REVIEW
Print ISSN 2234-2400 / On-line ISSN 2234-2443
Clin Endosc 2013;46:503-505
http://dx.doi.org/10.5946/ce.2013.46.5.503

Open Access

Procore and Flexible 19 Gauge Needle Can Replace Trucut Biopsy Needle?

Ji Young Bang and Shyam Varadarajulu

Center for Interventional Endoscopy, Florida Hospital, Orlando, FL, USA

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) is routinely performed for establishing tissue diagnosis in patients with gastrointestinal tumors. The concept of delivering chemotherapy based on molecular markers and the ability to establish a reliable diagnosis in lieu of an onsite cytopathologist has fuelled the recent trend in procuring core tissue by means of EUS-guided fine needle biopsy. To overcome the technical limitations induced by the rigidity of the Trucut biopsy needle, a new ProCore needle with reverse bevel technology has been developed. Recent data suggests that the newly developed flexible 19 gauge needle can also procure core tissue and has easy maneuverability when navigating the transduodenal route. Irrespective of the needles being used, the best clinical outcomes can be attained only by practicing evidence-based techniques, procuring adequate quantity of sample for ancillary studies, and processing the specimens appropriately.

Key Words: Endoscopic ultrasound-guided biopsy; Endoscopic ultrasound-guided fine needle aspiration; Trucut biopsy; ProCore; Flexible 19 G

INTRODUCTION

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) is a safe, accurate and inexpensive technique, and the interpretation is reliable when performed by trained cytopathologists. However, the diagnostic sensitivity is superior only when the specimen is assessed onsite for diagnostic adequacy and most institutions do not have skilled individuals to render onsite assessment. A fine needle biopsy (FNB) specimen contains core tissue with better preservation of cellular architecture than an FNA specimen and therefore has greater diagnostic accuracy and provides more tissue for ancillary studies. It may be specifically requested by pathologists to establish a definitive diagnosis in challenging cases when FNA is inconclusive or for identification of molecular markers that are specific for neoplasms such as pancreatic neuroendocrine tumors, malignant melanoma, and metastatic lung or breast cancer. To meet these expectations, a 19 gauge (G) Trucut needle biopsy (EUS-TNB; Cook Endoscopy, Winston-Salem, NC, USA) was developed to procure larger amounts of tissue with conserved architecture that would enable histological analysis. The overall diagnostic accuracy of EUS-TNB for evaluating suspicious lesions at various sites in the body is reported to be 75% to 84% and 61% to 67.5% for pancreatic masses.[1,2]

Procore needle

While the EUS-TNB technique has some advantages over FNA, the rigidity induced by the 19 G caliber needle and the mechanical friction of the firing mechanism produced by the torqued echoendoscope, limits its use for evaluating pancreatic head and duodenal lesions. To overcome this limitation, a new 19 G FNB device was recently developed with ProCore (Cook Endoscopy) reverse bevel technology to enable the acquisition of core specimens. In a recent study from Europe, histologic samples were obtained successfully with this Procore needle in a majority of patients with a diagnostic accuracy of more than 90%.[3] However, some technical difficulties were still encountered when performing transduodenal

Received: May 8, 2013 **Revised:** June 24, 2013
Accepted: June 24, 2013

Correspondence: Shyam Varadarajulu
Center for Interventional Endoscopy, Florida Hospital, 601 East Rollins St, Orlando, FL 32803, USA
Tel: +1-407-303-2570, **Fax:** +1-407-303-2585,
E-mail: svaradarajulu@yahoo.com

Table 1. Select Studies Comparing the Performance of ProCore versus Fine Needle Aspiration Needles That Were Presented at Digestive Diseases Week 2013

