First experience with the new 20 Gauge EchoTip ProCore® FNB needle:

Diagnosis and staging of a pancreatic neuroendocrine tumor



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Background

Pancreatic neuroendocrine tumors (p-NET) comprise an intriguing disease entity posing clinicians with some interesting differential diagnostic challenges. Currently available imaging techniques can identify p-NETs in most cases, but histological confirmation is required to select the best management strategy. EUS-guided tissue sampling is the procedure of choice for preoperative tissue collection in p-NETs. To obtain a reliable diagnosis, pathologists require a tissue sample of sufficient size and quality that allows for the full range of diagnostic tests. Importantly, sample adequacy is influenced by several factors, including the type of device and sampling technique used.

Recently, a new EUS sampling device has been launched: the 20 gauge EchoTip

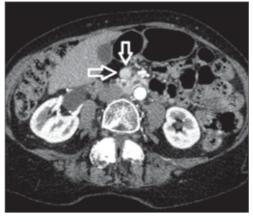


Figure 1

Abdominal CT scan with contrast enhancement, showing a hypervascular, nodular lesion near the head of the pancreas (arrows).

ProCore FNB needle. This EUS needle is designed to combine the best features of currently available sampling tools; a large core size for optimal histological tissue acquisition, yet easy to be handled in anatomically challenging locations because it has a flexibility that approximates that of a 25 gauge needle. We share our first experience with the new ProCore FNB device in diagnosing and staging a pancreatic neuroendocrine tumor.

Case

A 73-year-old patient was referred to our outpatient department with complaints of weight loss (13 kg in 2 years), flushes and intermittent epigastric pain. Her medical history reported hypertension and de novo diabetes since 2014. Previously, the patient had undergone an abdominal CT scan, which showed a hypodense, nodular lesion in or near the head of the pancreas (*Figure 1*). Because of the suspicion of either a neuroendocrine tumor or enlarged peripancreatic lymph nodes, the patient was scheduled for EUS-guided tissue sampling under conscious sedation in an outpatient setting. On EUS, a hypoechogenic, hypervascular, contrast-enhancing lesion (9 x 12 mm) was observed, located in the head of

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the pancreas (Figure 2). The patient had EUS-guided tissue sampling using the new 20 EchoTip ProCore FNB needle. The lesion was punctured from the duodenum (D2) and three consecutive needle passes were performed, using suction with a syringe. Excellent tissue samples were obtained from all three passes. Each pass contained both tissue cores and material for cytology. Immunohistochemical staining was performed (Figure 3a and 3b) and found positive for Pancreatin, CD 56, Synaptophysin, Chromogranin A, and the somatostatin receptor SSTR-2a. A proportion of mitotic cells between 3-20% (MIB-1 or Ki67) confirmed a pancreatic neuroendocrine tumor, grade 2.

Conclusion

In this patient with a neuroendocrine tumor in the head of the pancreas the 20 gauge EchoTip ProCore FNB needle provided a reliable tissue diagnosis to guide further management. The ultimate benefit of the 20 gauge EchoTip ProCore FNB needle is currently being tested in a large scale international study (ASPRO study) of which the results are eagerly awaited.



Figure 2 EUS procedure, showing a hypoechogenic mass (9 x 12 mm) between the pancreatic head and the uncinate process with sharp margins, before insertion of the FNB needle.

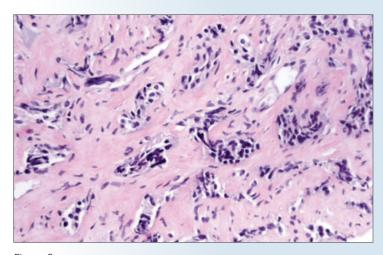


Figure 3a Histology of a 20 gauge Echotip ProCore FNB biopsy. H&E staining of the tissue core showing nests of tumor cells imbedded in fibrous stroma.

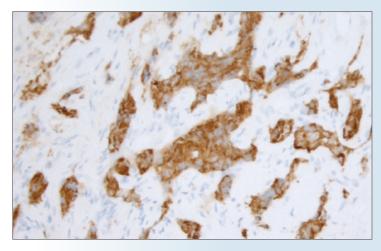


Figure 3b Synoptophysin immunohistochemistry with strong positivity of tumor cells. Magnification x200. The final diagnosis is a neuroendocrine tumor in the head of the pancreas, grade 2.

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If manufacturers didn't work together to: a) come up with a transition plan, b) decide to introduce the new connectors in the same time period and c) to make sure we are all saying the same thing, we would confuse our customers. If there weren't that type of collaboration, it would be mass confusion and worse. It would lead to disruption of therapy. The biggest single driver is patient safety, ensuring that we carefully transition the market without disruption of therapy.

So collaboration between the manufacturers is really important, as is collaboration with the various associations. We have been able to make a great connection with the folks at A.S.P.E.N., the American Society for Parenteral and Enteral Nutrition. That organization and in particular, Dr. Peggi Guenter has been a huge proponent of our efforts. They have helped lead the development of our FAQs and other training tools as well as lead the charge presenting these changes at various conferences and webinars.

The Joint Commission has been working with us and they recently released Sentinel Event Alert #53 to demonstrate the importance if these changes. The FDA is also available to provide guidance and answer questions for us. The Institute for Safe Medication

Practices has also been strong contributor as has the Association for Advancement of Medical Instrumentation.

The Oley Foundation is another great collaborator. They are a patient care advocacy group and they are a very strong voice within that community. We are working with them to make sure that we have the right transition plan in place and we are addressing their issues and doing studies to make sure that when we make the transition it is suitable. They, too, are helping get the word out.

For medication administration concerns, we are working with the American Society of Health-System Pharmacists (ASHP). We have participated in their Medication Safety Collaborative, where we did a talk and a breakout session for hands-on training. So we are going to continue to foster that relationship to get the word out to pharmacists in the hospital setting. We are also working with the Walgreens of the world that deliver home infusion. They will also communicate the message through to their pharmacies at the community level.

So the collaboration just continues to build and we are continuing to create relationships with various associations that represent the various personnel and functions that we need to try to reach through hospitals, long-term care and home care settings.