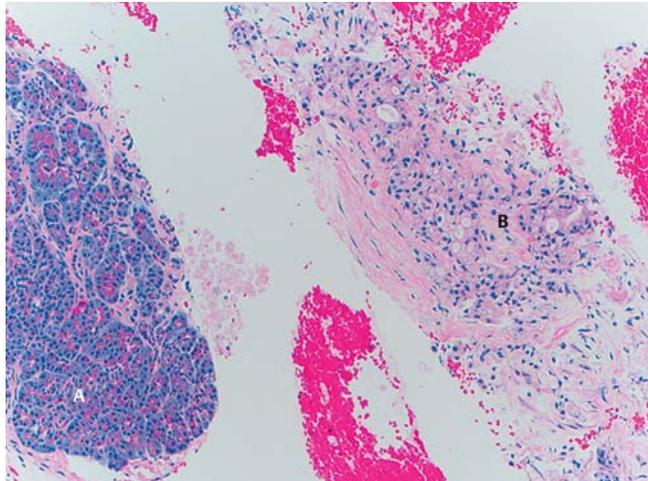


Fig. 2 Core biopsy revealing normal pancreatic tissue (a) and pancreatic adenocarcinoma (b) (medium power).

was 85%. When ROSE was not utilized, the cytologic diagnostic yield was 31/45 (69%). When ROSE was used, the cytologic diagnostic yield was 126/149 (85%, $P = 0.03$)

A total of 147 cases had specimen sent for pathologic analysis; the median number of passes used was 2 [1–10]. The overall pathologic diagnostic yield was 130/147 (88%, NS compared to overall cytologic yield). Final pathologic diagnoses were as follows: Non-diagnostic 7 (5%), benign 30 (20%), atypical 4 (3%), suspicious 6 (4%), malignant 100 (68%).

Diagnostic yield by type of lesion

The cytologic and pathologic yields were separately calculated for pancreatic lesions, subepithelial lesions, and lymph nodes (► **Table 2**) (► **Fig. 2** and ► **Fig. 3**). Overall pathologic yield for each lesion subtype were as follows: pancreatic lesions 86%, subepithelial lesions 87%, lymph nodes 93%. Pathologic yield was significantly higher than cytologic yield in lymph nodes (93% vs 50%, $P = 0.0002$).

Diagnostic yield by needle size 25-gauge

Seventy-three lesions underwent EUS-TA with a 25-gauge needle. These lesions included: subepithelial tumor (SET) 4, pancreatic mass 45, lymph node 12, bile duct mass 2, liver 8, other 2. The median size of these lesions was 24 (4–72) mm.