Author	Study design, needle size, G	Patients, no.	Target organ	Diagnostic accuracy/ sufficiency, ProCore vs. FNA	Median passes, ProCore vs. FNA	Comments
Nagula et al.[6]	Randomized trial, 25	ProCore, 47; FNA, 55	Solid masses	89.1% vs. 87.2%; p=NS	1 vs. 1	Equal efficacy
Strand et al.[7]	Prospective, 22	Both needles in 32 cases	Pancreatic masses	93.8% vs. 28.1%; p<0.001	1.4 vs. 2.9; p<0.001	FNA superior
Korenblit et al.[8]	Randomized trial, 22	Both needles in 101 cases	Solid masses	1st pass diagnosis, 53% vs. 35%	Fewer with ProCore	ProCore superior
Vanbiervliet et al.[9]	Randomized cross-over, 22	Both needles in 80 cases	Pancreatic masses	83.7% vs. 87.5%; p=NS	-	FNA yielded better histology
Ramay et al.[10]	Retrospective, 22	Both needles in 24 cases	Lymph nodes	100% vs. 87.5%; p=NS	-	Equal efficacy
Choi et al.[11]	Retrospective, 22	ProCore, 38; FNA, 42	Pancreatic masses	89.5% vs. 61.9%; p<0.005	1.2 vs. 1.3; p=NS	ProCore superior
Singh et al.[12]	Retrospective, 22	Both needles in 40 cases	Pancreatic masses	100% vs. 92.5%; p=NS	-	Equal efficacy
De La Mora-Levy et al.[13]	Retrospective, 22	ProCore, 51; FNA, 52	Solid masses	86.5% vs. 82.3%; p=NS	-	Equal efficacy

Gi gauge; FNA, fine needle aspiration; NS, not significant.

passes. The same FNB device is also available in a 22 and 25 G platform to facilitate easy transduodenal sampling. In a recent randomized trial that compared the 22 G ProCore and the standard 22 G FNA needle for sampling of pancreatic mass lesions, there was no significant difference in the rates of diagnostic sufficiency (100% vs. 89.3%), technical failure (0% vs. 3.6%), or complications (3.6% for both) between the standard FNA and ProCore needles, respectively.[4] Patients in whom diagnosis was established in passes 1, 2, and 3 were 64.3% versus 67.9%, 10.7% versus 17.9%, and 25% versus 3.6%, respectively, for the FNA and ProCore cohorts. Also, there was no significant difference in procurement of histologic core (100% vs. 83.3%) or the presence of diagnostic histologic specimens (66.7% vs. 80%) between the FNA and ProCore cohorts, respectively. In a prospective study of 50 patients with solid pancreatic masses, EUS-guided sampling was performed using the 25 G ProCore needle.[5] Malignancy was diagnosed in 38 patients on the first pass, with a cumulative sensitivity of 83%, 91%, and 96% on passes 1, 2, and 3, respectively. Although visible core was reported in 46 patients (92%), histologic core was seen in only 16 patients (32%). Histologic analysis showed malignancy in 29 patients on the first pass, with a cumulative sensitivity of 63% and 87% on pass 1 and passes 1 to 4, respectively. A summary of findings from key abstracts presented at Digestive Diseases Week 2013 that compared the FNA and ProCore needle is shown in Table 1.[6-13] As evident from the table, heterogeneity in clinical trials makes interpretation of results difficult. Well designed randomized trials comparing the different gauge ProCore and standard FNA needles in pancreatic masses and other solid organ lesions is required to establish conclusive results.

Flexible 19 G needle

The role of the standard 19 G FNA needle for yielding histological samples was assessed prospectively in a recent study.[14] Of the 120 patients who underwent EUS-guided tissue acquisition, the procedure was technically successful in 119 patients (98.9%) and adequate histological sample was obtained in 116 (97.5%). A major limitation of the study was that patients with pancreatic head or uncinate masses were excluded. As the standard 19 G needle is too stiff to navigate the transduodenal route, a flexible 19 G needle made of nitinol has been recently introduced. In a pilot study of 50 patients, which included several patients that underwent EUS-FNA via the transduodenal route, tissue acquisition was successful and adequate for cytologic assessment in 100% of patients and satisfactory histologic specimens were procured in 94.7% of patients.[15] Needle dysfunction or procedural complications were not encountered in this study.

While manufacturer guidelines must be followed when using specially designed biopsy needles, when using a 19 G needle, to minimize bloodiness, one must not use suction or a stylet and repeated jabbing at the same area should be avoided. It is usually not necessary to perform more than three FNB passes in a lesion as repeated biopsies are more likely to yield blood clots.

CONCLUSIONS

The currently available ProCore and flexible 19 G needles are a significant advancement in acquiring core tissue during EUS-guided procedures. Although there are no randomized trials comparing the performance of the ProCore and flexible 19 G needle, the decision to choose either needle should be based on operator preference and costs. However, EUS-guided tissue acquisition is a multistep procedure and must be patient-centered. Providing the correct type of sample based on clinical need, sampling the lesion using the best evidence-based techniques, procuring adequate tissue for ancillary studies and closely collaborating with cytopathologists and oncologists are all important in order to have good technical and clinical outcomes.

