NEW YORK SOCIETY FOR GASTROENTEROLOGY & ENDOSCOPY

48th Annual NEW YORK COURSE

December 12-13, 2024 • New York, NY





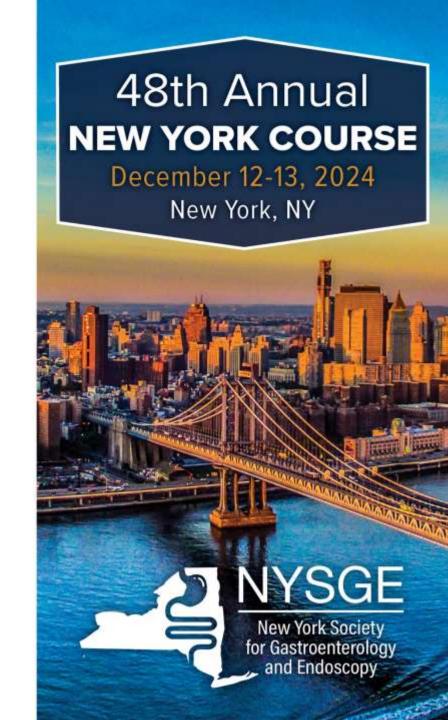
Maximizing the Yield of EUS Tissue Acquisition

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OBJECTIVES

1) Understand the variables associated with successful EUS-guided tissue acquisition

2) Understand the role of FNA vs FNB



PLAN

- EXPECTED YIELD
- FNA vs FNB: PROS-CONS
- SCRAPING vs CUTTING NEEDLES
- HOW TO MAXIMIZE FNA-FNB YIELD



TAKE HOME POINTS

- Due to development of <u>cutting</u> FNB needles, the issue of EUS-guided tissue acquisition has been SOLVED
- Suboptimal results are due to poor technique
- YOU MUST MOVE THE NEEDLE ADEQUATELY and BROADLY IN THE TARGET LESION
- The techniques for maximizing the yield of FNA and FNB are the **same**.
- ROSE may still be helpful for FNA, but not needed for FNB.



EUS-FNA ACCURACY: META-ANALYSIS

Hébert-Magee S, ET AL, Cytopathology. 2013 Jun;24(3):159-71

- Identified studies, in which the pooled sensitivity, specificity, likelihood ratios for a positive or negative test (LR+, LR-) and summary receiver-operating curves (SROC) could be determined for EUS-FNA of the pancreas for ductal adenocarcinoma
- 34 distinct studies (3644 patients)
- pooled sensitivity and specificity for EUS-FNA for pancreatic ductal adenocarcinoma:
 - SENSITIVITY 88.6% [95% confidence interval (CI): 87.2-89.9]
 - SPECIFICITY 99.3% (95% C/: 98.7-99.7),
- ROSE (P = 0.001) remained a significant determinant of EUS-FNA accuracy after correcting for study population number and reference standard.



CYTOLOGY

- "EASY" cases: >95% (Sn + special stains)
 - Obvious cancers
 - Huge masses and nodes
 - Large SMTs
- "HARDER" cases: ?
 - Questionable masses (Ca vs CP, AIP, etc.)
 - Small lesions (esp SMTs)
 - Difficult positions
 - Metal stents



IS FNA SUFFICIENT?

- Most EUS-FNA is for diagnosis <u>epithelial</u> cancers and ancillary tests are needed in a <u>minority</u> of cases.
- There is evidence that getting a core increases the diagnostic yield for <u>epithelial</u> cancer, but by only about 5%
- FNB may also however reduce the number of passes required.
- QUESTION: Instead of using a more expensive needle, why not do another pass +/- cell block?



FNA + CELL BLOCK: AS GOOD AS FNB?

	CELL BLOCK	CORE BIOPSY
MEDIUM	ETOH	FORMALIN
PARRAFIN	✓	✓
IMMUNO	✓	✓
TUMOR MARKERS	✓	✓
GENETICS	✓	✓
MITOTIC INDEX	✓	✓
ON SITE READ	✓	✓
STRUCTURE	*	✓
OTHER BENEFITS**	?	?



FNA vs FNB: WHY GET A CORE?