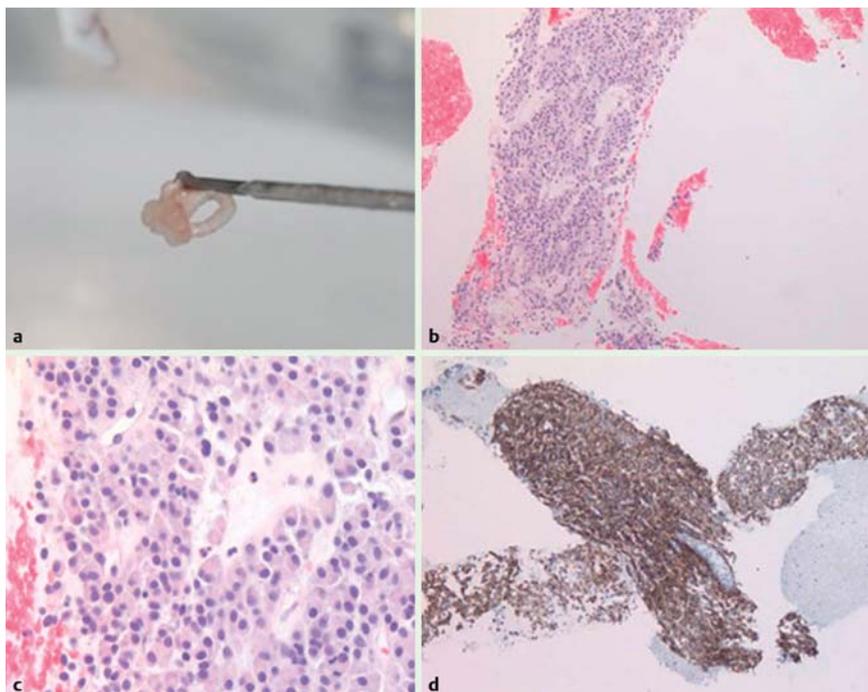


Fig. 3 Core biopsy of a gastrointestinal stromal tumor (a, b, and c), with positive c-kit staining (d).

A total of 63 cases had specimen sent for cytology; the median number of passes sent for cytologic analysis was 3 [1–7]. The overall cytologic diagnostic yield in cases performed with a 25-gauge needle was 49/63 (78%). ROSE was utilized in 49 cases. In cases in which ROSE was not utilized, the cytologic diagnostic yield was 11/14 (79%). When ROSE was used, the cytologic diagnostic yield was 38/49 (78%, NS).

A total of 29 cases had specimen sent for pathology; the median number of passes sent for pathologic analysis was 2 [1–4]. The overall pathologic diagnostic yield in cases performed with a 25-gauge needle was 25/29 (86%, NS compared to overall cytologic yield).

22-gauge

One hundred sixty-one lesions underwent EUS-TA with a 22-gauge needle. These lesions included: SET 21, pancreas 83, bile duct mass 3, liver 11, lymph nodes 34, other 9. The median size of these lesions was 27 (2–150) mm.

A total of 116 cases had specimen sent for cytology; the median number of passes sent for cytologic analysis was 3 (1–7). The overall cytologic diagnostic yield in cases performed with a 22-gauge needle was 94/116 (81%). ROSE was utilized in 88 cases. In cases in which ROSE was not utilized, the cytologic diagnostic yield was 19/28 (68%). When ROSE was used, the cytologic diagnostic yield was 75/88 (85%, $P=0.05$).

A total of 111 cases had specimen sent for pathology; 2 of these cases were liver biopsies. The overall pathologic diagnostic yield in cases performed with a 22-gauge needle was 99/111 (89%, NS compared to overall cytologic yield).

Sixteen cases had FNA performed with both a 25-gauge needle and a 22-gauge needle and were excluded from the above needle size analysis.

Diagnostic yield by lesion type and needle size

The cytologic and pathologic yields were separately calculated for pancreatic lesions, SET, and lymph nodes for both 25-gauge and 22-gauge needles (● Table 3).

Adverse events

Adverse events (AEs) were encountered in 10/250 (4%) cases. These included post-procedure pain in 5 patients, mild acute pancreatitis in 4 patients, and fever/cholangitis in one patient 12 days after combined EUS/ERCP for a pancreatic head cancer (● Table 4).

Discussion

This large, multicenter retrospective analysis demonstrates that the use of a novel core biopsy needle results in excellent pathologic diagnostic yield among all lesion types with a minimum required number of needle passes.

There are a number of findings to highlight from this study. The first is the overall excellent pathologic diagnostic rate of 88% obtained with this novel needle. Previously published prospective studies examining the diagnostic yield of core biopsies obtained by using the Quick-Core (Cook Medical, Bloomington, IN, United States) biopsy needle demonstrated diagnostic yields ranging from 42% to 95%, with an mean yield of 75% [3–12]. Similarly, numerous prospective studies examining the diagnostic yield of core biopsies obtained by using the Procore (Cook Medical, Bloomington, IN, United States) biopsy needle demonstrated diagnos-

Table 3 Diagnostic yield by needle size and lesion type.

	25-gauge n (%)	22-gauge n (%)
Pancreas		
Cytology	27/37 (73)	51/61 (84)
Pathology	17/20 (85)	50/58 (86)
Subepithelial tumor		
Cytology	3/4 (75)	12/15 (80)
Pathology	0/1 (0)	12/13 (92)
Lymph node		
Cytology	9/12 (75)	18/25 (72)
Pathology	2/2 (100)	22/23 (96)

Table 4 Adverse events.

