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Initial experience with transmural use of a new endoscopic ultrasound electric core needle biopsy device: Case series

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ABSTRACT

Background and study aims Endoscopic ultrasound-guided biopsy via fine-needle biopsy/fine-needle aspiration (FNB/FNA) is currently the standard method to sample tumors in the mediastinum and abdomen. Although specimens obtained with these needles are acceptable, a histological diagnosis is not always possible. Recently, a new EUS-guided core needle biopsy (EUS-CNB) device became available. Herein, we describe the first experience with its use in a transmural fashion.

Patients and methods This was a case series of patients who underwent EUS-CNB at an academic center. All patients provided written informed consent and were observed in the hospital ≥ 48 hours after the procedure.

Results A total of 8 patients underwent EUSC-CNB: five in the pancreas, two in the retroperitoneum, and one in the mediastinum. The diagnostic accuracy of EUS-CNB was 100% after one actuation. In four patients, same-session FNB and EUS-CNB were obtained from the same lesion with superior tissue sample in the latter. No adverse events were documented.

Conclusions To our knowledge this is the first report on transmural use of EUS-CNB in gastroenterology. Our findings suggest that the device is effective and safe. Larger studies comparing it with FNA/FNB needles will be required to further assess performance and safety.

Introduction

Endoscopic ultrasound-guided tissue acquisition (EUSTA) is currently the gold standard to sample tumors in the mediastinum and abdomen via fine-needle aspiration or fine-needle biopsy needles. Although effective, their performance is frequently hindered by factors such as scarce sample and fragmented cores. Despite extensive literature, a frank superiority of one over the other is still a matter of debate, given inconsistent rates of histological diagnosis (60%-80%) [1]. The advent of personalized medicine has increased the need for abundant high-quality samples, and therefore, has created an unmet clinical gap in EUSTA.

Recently, a new device for EUS-guided core needle biopsies (EUS-CNB) was approved by the US Food and Drug Administration (FDA), but at present, the only published literature on its performance in gastrointestinal EUSTA is limited to sampling of subepithelial lesions [2]. Therefore, we herein describe the first clinical experience using this device in a transmural fashion to sample a variety of tumors.

Patients and methods

Data source, study population, measures, and pathology

This was a case series of hospitalized patients who underwent EUS-CNB of a variety of tumors from January to May of 2024 at a single academic center. Demographic and clinical information was obtained from the medical record.

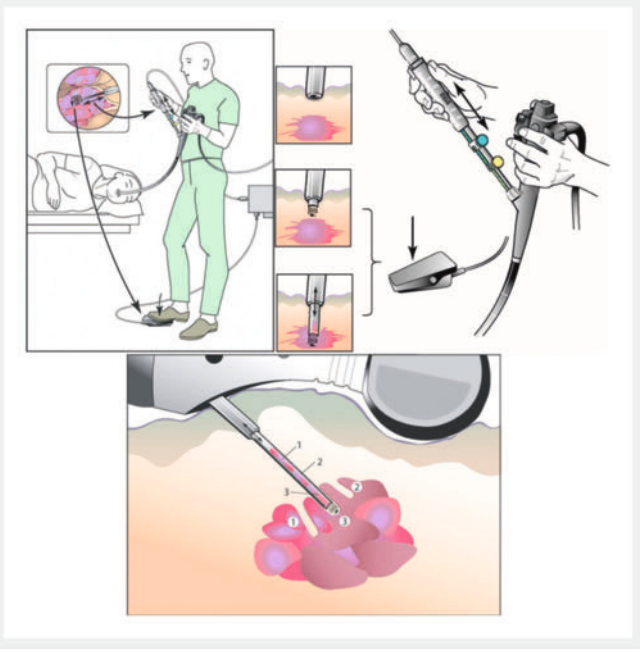
Device

EndoDrill (Bibb instruments, Sweden) is the first electro mechanical device that allows procurement of EUS-CNB. Despite being cleared by the FDA in March of 2023, the device is not yet commercially available in the United States. It consists of a handle that is mounted to the working channel of the echoendoscope, the biopsy instrument, and a motor unit. The handle is connected to the motor unit through a drive cable. The biopsy instrument is made of a stainless-steel flexible sheath with a similarly flexible 17G coring drill cylinder inside. Inside the cylinder's lumen, a stylet is present which is used to expel tissue from it. The outer sheath covers the cylinder to protect its sharp tip as well as to facilitate insertion and extraction of the instrument.