- PATHOLOGIST INSISTS
- NEED <u>STRUCTURE</u>
 - Lymphoma, AIP, etc.
 - Liver**
- FAILED CYTOLOGY ("Dry" pass)
 - LINITIS
 - SCLEROTIC TUMORS
 - Small SMTs (Really???)
 - Etc.
- **NO ROSE?



FNB (CORE): UNFORSEEN BENEFITS

- The "positive" negative result...
- The surprise positive...
- The serious pathology report...



WHY NOT GET A CORE?



SUMMARY:

- In selected difficult EUS tissue sampling cases, the 22ga Franseen tip needle:
- 1) Provides samples adequate for histological analysis in 92%,
- 2) The sensitivity for malignancy is 91.7%.
- These results were obtained without ROSE.

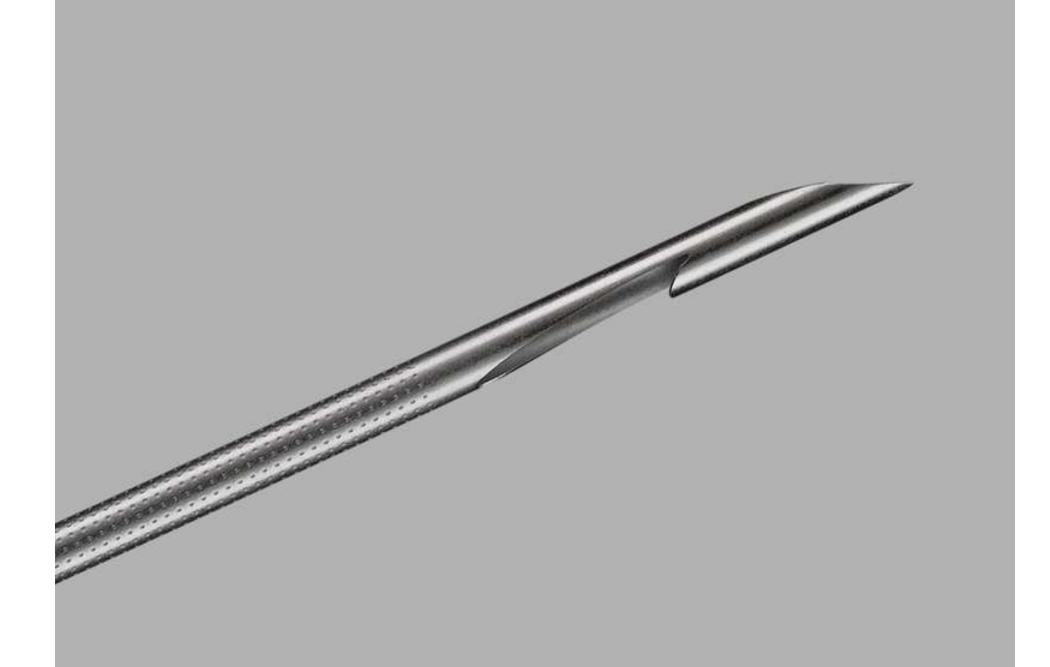
• CONCLUSION:

• The 22ga Franseen tip needle is an excellent choice in cases where traditional EUS-FNA results are inadequate.



