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

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A New Bite in to Gastrointestinal Histological Sampling

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Background

- Sharkcore Fine Needle Biopsy (FNB) system allows for interchangeability of all needle sizes through a universal delivery system for rapid needle exchange and passes and for the possible collection of histological samples.
- Studies suggest that diagnostic accuracy/adequacy can be enhanced with the use of rapid onsite evaluation (ROSE).
- Advantage of FNB vs FNA
  - Accurate diagnosis of an otherwise undifferentiated tumor with tissue acquisition
  - Options involving surgical and oncologic care can be guided by the results
  - Prevent inappropriate treatment

Study Aims

- Assess the adequacy of tissue samples obtained from the SharkCore FNB
- Determine if location of the mass/ lesion effects adequacy
- Assess if ROSE is necessary in assisting with adequacy
- Determine if the SharkCore FNB system can produce core tissue specimens for histological sampling

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 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 OD 0.028" and 0.020"), respectively.
  - Localization of mass followed by needle puncture, stylet removed, and needle moved to-and-fro within the lesion four times. All tissue sampling performed with slow pull technique.[4] 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 Papanicolaou stain.
    - If core biopsy present, tissue material placed into a formalin container.
  - Samples that not evaluated with ROSE were collected and sent directly 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.
    - If thick tissue fragments present, cell block for histological processing was created.
- Statistical analysis:
  - The analysis was purely descriptive and exploratory in nature with descriptive statistics presented for the entire sample as a whole.
  - Means presented with the standard deviation for the continuous variables (age)
  - Percentages given for all cases that resulted in an adequate tissue sample overall and broken down by location of the mass.

Table 1. FNB Background

Indications for FNB[1]	Contraindications[1]	Complications[2-3]
• Pancreatic mass • Cystic lesion with solid components • Mediastinal lymph node and/or mass • Retroperitoneal lymph node and/or mass • Perirectal lymph node and/or mass • Lesion(s) in the left liver lobe • Left adrenal mass • Intestinal/gastric Subepithelial mass/lesion	• Severe thrombocytopenia • Severe coagulopathies • Inability to properly visualize lesion/mass	• Pancreatitis • Post procedure hypotension • Seizure • Laryngospasm • Post procedural abdominal pain

Study Inclusion Criteria	Exclusion Criteria
Age > 18 years old	Untreated coagulopathy
Pancreatic, hepatic, gastric, intra-abdominal or mediastinal mass seen on prior imaging (CT, MRI or EGD)	Active pancreatitis
Masses/lesions were accessible with 19g, 22g or 25g needle	Biopsies performed utilizing a different FNA system
Mass/lesion composed of some solid components	Mass/lesion felt not to be safely accessible
EUS-FNB performed by one of two advanced endosonographers	

Figure 1. Shark Core fine needle biopsy system with 6 beveled cutting edge surface to decrease tissue fracturing and penetration force while maintaining intact tissue structure.

Results

Table 2. Clinical Characteristics of Patients

Variable	Patients (n=33)
Average Age ±SD, yrs	63.3 ± 16.8
Sex	
• Male	16 (48.5%)
• Female	17 (51.5%)
Race/ethnicity	
• Caucasian	29 (87.9%)
• African American	1 (3.0%)
• Other	3 (9.1%)
Location of mass*	
• Pancreas	19 (57.6%)
– Head	8 (24.2%)
– Body	9 (27.3%)
– Tail	2 (6.1%)
• Intra-abdominal lymph node	6 (18.2%)
• Hepatic	2 (6.1%)
• Gastric/Submucosa	4 (12.1%)
• Biliary	2 (6.1%)
FNB Adequacy	
• Inadequate	3 (9.1%)
• Adequate	29 (87.9%)
• Less than optimal/inconclusive	1 (3.0%)
FNB Results	
• Benign/Non-malignant	12 (36.4%)
• Malignant	16 (48.5%)
• Inconclusive	5 (15.2%)

* Some percentages may not equal 100% due to rounding.

Table 3. ROSE EUS-FNB Adequacy Compared with Non ROSE EUS-FNB

		ROSE Present	ROSE Absent
FNB Adequacy	Adequate	25 (96.2%)	4 (57.1%)
	Inadequate	1 (3.8%)	2 (28.6%)
	Less than optimal	0 (0.0%)	1 (14.3%)
Total Patients (n)		26	7

Table 4. Adequacy Based on Location of Mass

	FNB Adequacy			
Location of Mass	Adequate	Inadequate	Less than Optimal	Total Patients (n)
Pancreatic	16 (84.2%)	2 (10.5%)	1 (5.3%)	19
• Head	7 (87.5%)	0 (0.0%)	1 (12.5%)	
• Body	8 (88.9%)	1 (11.1%)	0 (0.0%)	
• Tail	1 (50.0%)	1 (50.0%)	0 (0.0%)	
Intra-abdominal Lymph Node	6 (100%)	0 (0.0%)	0 (0.0%)	6
Hepatic	2 (100%)	0 (0.0%)	0 (0.0%)	2
Gastric/Submucosa	3 (75.0%)	1 (25.0%)	0 (0.0%)	4
Biliary	2 (100%)	0 (0.0%)	0 (0.0%)	2

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.[5-7]
- 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 system.[8]
- 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.[3]
  - 96.2% of cases were able to obtain adequate sample, but with ROSE absent, a majority of cases were still found to have adequate samples.
- Adequacy based on location of mass
  - Majority of cases were sampled from pancreas with an adequacy rate of 84.2%.
  - Intra-abdominal lymph nodes, hepatic masses and biliary samples had 100% adequacy rate but were a low sample size
  - Our study is different in that it evaluates many different pathological sites not limited to solid pancreatic masses that are showing adequate sampling with the use of the SharkCore FNB system.

Limitations

- Small sample size (n = 33), single center
- Short time period (6 months) for both advanced endosonographers to access and train with new FNB system
- Pathology protocol for core tissue biopsies

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

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