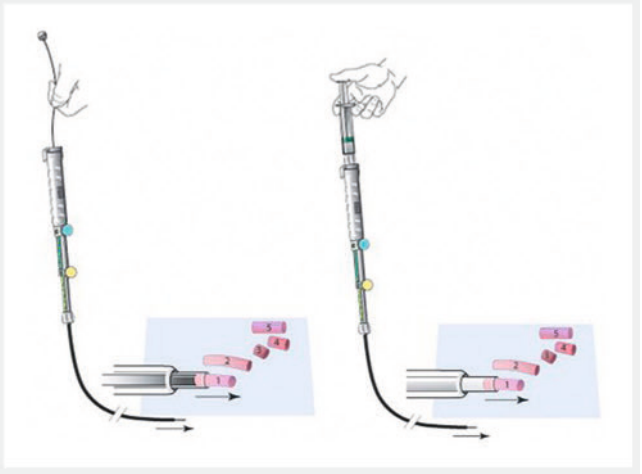
Unlike traditional needles, biopsies are obtained by drilling the device into the target lesion, rather than stabbing it. Once the cylinder tip is in contact with the gastrointestinal wall, the drilling motion is activated by the user via a foot pedal on the motor unit. This transmits torque from the motor unit to the handle and then onward to the revolving cylinder through the drive cable. By applying gentle forward pressure to the spinning cylinder, the device then drills through the gastrointestinal wall and the target lesion, obtaining a tissue core. The maximum length of the cylinder is 60 mm. Multiple tissue samples can be obtained continuously without removing the instrument for harvesting between biopsies (▶ **Fig. 1**, ▶ **Fig. 2**).

EUS-CNB procedure

All cases were performed by a single interventional endoscopist (AML). Prior to biopsy, surgical backup was arranged. All patients provided written informed consent and were observed in the hospital ≥ 48 hours after the procedure. All the procedures were done under general anesthesia in left lateral decubitus position and prophylactic antibiotics were given. A linear GF-UCT180 curvilinear array echoendoscope (Olympus, Japan) was introduced through the mouth and advanced to the area of the target lesion. Once the lesion was localized, a vessel-free window was identified using Doppler. The outer sheath was then advanced until it was visible on EUS. The cylinder was then pushed out of the sheath until gentle tenting of the gastric/duodenal wall was seen. The biopsy was then obtained by activating the drilling mechanism and performing a single gentle actuation through the gastrointestinal wall and into the target lesion, maintaining it under direct EUS visualization at all times. No fanning was performed and the interval from puncture to removal from the target lesion was ≤ 4 seconds.



▶ **Fig. 1** EndoDrill. Operating instructions. Stepping on the pedal activates the drill and allows puncture of the tumor in question.



▶ **Fig. 2** Tissue core obtained after a puncture can be expelled via a stylet or air/water flush, as with any other regular FNA/FNB needle.

The device was then withdrawn from the echoendoscope and the puncture site was evaluated to identify any visible defects or bleeding. The specimen was expelled from the cylinder by pushing the stylet through its lumen. All specimens were valuated with rapid onsite evaluation (ROSE). Once adequacy was confirmed, the specimens were placed in a formalin jar and submitted to pathology.

▶ **Table 1** Case characteristics.

Case	Gender	Age	Lesion location, size (cm)	Approach	Number of actuations	Pathology	Adverse events
1	M	67	HOP, 3	Transduodenal-bulb	1	Adenocarcinoma	None
2	M	49	HOP, 3.5	Transduodenal-bulb	1	Adenocarcinoma	None
3	F	69	RP, 11	Transgastric-GEJ	1	Leiomyosarcoma	None
4	M	66	HOP, 3.4	Transduodenal-bulb	1*	Adenocarcinoma	None
5	M	56	UNC, 4.3	Transduodenal-second portion	1*	Small Cell Carcinoma	None
6	F	75	RP, 7	Transgastric-body	1	Schwannoma	Bleeding
7	F	57	MED, 6	Transesophageal	1*	Adenocarcinoma	None
8	M	75	HOP,3.6	Transduodenal-bulb	1*	Adenocarcinoma	None

*Additional same-session FNB of the lesion done with a 22G needle.
GEJ, gastroesophageal junction; HOP, head of pancreas; RP, retroperitoneal; UNC, uncinate process; MED, mediastinum.