FNB NEEDLES: SCRAPING vs CUTTING







SCRAPING





CUTTING NEEDLES





CUTTING NEEDLE

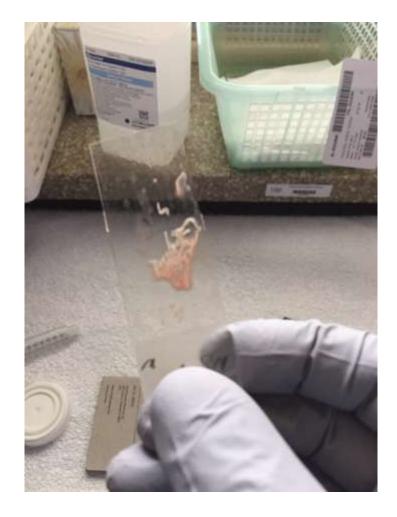






Table 3. Comparison of procedural details and outcomes

	_	FNB (n=46)	FNA (n=46)	p-value
ROSE - Diagnostic adequacy: n (%)		46 (100)	44 (95.7)	0.495
ROSE - Total no. of passes for diagnostic adequacy:*	Mean (SD)	1.15 (0.47)	1.18 (0.58)	8
	Median	1	1	0.929
	IQR	1 - 1	1 - 1	
	Range	1 - 3	1 - 4	1
	1	41 (89.1)	38 (86.4)	0.778
	2	3 (6.5)	4 (9.1)	50000000
	3	2 (4.3)	1 (2.3)	
	4	0	1 (2.3)	1
Specimen bloodiness: n (%)	Mild	12 (26.1)	16 (34.8)	0.736
sserieden meg vin betruste utseen dietersteern dez in tinderne van 111 desteurzu.	Moderate	29 (63.0)	26 (56.5)	- Provide Control Cales
	Severe	3 (10.9)	4 (8.7)	8
Cell block - Diagnostic adequacy: n (%)		45 (97.8)	38 (82.6)	0.030
Cell block - Diagnostic accuracy: n (%)	437	43 (93.5)	37 (80.4)	0.063
Adverse events: n (%)	8	0	0	0.999

Abbreviations: FNA, fine needle aspiration; FNB, fine needle biopsy; IQR, interquartile range; ROSE, Rapid onsite evaluation; SD, standard deviation



^{*} n=44 for calculation of the total no. of passes performed in the FNA group as sample was not diagnostically adequate on ROSE in two patients

FRANSEEN 22 VS REVERSE BEVEL 20

22G Acquire vs. 20G Procore needle for endoscopic ultrasound-guided biopsy of pancreatic masses: a randomized study comparing histologic sample quantity and diagnostic accuracy

David Karsenti, Laurent Palazzo, Bastien Perrot, Jacqueline Zago, Anne-Isabelle Lemaistre, Jérôme Cros, Bertrand Napoléon

Background Endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) has been suggested for obtaining high quality tissue samples from pancreatic tumors. We performed a multicenter randomized crossover trial comparing EUS-FNB with a 20G Procore needle vs. a 22G Acquire needle. The aims were to compare the quantity of targeted tissue (pancreas) and diagnostic accuracy for the two needles.

Methods 60 patients admitted for EUS-FNB in three endoscopy units were included. One pass was performed consecutively with each needle, in a randomized order. Histologic material was studied in a blinded manner with respect to the needle. The primary end point was mean cumulative length of tissue core biopsies per needle pass.

Results Final diagnosis was adenocarcinoma (n=46; 77%), neuroendocrine neoplasm (n=11; 18%), autoimmune pancreatitis (n=2), and mass-forming chronic pancreatitis (n=1). The mean cumulative length of tissue core biopsies per needle pass was significantly higher with the 22G Acquire needle at 11.4mm (95% confidence interval [CI] 9.0–13.8] vs. 5.4mm (95%CI 3.8–7.0) for the 20G Procore needle (P<0.001), as was the mean surface area (3.5mm² [95%CI 2.7–4.3] vs. 1.8mm² [95%CI 1.2–2.3]; P<0.001). Diagnostic adequacy and accuracy were 100% and 87% with the 22G Acquire needle, and 82% and 67% with the 20G Procore needle (P=0.001 and P=0.02, respectively).

Conclusions EUS-guided biopsy of pancreatic masses with the 22G Acquire needle provided more tissue for histologic evaluation and better diagnostic accuracy than the 20G Procore needle.

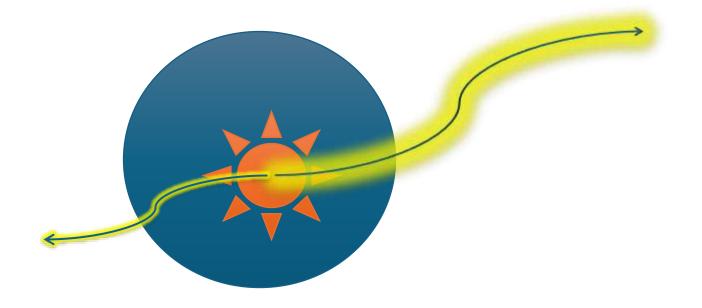


FNA-FNB: HOW TO MAXIMIZE YIELD

- TECHNIQUE FOR FNA-FNB ARE THE SAME
- VARIABLES THAT **DO** IMPACT:
 - WHO?
 - OPERATOR
 - CYTOLOGIST (EXPERIENCE, ON SITE)
 - WHAT?
 - LESION TYPE
 - WHERE?
 - LESION SITE
 - WHEN?
 - POST OP, STENTING? CHEMO-XRT?