Conflicts of Interest

The authors have no financial conflicts of interest.

REFERENCES

1. Thomas T, Kaye PV, Ragunath K, Aithal G. Efficacy, safety, and predictive factors for a positive yield of EUS-guided Trucut biopsy: a large tertiary referral center experience. Am J Gastroenterol 2009;104:584-591.
2. Larghi A, Verna EC, Stavropoulos SN, Rotterdam H, Lightdale CJ, Stevens PD. EUS-guided trucut needle biopsies in patients with solid pancreatic masses: a prospective study. Gastrointest Endosc 2004;59:185-190.
3. Iglesias-Garcia J, Poley JW, Larghi A, et al. Feasibility and yield of a new EUS histology needle: results from a multicenter, pooled, cohort study. Gastrointest Endosc 2011;73:1189-1196.
4. Bang JY, Hebert-Magee S, Trevino J, Ramesh J, Varadarajulu S. Randomized trial comparing the 22-gauge aspiration and 22-gauge biopsy needles for EUS-guided sampling of solid pancreatic mass lesions. Gastrointest Endosc 2012;76:321-327.
5. Iwashita T, Nakai Y, Samarasena JB, et al. High single-pass diagnostic yield of a new 25-gauge core biopsy needle for EUS-guided FNA biopsy in solid pancreatic lesions. Gastrointest Endosc 2013;77:909-915.
6. Nagula S, Pourmand K, Aslanian HR, et al. EUS-fine needle aspiration (FNA) vs. EUS-fine needle biopsy (FNB) for solid mass lesions: interim analysis of a large multicenter, randomized clinical trial. Gastrointest Endosc 2013;77(5 Suppl):AB357-AB358.
7. Strand DS, Shami VM, Sauer BG, Wang AY. EUS-guided 22-gauge fine needle aspiration is superior to EUS-guided 22-gauge core needle biopsy in the evaluation of solid pancreatic neoplasms. Gastrointest Endosc 2013;77(5 Suppl):AB403.
8. Korenblit J, Singh H, Butt M, et al. Prospective randomized trial of the 22G EchoTip Procore™ needle versus the 22G Cook EchoTip Ultra 3® needle in patients with solid mass lesions undergoing EUS-guided fine needle aspiration (FNA). Gastrointest Endosc 2013;77(5 Suppl):AB178.
9. Vanbiervliet G, Fumex F, Saint-Paul MC, et al. Prospective randomized controlled trial with crossover of endoscopic ultrasound fine needle aspiration (EUS-FNA) using 22G ProCore and 22G EchoTip needle for solid pancreatic mass: the "Picore" study. Gastrointest Endosc 2013;77(5 Suppl):AB178.
10. Ramay F, Singh M, Sood V. Retrospective study comparing yield of EUS 22G FNA/FNB of abnormal lymph nodes: single tertiary referral center experience. Gastrointest Endosc 2013;77(5 Suppl):AB360.
11. Choi HJ, Moon JH, Kim HK, et al. Comparison of EUS-fine needle biopsy with EUS-fine needle aspiration as a historical control for diagnosis of pancreatic solid masses. Gastrointest Endosc 2013;77(5 Suppl):AB401.
12. Singh M, Ramay F, Sood V. EUS FNA/FNB of pancreatic mass lesions: single tertiary referral center experience. Gastrointest Endosc 2013;77(5 Suppl):AB402.
13. De La Mora-Levy JG, Florez-Sarmiento CF, Alonso-Larraga JO, Campuzano JO, Del Monte JS, Hernandez-Guerrero A. Direct comparison between Procore™, and non-Procore™ fine needle aspiration biopsy needles: does it make any difference in expert hands? Gastrointest Endosc 2013;77(5 Suppl):AB360.
14. Larghi A, Verna EC, Ricci R, et al. EUS-guided fine-needle tissue acquisition by using a 19-gauge needle in a selected patient population: a prospective study. Gastrointest Endosc 2011;74:504-510.
15. Varadarajulu S, Bang JY, Hebert-Magee S. Assessment of the technical performance of the flexible 19-gauge EUS-FNA needle. Gastrointest Endosc 2012;76:336-343.