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ABOUT COVER

Editor-in-Chief of *World Journal of Gastrointestinal Endoscopy*, Dr. Sang Chul Lee is a Professor in the Department of General Surgery of the College of Medicine, Catholic University of Korea and a Colorectal Surgeon at Daejeon St. Mary's Hospital, which is famous for minimally invasive surgery in Korea. His clinical practice specialization in laparoscopic surgery involves a focus in the field of single-port laparoscopic techniques. His standard and routine operation modality is single-port laparoscopic SOLO surgery, with application in a vast spectrum of disease entities and conducted by use of a camera-holder instead of a human assistant. His ongoing research interests are minimally invasive surgery and endoscopic procedures, and for the last several years, he has been performing completely scar-less surgeries. He serves as editorial board member and reviewer for several scientific journals and has published more than 120 peer-reviewed articles. (L-Editor: Filipodia)

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ORIGINAL ARTICLE

Retrospective Study

Comparison of the reverse bevel versus Franseen type endoscopic ultrasound needle

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Author contributions: Venkatachalapathy SV did the conception of the study, design of the study, writing of manuscript, critical review and overall supervision of the study; Chow CW did the design of the study, data gathering, statistical analysis of data, writing of manuscript and critical review; Haider SA reviewed cytology and did critical review; Ragunath K, Aithal GP, James MW, Ortiz-Fernandez-Sordo J designed the study and did critical review; Aravinthan AD did the statistical analysis of data, writing of manuscript and critical review.

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Abstract

BACKGROUND

Reverse bevel (RB) needle is widely used for endoscopic ultrasound fine needle biopsy (EUS-FNB). A 3-plane symmetrical needle with Franseen geometry (FG) has recently become available.

AIM

To compare the clinical efficacy of FG to that of RB needle.

METHODS

A retrospective cohort study of all adult patients who underwent EUS-FNB for solid and mixed lesions either with 22G RB needle or 22G FG needle between January 2016 and February 2019 was undertaken. All cytology slides were reviewed by an independent gastrointestinal cytopathologist blinded to the needle used and the initial cytology report. The primary and secondary outcomes were to assess the sample adequacy using Euro-cytology criteria and the number

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of cell clusters, respectively.

RESULTS

Two hundred and twenty six procedures were included in the study. RB needle was used in 128 procedures and FG needle in 98 procedures. The baseline characteristics of both groups were comparable. On multivariable analysis, FG needle ($P = 0.02$) and location of the lesion ($P < 0.01$) were independently associated with adequate tissue. Further, the use of FG needle ($P = 0.04$) and the size of the lesion ($P = 0.02$) were independently associated with acquisition of increased number of cell clusters.

CONCLUSION

FG needle is superior to RB needle in acquiring adequate tissue and attaining higher number of cell clusters for solid and mixed lesions.

Key Words: Endoscopic ultrasound; Fine needle aspiration; Fine needle biopsy; Reverse bevel; Franseen geometry; Tissue acquisition

Core Tip: Despite retrospective, it is the first paper to try to compare the performance of reverse bevel fine needle biopsy (FNB) needle with Franseen geometry FNB needle in term of tissue acquisition and number of cell groups in specimen. Slides reviewed by an independent expert gastrointestinal cytopathologist blinded to needle type used and original cytology reports to minimize bias.

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INTRODUCTION

Endoscopic ultrasound (EUS) is widely used as a diagnostic tool to obtain tissue from abdominal and thoracic lesions *via* the gastrointestinal (GI) tract. The procedure is minimally-invasive and well-tolerated by patients[1,2]. A number of factors have been shown to influence successful tissue acquisition including lesion position[3,4], lesion size[5-8], needle type[9-12], needle size[13-16], number of passes[17-21], technical skills[22-25] and the presence of rapid on-site cytological evaluation (ROSE)[1,26-28].