Results

A total of eight cases were included in this series and their main characteristics are summarized in (▶ **Table 1**).

Case 1

A 67-year-old male presented to the emergency room with epigastric pain and painless jaundice. Abdominal MRI revealed a 3-cm mass in the head of the pancreas (HOP) with intrahepatic and extrahepatic biliary dilation. Pathology revealed pancreatic ductal adenocarcinoma (PDAC) (▶ **Fig. 3**).

Case 2

A 49-year-old male presented with a 3.5-cm HOP mass to an outside hospital, where he underwent a non-diagnostic EUS-FNB. A second EUS-FNB with a 22G needle at our hospital was similarly non-diagnostic. A third biopsy was then obtained with EUS-CNB and pathology revealed PDAC.

Case 3

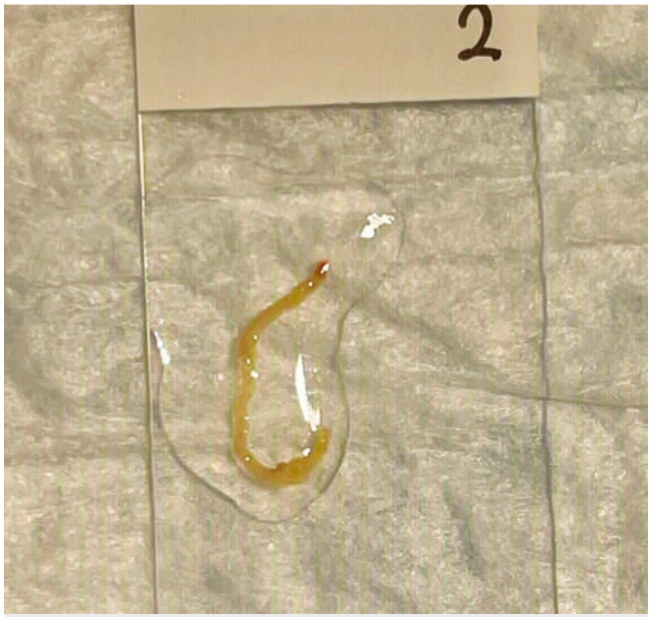
A 69-year-old female with a history of left temple leiomyosarcoma was referred for an 11-cm retroperitoneal mass. Pathology revealed high-grade leiomyosarcoma.

Case 4

A 66-year-old male was admitted for painless jaundice and clay-colored stools. Abdominal CT revealed a 3.4-cm mass in the HOP with intrahepatic and extrahepatic biliary dilation. An initial FNB with a 22G needle was not diagnostic, so same-session EUS-CNB was performed (▶ **Video 1**, ▶ **Fig. 4**). Pathology revealed PDAC.

Case 5

A 56-year-old male presented with abdominal pain, nausea, vomiting, and weight loss. CT of the abdomen/pelvis revealed a 4.3-cm mass in the uncinate process. A chest CT showed a 2.0-cm mass in the lower lobe of the left lung concerning for a primary pulmonary malignancy. Initial FNB with a 22G needle was non-diagnostic so a same-session EUS-CNB was performed. Pathology revealed pulmonary small cell tumor metastasis. Endobronchial ultrasound biopsy of the pulmonary mass confirmed a primary small cell lung tumor.

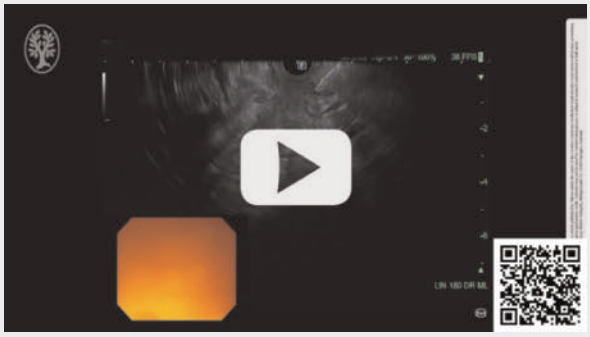


▶ **Fig. 3** Core biopsy of a pancreatic tumor obtained after one actuation with no fanning.