ONE MORE FACTOR: <u>HOW</u> SAMPLING PATTERN

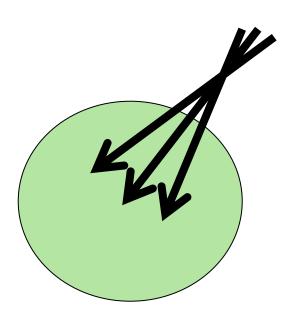


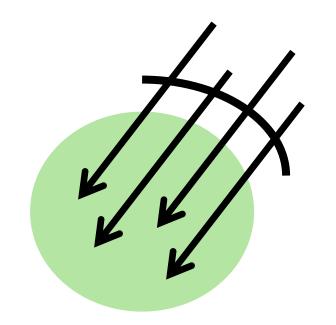


FANNING vs MULTI-PASS

FANNING

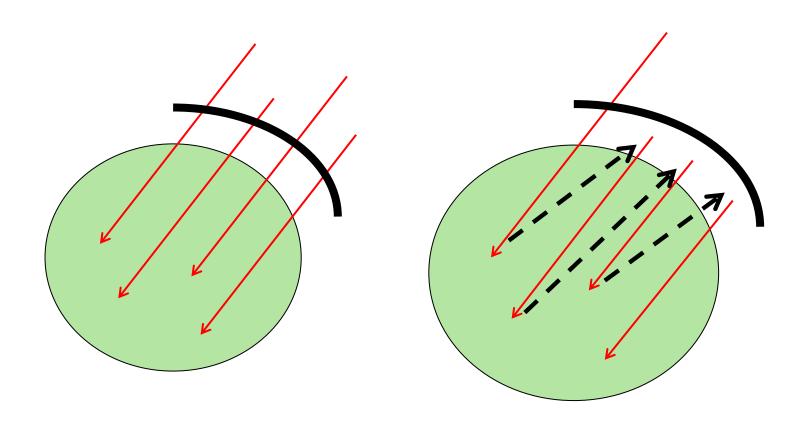
MULTIPASS







LIMITING WALL CELL CONTAMINATION WITH "MULTIPASS" TECHNIQUE





SIZE DOES MATTER

- SMALLER APPEARS BETTER
 - EASIER TO MANIPULATE
 - LESS BLOOD
 - 19G NO VALUE (EXCEPT LIVER BX)
 - FNA
 - 25g > 22g
 - FNB
 - 22g>25g



The diagnostic accuracy of 22-gauge and 25-gauge needles in endoscopic ultrasound-guided fine needle aspiration of solid pancreatic lesions: a meta-analysis.

Madoun MF, et al.

- 8 studies
- 1292 patients:
 - 799 22 G
 - 565 25 G

The pooled sensitivity and specificity:

22 G 0.85 (95%Cl 0.82-0.88)

25 G 0.93 (95%Cl 0/91-0.96)



FNA: ON-SITE CYTOLOGY?

- NOT SURE IT INCREASES YIELD OF MULTIPASS TECHNIQUE
- YES: IF YOU CAN
 - RAPID REPONSE
 - SAVES PASSES/TIME
 - SHOWS WHETHER SUPPLEMENTARY ANALYSIS NEEDED
 - PARTICULARLY GOOD FOR PANCREATIC LESIONS
 - IF TUMOR SEEDING IS A CONCERN
- NO:
 - POLYADENOPATHY (SUSPECTED LYMPHOMA)
 - SMTSs
 - LOW PROBABILITY LESIONS



Table 1 Studies evaluating the role of onsite cytopathology support for EUS-guided FNA procedures