Fine needle biopsy (FNB) needles have been in use since 2003[29]. European Society of Gastroenterology recommends using 22G or 25G needles for the sampling of solid masses and lymph nodes[1]. Reverse bevel (RB) needle (ProCore®, Cook Medical) is the most widely studied FNB needle[13,15,17,30-41]. Evidence for needles such as Franseen geometry (FG) needle (Acquire™, Boston Scientific), fork-tip needle (Shark Core; Medtronic) and antegrade core trap needle (ProCore® 20G, Cook Medical) are emerging, but limited. Two meta-analysis comparing RB needle with fine needle aspiration (FNA) needle reported no significant difference in sample adequacy, diagnostic accuracy or core tissue acquisition rate; however, RB needle was able to establish the diagnosis with less number of passes[30,31].

On the other hand, in recent studies, FG needle has been shown to have a better tissue acquisition, better tissue architecture, higher diagnostic accuracy compared to standard FNA needle[42-44]. Studies have also shown better performance of FG needle against other newer needles such as Echo-Tip Ultra needle (Cook Medical, Indiana)[45] and antegrade core trap needle (ProCore® 20G, Cook Medical)[46]. However, the literature on direct comparison of FG needle with the commonly used RB needle is lacking. In this retrospective study, we compare the real-life efficacy of 22G FG needle to that of 22G RB needle.

MATERIALS AND METHODS

Patient selection and data collection

A single centre retrospective cohort study was undertaken at Nottingham University Hospitals NHS Trust, a high-volume regional referral centre. All adult (age ≥ 18 years) patients who underwent EUS-FNB between January 2016 and February 2019, using either 22G RB needle or 22G FG needle were included in this study. Those who underwent EUS-FNB with other types of needles and 25G FG were excluded due to small numbers. Demographic characteristics, details of EUS procedure and cytopathology reports were extracted from the electronic patient record and endoscopy database.

The study was approved by Nottingham University Hospitals National Health Service Trust review board (ID number 19-551C).

Endoscopic ultrasound and tissue acquisition

All procedures were carried out under conscious sedation or deep sedation with general anaesthesia using either Olympus GF-UCT240 or Olympus GF-UCT260 curvilinear-array echo-endoscope. Fanning technique with dry suction or slow pull through was used for tissue acquisition. The specimens were collected in either Cytorich preservative fluid or formalin, and then sent to pathology department for processing and reporting. ROSE of specimens was not performed in any of the procedures as it was not available. For the purposes of this study, location of the lesion was categorised into four groups–gut wall lesions, pancreatic lesions, extramural lesions and lymph nodes. The nature of lesion was categorised into solid or mixed (solid with cystic component).

Blinded review of cytology slides

All cytology slides were reviewed by an independent expert GI cytopathologist (Haider SA), who was blinded to the type of needle used and previous cytology report, and reported according to the Euro-cytology criteria[46] (C1: Inadequate and non-diagnostic; C2: Benign; C3: Atypical cells found which favour benign; C4: Suspicious of malignancy; C5: Malignant). For the purpose of assessing tissue adequacy, C1 category was defined as inadequate tissue acquisition; C2, C3, C4, and C5 categories were defined as adequate tissue acquisition. The number of cell clusters per slide was also reported by the cytopathologist. A cell cluster was defined as group of cells with more than 2 cells; individual scattered cells were not counted as cell clusters. Cell cluster data was divided into greater than or equal to 50 cell clusters and less than 50 cell clusters for analysis.

Outcomes

The primary outcome was to identify factors that impact tissue adequacy (Euro-cytology C1 *vs* C2-C5) and the secondary outcome was to identify factors that impact the number of cell clusters in the specimen slides.

Statistical analysis

Continuous variables were presented as mean and standard deviation. Categorical variables were presented as number and percentage. All statistical analyses were performed using SPSS for Windows v26 (IBM Corp, Armonk, NY, United States). Fisher's exact test was used for categorical parameters with 2 × 2 contingency table and Pearson's chi-square test was used for categorical parameters with contingency table dimensions that exceeded 2 × 2. Unpaired student's *t* test or 1-way ANOVA test was used to study the relationship between categorical parameters with continuous parametric parameters. A P value of < 0.05 was considered significant. Variables with a P value ≤ 0.10 were included in the multivariable logistic regression analysis to identify independent factors. Cohen's kappa test was used to measure the inter-rater agreement between the interpretation of the independent GI cytopathologist and the original cytology reports.