Patient Number	Lesion	Adverse Event	Needle gauge
1	Porta hepatis lymph node	Pain	25-g and 22-g
2	Pancreatic head cancer	Pain	25-g
3	Porta hepatis lymph node	Pain	22-g
4	Pancreatic head cancer	Pain	22-g
5	Pancreatic head cancer	Pain	22-g
6	Pancreatic head cancer	Fever/cholangitis 12 days after combined EUS/ERCP	25-g
7	Chronic pancreatitis (pancreatic head)	Mild acute pancreatitis	22-g
8	Distal bile duct mass	Mild acute pancreatitis	22-g
9	Pancreatic uncinatate cancer	Mild acute pancreatitis	22-g
10	Retroperitoneal mass	Mild acute pancreatitis	22-g

tic yields ranging from 70% to 90.2% with a mean yield of 81.1% (13–21). Based on the results of our study, a randomized prospective trial comparing outcomes with the SharkCore needle versus these other needle types may answer the question about which needle design is superior in achieving diagnostic core biopsy specimens. It should be noted that core specimens for pathologic analysis can be obtained by the use of standard FNA needles. Multiple prospective studies have demonstrated high pathologic diagnostic yields ranging from 81% to 96% when using a standard 22 gauge needle and 59% to 100% when using a standard 19-gauge needle [22–29]. As such, it is unclear at this time how the SharkCore FNB needle would perform against standard FNA needles.

Pathologic yields for specific lesion subtypes included 86% for pancreatic lesions, 87% for SET, and 93% for lymph nodes. The high pathologic diagnostic yield for SET is particularly interesting, as these lesions often present a challenge for tissue acquisition by endosonographers. Published studies demonstrate a cytologic diagnostic yield ranging from 46% to 98% [12,28,30–34]. Diagnostic yield when using the Tru-Cut biopsy needle produced pathologic diagnoses in 55% to 79% of cases, with mean number of required passes ranging from 1.9 to 4 [8,12,31]. One

small prospective RCT comparing 22-gauge FNA needle to a 22-gauge Procore needle demonstrated a significantly higher diagnostic yield with the FNB needle compared to FNA (75% vs 20%, $P=0.01$) and requiring significantly fewer needle passes to achieve this endpoint (2 vs 4, $P=0.025$) [35]. In the current study, we demonstrated a strong trend towards a higher pathologic yield compared to cytologic yield (87% vs 68%, NS) for EUS-TA of SET, with a median number of 2 needle passes required for core biopsy. Subgroup analysis demonstrated that use of the 22-gauge SharkCore needle resulted in both a relatively high pathologic and cytologic diagnostic yield for SET (12/13, 92% vs 12/15, 80%, NS). As such, further studies involving a larger number of subjects may be warranted to assess the performance of the SharkCore FNB needle in EUS-TA of SET.

Another noteworthy finding from this study is that needle size did not have an impact on pathologic diagnostic yield, as both the 25-gauge needle and the 22-gauge needle performed at a very high level, 86% and 89%, respectively. Future prospective studies should be designed to ascertain the effect of needle size on diagnostic outcomes. It should be noted that in regards to cytologic yield, the needle performed at an acceptable level (81% diagnostic yield), and that this was not significantly different compared to the overall pathologic yield (88%). The results of this study also confirm that the utilization of ROSE has a significant impact on cytologic diagnostic yield compared to when ROSE is not used or available (85% vs 69%, $P=0.03$), as has been demonstrated in numerous prior studies [36–38].