Author (ref.)	No. patients	Diagnostic yield	Indeterminate/Inadequate samples	Unsatisfactory
		OP vs no OP	OP vs no OP	OP vs no OP
Klapman et al. ²	195	78% vs 32%, P = 0.001	10% vs 12%, P = 0.9	9% vs 20%, P = 0.003
Iglesias-Garcia et al.3	182	97% vs 86%, P = 0.01	2.1% vs 10.3%, P = 0.02	1 vs 13%, P = 0.002
Alsohaibani et al.⁴	104	77% vs 53%, P = 0.01	23% vs 47%, P = 0.001	0 vs 17%, $P = NS$
Wani et al.21	131	87.9% vs 70.8%, P = 0.01	6.1% vs 18.5%, P = 0.03	NA
Hayashi et al.22+	138	91.8% vs 69.2%, P < 0.001	26.4% vs 8.2%, P = 0.004	NA

[†]Endoscopists interpreted specimens themselves after being proctored in cytopathology. EUS, endoscopic ultrasound; FNA, fine-needle aspiration; NA, data not available; OP, onsite cytopathology.



FNB: ROSE NOT NEEDED

Comparative Study > Gastroenterology. 2021 Sep;161(3):899-909.e5. doi: 10.1053/j.gastro.2021.06.005. Epub 2021 Jun 9.

Endoscopic Ultrasound-guided Fine-needle Biopsy With or Without Rapid On-site Evaluation for Diagnosis of Solid Pancreatic Lesions: A Randomized Controlled Non-Inferiority Trial

Abstract

Background and aims: The benefit of rapid on-site evaluation (ROSE) on the diagnostic accuracy of endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) has never been evaluated in a randomized study. This trial aimed to test the hypothesis that in solid pancreatic lesions (SPLs), diagnostic accuracy of EUS-FNB without ROSE was not inferior to that of EUS-FNB with ROSE.

Methods: A noninferiority study (noninferiority margin, 5%) was conducted at 14 centers in 8 countries. Patients with SPLs requiring tissue sampling were randomly assigned (1:1) to undergo EUS-FNB with or without ROSE using new-generation FNB needles. The touch-imprint cytology technique was used to perform ROSE. The primary endpoint was diagnostic accuracy, and secondary endpoints were safety, tissue core procurement, specimen quality, and sampling procedural time.

Results: Eight hundred patients were randomized over an 18-month period, and 771 were analyzed (385 with ROSE and 386 without). Comparable diagnostic accuracies were obtained in both arms (96.4% with ROSE and 97.4% without ROSE, P = .396). Noninferiority of EUS-FNB without ROSE was confirmed with an absolute risk difference of 1.0% (1-sided 90% confidence interval, -1.1% to 3.1%; noninferiority P < .001). Safety and sample quality of histologic specimens were similar in both groups. A significantly higher tissue core rate was obtained by EUS-FNB without ROSE (70.7% vs. 78.0%, P = .021), with a significantly shorter mean sampling procedural time (17.9 \pm 8.8 vs 11.7 \pm 0.0 minutes, P < .0001).

Conclusions: EUS-FNB demonstrated high diagnostic accuracy in evaluating SPLs independently on execution of ROSE. When new-generation FNB needles are used, ROSE should not be routinely recommended. (ClinicalTrial.gov number NCT03322592.).