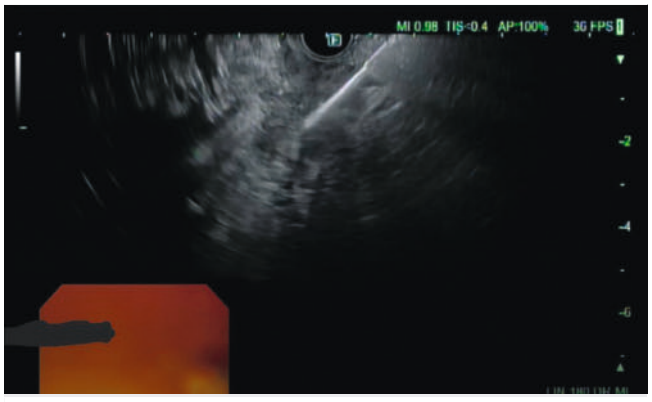
Case 6

A 75-year-old female was referred for a 7-cm retroperitoneal solid/cystic lesion abutting the pancreas. Mild bleeding occurred after EUS-CNB, so an over-the-scope clip was placed at the puncture site, successfully stopping the bleed. Pathology revealed schwannoma.

VIDEO



▶ **Video 1** EUS-CNB of a 3.4-cm HOP tumor. Puncture with EndoDrill from the duodenum. The drill is advanced out of the sheath, the spinning mechanism is activated by the pedal, and the lesion is drilled. Approximate depth of insertion of the drill was 2 cm.



▶ **Fig. 4** EUS view of the drill inside the tumor.

Case 7

A 57-year-old female with a history of smoking and alcohol consumption presented with dysphagia and weight loss. Esophagogastroduodenoscopy revealed extrinsic compression at the gastroesophageal junction without intraluminal mass. A CT showed a 6-cm mediastinal mass completely encasing the distal esophagus. Pathology revealed adenocarcinoma.

Case 8

A 75-year-old male was admitted after a fall and diagnostic workup revealed an incidental 3.6-cm mass in the uncinate process. Pathology showed PDAC.

Discussion

The first EUSTA of a pancreatic tumor was reported by Vilmann et al in 1992 [3]. Given its clinical impact, this was followed by subsequent publications describing the technique in other organs and conditions [4, 5].

Since then, EUSTA has evolved due to advances in EUS image resolution, but more importantly, to development of dedicated biopsy devices. Although FNA needles appeared effective for cytological diagnosis, their performance has been suboptimal, with sensitivity and specificity reported as low as 64% and 75%, respectively [1, 6]. Different methods of suction (dry suction, wet suction, or stylet suction) have been studied in an effort to improve tissue quantity but all have yielded inconclusive and heterogenous results.

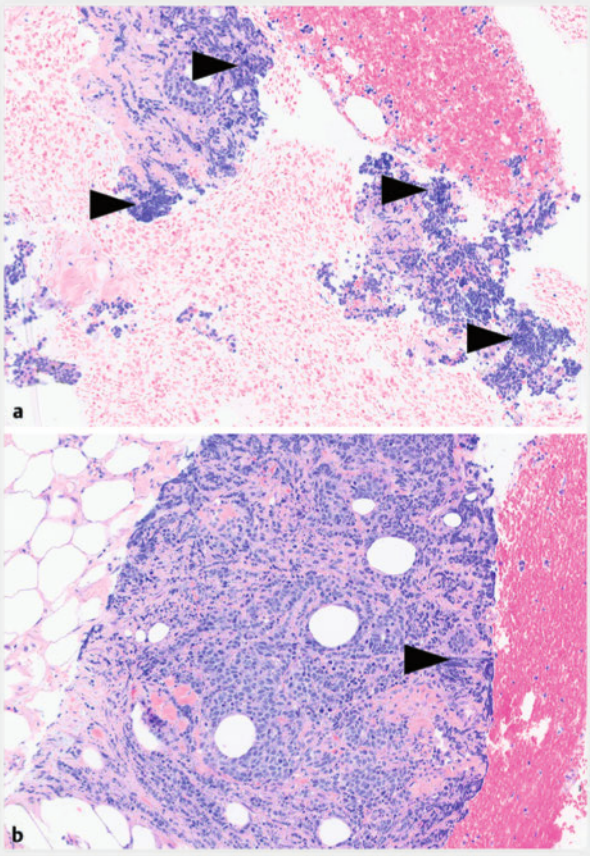
In 2011, the first FNB needle that allowed histological diagnosis was introduced [7]. It had an opening on the side with a reverse bevel aimed at cutting tissue during backwards retraction. This needle was then redesigned to have forward beveled side holes and soon other needles with different tips (fork-tip, Franseen and three point) came to the market [8]. Since their introduction, multiple studies have reported some superiority over FNA needles, but the benefits are rather modest [1, 9, 10].