AEs related to the use of the SharkCore FNB needle were encountered in 10/250 (4%) of overall cases. The vast majority of AEs were encountered in patients undergoing EUS-TA of the pancreas, with 4/136 (2.9%) experiencing mild pancreatitis, and 3/136 (2.2%) experiencing pain. This AE rate is slightly higher than what would be anticipated, as EUS-TA of the pancreas is generally considered very safe, with a reported rate of pancreatitis of no more than 2% [39]. One large systematic review of more than 10,000 patients demonstrated that in patients undergoing pancreatic EUS-FNA, the rate of procedure-related pancreatitis was 0.44% and procedure-related pain was 0.34% [40]. It was noted by numerous participants in this study that the SharkCore FNB needle produced a tactile “pop” or “catch” when advanced through the tissue. It is theoretically possible that the novel design of the needle tip may allow for more effective capture of tissue prior to shearing it off, but that this may subsequently result in more localized trauma which can result in higher rates of AEs. Larger studies including more patients with pancreatic lesions should help clarify if there are in fact higher risks with using this needle in the pancreas.

There are a number of strengths and limitations to this study. This is the largest study to date examining the performance of an EUS-TA device, with 250 lesions sampled in 226 subjects. The study was a multicenter study, involving highly experienced expert endosonographers at both large academic referral centers and large, high-volume community-based practices, thus creating a real world environment to assess the performance of this novel needle. In addition, we examined outcomes related to both cytologic and pathologic diagnostic yields. The main limitation of the study is its retrospective design and the issues inherent in such studies. In particular, this study is largely subject to selection bias, as patients enrolled were non-consecutive, and it was left to the discretion of each endoscopist at each center whether any particular lesion underwent an FNA, FNB, or both, as well as whether ROSE was utilized or not. Another major lim-

itation is that the cytologic and pathologic analysis was not standardized and the specimens were not centrally reviewed. This may have resulted in considerable heterogeneity in interpretation of the specimens, and greatly affected the results either positively or negatively. Another major limitation of this study is that the final diagnosis of enrolled lesions was not described. As a result, we are leaving open the possibility of both false-positive and false-negative results in our reported diagnostic yield, which could significantly impact the results of our reported outcomes. Thus, it is difficult to make comparisons of needle performance in this study with other studies. However, our intent was to examine the initial experience with this device at expert centers rather than to assert its superiority to other devices. It is our feeling that based on these results, further prospective, randomized, and controlled studies are warranted to assess needle performance and technique with other available devices.

In conclusion, this large, multicenter, North American studying examining the performance and initial experience with a novel core biopsy needle demonstrated an excellent overall pathologic diagnostic yield of 88% among all lesions types, with a minimum number of passes required to obtain diagnostic tissue. The needle performed particularly well in achieving diagnostic core biopsies of SET. There was no difference in pathologic yield between the 25-gauge needle and the 22-gauge needle. Further prospective studies are warranted to determine if the use of this device can make the need for FNA and/or ROSE obsolete.

Competing interests: Dr. Adler is a consultant for Medtronic. Dr. Berzin is a consultant for Boston Scientific and Medtronic. Dr. DiMaio is a consultant for Boston Scientific and Medtronic. Dr. Haluszka is a consultant for Boston Scientific and Medtronic; research support from Boston Scientific. Dr. Ho is a consultant for Boston Scientific and has a speaking agreement with Cook Medical and Medtronic. Dr. Kothari is a consultant for Cook and Medtronic. Dr. Lam is on the advisory board for Boston Scientific and has received an honorarium from Medtronic. Dr. Maranki is a consultant for Boston Scientific. Dr. Muthusamy is a consultant for Boston Scientific and Medtronic and has received honoraria from Boston Scientific and Cook Medical and Medtronic and research support from Medtronic. Dr. Nieto is a consultant for Boston Scientific and Medtronic. Dr. Pleskow is a consultant for Boston Scientific and Medtronic. Dr. Ryou is a consultant for Medtronic. Dr. Sethi is a consultant for Boston Scientific and Xlumena. Dr. Sharma is a consultant for Boston Scientific and Medtronic and has received research support from Medtronic. Dr. Watson is a consultant for Medtronic. Dr. Wong is a consultant for Boston Scientific and Medtronic.

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