FNA: YIELD

- VARIABLES THAT **DO NOT** IMPACT:
 - SAMPLE PREPARATION
 - SUCTION
 - STYLET
 - NEEDLE TYPE



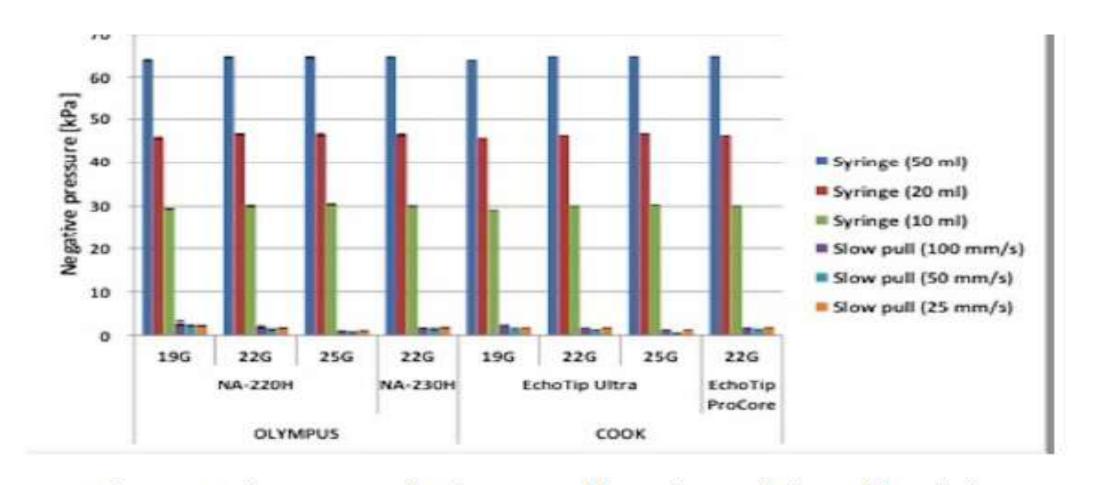
Author	Study design	No. of patients/lesions	EUS-FNA with suction	EUS-FNA without suction	P value
Puri ¹⁴	RCT	52/52			
		19% pancreas			
		66% lymph nodes			
Adequate specimens			100%	100%	NS
Bloodiness			76.9%	88.5%	.14
DY of malignancy			85.7%	66.7%	.05
Wallace ¹⁶	RCT	43/46			
Adequate specimens			Higher	NA	.01 (OR 2.8; 95% CI, 1.2-6.6)
Bloodiness			Higher	NA	.0004 (OR 4.7; 95% CI, 1.9-11.2)
DY of malignancy			No difference		.19 (OR 1.5; 95% CI, 0.8-2.8)
Lee ¹¹	RCT	81/81			
		Pancreas only			
Adequate specimens			72.8%	58.6%	.001
Bloodiness			6.2%	0.6%	< .001
DY of malignancy			82.4%	72.1%	.005



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Lee ¹¹	RCT	81/81			
		Pancreas only			
Adequate specimens			72.8%	58.6%	.001
Bloodiness			6.2%	0.6%	< .001
DY of malignancy			82.4%	72.1%	.005



SUCTION PRESSURES





A prospective comparison of endoscopic ultrasoundguided fine needle aspiration results obtained in the same lesion, with and without the needle stylet

	With Stylet (S+) [95% CI]	Without Stylet (S-) [95 % CI]	P
Yield for malignancy*			
Equal to or better than, n/N (%)	41/46 (89) [77 – 95]	40/46 (87) [74-94]	NS
Better than, n/N (%)†	5/46 (11) [5-23]	4/46(9) [4-20]	NS
Sensitivity, %	87 [70-95]	83 [66-93]	NS
Specificity, %	100 [86 - 100]	100 [87-100]	NS
False negatives, n/N (%)			
Pancreatic masses	3/20 (15) [5-36]	4/20(20) [8-42]	NS
Nodes	3/15 (20) [7-46]	2/15(13) [4-38]	NS
Othermasses	1/11 (9) [2-38]	1/11(9) [2-38]	NS
Sample adequacy, n/N (%)			
Adequate samples	89/118 (75) [66 – 82]	16/191 (87) [81-91]	0.013
Bloody samples	89/118 (75) [66 - 82]	99/191 (52) [45 - 59]	< 0.0001



FNA-FNB: HOW TO MAXIMIZE YIELD

- USE A MULTIPASS TECHNIQUE
- FNA:
 - 25g NEEDLE
 - MAKE SLIDES + CELL BLOCK
 - GET A CYTOLOGIST IN THE ROOM
- FNB:
 - 22g NEEDLE
 - MOSE (NOT ROSE)
- SUCTION (INCL. SLOW PULL), STYLET
 - ARE ALL A <u>UNNECESSARY</u> AND NEEDLESSLY <u>WASTE TIME</u>
 - EXCESS BLOOD MAKES MOSE MORE DIFFICULT



FNA vs FNB: STATE OF THE ART

- We know Fine Needle Aspiration (FNA) works well, is cheaper than FNB, and is sufficient in many cases.
- If you need a core, now you can truly get a core with >95% success.
- People with access to both are migrating to CORE:
 - UNFORSEEN BENEFITS
 - OBVIATES ROSE
- "CORE" needles are not all equal:
 - CYTOLOGY VS SCRAPING VS CUTTING