Currently, it is not uncommon to have inadequate samples with FNA/FNB needles, especially in tumors with high desmoplastic reactions, necrotic areas, or those located in difficult locations (uncinate process of pancreas). The advent of personalized medicine has increased the need for unfragmented tissue for extra stains and molecular/genetic analyses. Therefore, better sampling devices are needed

From a clinical perspective, this initial experience with the device was positive. We obtained a diagnostic accuracy of 100% in all cases. Given its wider diameter (17G), one of the main concerns was the possibility of gastric/duodenal perforation and other adverse events (AEs). However, the wall defect left by the device did not require closure afterward. In fact, four patients underwent both EUS-CNB and regular FNB of the same lesion during the same session out of concern about insufficient sample from the initial FNB pass. The only AE seen was mild bleeding in one case that was successfully treated endoscopically.

Pathological examination of the samples revealed less blood contamination and more evaluable tissue than what is typically seen in FNA/FNB ones. All five pancreatic biopsies showed essentially no blood in the background. Overall, the tissue cores were more intact and contained abundant background non-neoplastic tissue that provided a better context for the overall disease process and helped provide a more informative diagnosis. In this series, EUS-CNB proved especially helpful in two patients. The first one was the patient with metastatic small cell carcinoma. This neoplasm is notorious for being easily crushed and destroyed during biopsy. When the samples obtained with FNB and CNB were compared, the latter preserved the tissue intact and with less crush artifact, allowing for better visualization of the cytomorphology (▶ **Fig. 5**). The second one was the patient who had undergone previous EUSTA twice with non-diagnostic samples. The cores obtained in this patient with the EUS-CNB were finally able to establish an official diagnosis.

From a technical perspective, overall, the device was easy to set up and operate. No concerning difficulties were experienced during its operation. The metal sheath of the drill is stiffer than the plastic one on FNB needles. This facilitates its use when the echoendoscope is in difficult locations in which the plastic sheath can bend and interfere with needle movement (i. e. second portion of the duodenum). The metal sheath



▶ **Fig. 5** Composite image of **a** FNB and **b** CNB of a pancreatic biopsy with a diagnosis of metastatic small cell carcinoma, showing the differences in blood contamination and malignant tissue quantity.

allows for multiple passes of the cylinder in such locations without disrupting it. Two important differences from an FNA/FNB needles are important to mention. The first one is that once the device is attached to the echoendoscope, the handle rotates freely and can lead the endoscopist to believe it is not properly attached. The second one is that the device did not require the typical "stabbing" motion that FNA/FNB needles do during the initial gastric/duodenal wall puncture. Similarly, advancing it through the target lesion was significantly easier, given that the drilling motion reduces tissue resistance. This is of critical importance because it can potentially lead to a "through and through" puncture of the target lesion and injury of nearby structures. For these reasons, it is our opinion that the device should only be operated by experienced endoscopists.

Conclusions

In summary, to our knowledge, this is the first report of the transmural use of a new EUS-CNB for EUSTA in the gastrointestinal tract. Our initial findings suggest that the device is safe and effective. Clinical scenarios in which the device could make a meaningful clinical impact include EUS-guided liver biopsy, tumors with prior non-diagnostic sampling, and tumors of difficult location (i.e. uncinate process). At this time however, it is unclear how this device will position itself in clinical practice. Randomized trials comparing it with FNA/FNB needles will be required to further assess its safety and efficacy.

Conflict of Interest

The corresponding author has a personal relationship with the inventor of the device. The inventor of the device is paying for the article processing fee. The remaining authors have no conflicts of interest to declare.

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