A Retrospective, Single Center Experience with the SharkCore Fine Needle Biopsy System: A New Bite in to Gastrointestinal Histological Sampling

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Materials and Methods

- **Study type:**
  - Retrospective, hypothesis-generating study conducted at a large, tertiary, single center teaching hospital for 6 months.

- **Equipment and Endoscopic Ultrasound (EUS) Procedure:**
  - Patients monitored under anesthesia care with procedures performed using a linear array or radial echoendoscope in left lateral decubitus position. EUS-guided FNB was done with the 22G and 25G FNB needle of stainless steel (ID 0.020", 0.014" and 0.025" and 0.028"), respectively.
  - Localization of mass followed by needle puncture, styli removed, and needle moved to and fro within the lesion four times. All tissue sampling performed with slow pull technique. Specimen then expressed onto slides by flushing air into needle assembly.

- **Sampling Process:**
  - Sample is obtained from needle onto two slides, one for Diff Quick staining, one Papcoulousta stain, if core biopsy present, tissue material placed into a formalin container.
  - Samples that were evaluated and sent direct to the pathology department.
  - Initial adequacy during ROSE determined by cytotechnologist and final adequacy verified by final pathology report.
  - Adequacy based on cells appearing to be malignant or a different architecture compared to normal tissue.
  - All biopsy needles are rinsed in CytoLyt.

- **Statistical analysis:**
  - The analysis was purely descriptive and exploratory in nature with descriptive statistics presented for each variable.

- **Study Inclusion Criteria:**
  - Age > 18 years old
  - Active pancreatitis
  - Biliary obstruction
  - Age > 18 years old
  - EUS-FNB performed by one of two advanced endosonographers
  - Lesion(s) in the left liver and/or mass
  - Retroperitoneal lymph node and/or mass
  - Perirectal lymph node and/or mass
  - Intestinal/gastric lobe

- **Study Exclusion Criteria:**
  - Pancreatic, hepatic, gastric, intra-abdominal or mediastinal components
  - Mass seen on prior imaging (CT, MRI or EGD)
  - Masses/lesions were accessible with 19G, 22G or 25G needle
  - Patients with active pancreatitis
  - Patients with enzymatic pancreatitis
  - Patients with acute thrombocytopenia

- **Equipment and Endoscopic Ultrasound (EUS) Procedure:**
  - New Bite into Gastrointestinal Histological Sampling. Shark Core fine needle biopsy system with 6 beveled cutting edge surface to decrease tissue fracturing and penetration force while maintaining intact tissue structure.

- **Study Aims:**
  - To assess if ROSE is necessary in endoscopic ultrasound-guided fine needle aspiration biopsy.
  - To determine whether ROSE allowed for adequate tissue collection of histological samples.
  - To study diagnostic accuracy of core tissue samples.

- **Advantage of FNB vs FNA:**
  - Studies suggest that diagnostic accuracy/adequacy can be enhanced with the use of rapid onsite evaluation (ROSE).

- **Limited FNB vs FNA:**
  - Accuracy of diagnosis of an oncologic case can be guided by ROSE.
  - Improves diagnostic and therapeutic yield.

- **Discussion:**
  - Adequacy of samples determined by final pathological read was 87.9%.
  - Factors to increase adequacy in sampling are ROSE availability, experience of the endosonographer and familiarity or continued exposure to EUS procedures.

  - Our study indicated, based on the pathology protocol, that this needle system did not provide core tissue samples.
  - Majority of samples underwent histological processing, but were done so as an afterthought.
  - One study reviewed the use of both FNA and FNB systems to obtain histological samples and revealed the FNB to be unsatisfactory in yielding core specimen compared to the FNA systems.

  - ROSE allows real time feedback to endosonographers to assist in adequacy samples for biological sampling with about a 10-15% increase in specimen yield in at least solid pancreatic masses.

  - 96.2% of cases were able to obtain adequate samples, but with ROSE absent, a majority of cases were still found to have adequate samples.

  - Adequacy of samples determined by final pathological read was 87.9%.

- **Limitations:**
  - Small sample size (n = 33), single center
  - Short time period (6 months)

- **Future Studies:**
  - Utilizing this technology for intra-thoracic malignancy
  - Comparing ROSE adequacy with final pathology
  - If increase familiarity with the system decreases the need for ROSE
  - Change in how samples are processed by pathology

References:


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