RESULTS

Demographics and clinical characteristics

A total of 226 patient episodes were included in this study. Of which, 128 procedures were sampled using 22G RB needle and 98 were sampled using 22G FG needle. The

demographic characteristics of RB and FG needle groups were comparable and summarised in Table 1. There were no differences in age (P = 0.29), gender distribution (P = 0.42), location of the lesion (P = 0.55), nature of the lesion (P = 0.34), size of the lesion (P = 0.67), number of needle passes (P = 0.77), presence of trainee (P = 0.12) and the use of Sonovue contrast (P = 0.17) between the two groups.

Assessment by a GI cytopathologist

The kappa score of agreement between the independent GI cytopathologist review and the original cytology results was 0.671 (95%CI: 0.595-0.747; P < 0.01).

Primary outcome

The overall sample adequacy of the entire study cohort was 87.6%. The tissue adequacy in the FG needle group was 93% and RB needle group was 83%.

On univariable analysis, use of FG needle (P = 0.03) and the location of lesion (P < 0.01) were associated with adequate tissue acquisition (Table 2). Age (P = 0.88), gender (P = 1.00), presence of trainee (P = 1.00), lesion size (P = 0.11), nature of lesion (P = 0.62), number of passes (P = 0.61) and Sonovue contrast (P = 0.50) were not associated with adequate tissue acquisition (Table 2). On binary logistic regression analysis, the use of FG needle (OR 3.01; 95%CI: 1.15-7.86, P = 0.02) and the location of the lesion with pancreas (OR 9.42; 95%CI: 3.51-25.33, P < 0.01) were independently associated with adequate tissue acquisition (Table 2).

Secondary outcome

On univariable analysis, only the lesion size (P = 0.02) was associated with acquisition of ≥ 50 cell clusters; use of FG needle (P = 0.07) and solid lesions (P = 0.09) approached, but did not reach statistical significance (Table 3). Age (P = 0.67), gender (P = 0.13), location of the lesion (P = 0.39), presence of trainee (P = 0.25), number of passes (P = 0.65) and Sonovue contrast (P = 1.00) were not associated with acquisition of ≥ 50 cell clusters (Table 3). Lesion size, type of needle and nature of the lesion were included in the binary logistic regression analysis. Use of FG needle (OR 1.79; 95%CI: 1.02-3.12, P = 0.04) and larger lesion size (OR 1.02; 95%CI: 1.00-1.03, P = 0.02) were independently associated with acquisition of ≥ 50 cell clusters (Table 3).

DISCUSSION

This is the first study to report on the comparative performance of 22G FG needle and 22G RB needle in acquiring adequate tissue after blinded assessment. There was good correlation between the independent cytopathological review and original report. The location of the lesion and the use of FG needle were independent predictors of improved tissue adequacy; however, the latter was the only modifiable variable in this study that could improve tissue acquisition.

The superior performance of FG needle is likely due to its three plane (Franseen geometry) cutting tip which may have enhanced tissue acquisition. A prospective study comparing FG needle and FNA needle reported that the FG needle performed significantly better compared to FNA needle for median area of total tissue and cell block diagnostic yield[47]. However, the study did not report an independent association between FG needle and improved sample adequacy.

Lesion location was also independently associated with improved sample adequacy. This finding is in line with a retrospective study analysing EUS-guided Trucut biopsy from 247 patients which reported that the site of biopsy was an independent predictor of diagnostic yield[3].

In addition to Euro-cytology classification, we also assessed the number of cell clusters as an indirect marker of tissue acquisition. Larger lesions and the use of FG FNB needle were significantly associated with ≥ 50 cell clusters in the specimens. Bethesda system of classification for thyroid nodule FNA specimens suggests that there should be at least 6 cell clusters with each cluster having at least 10 representative cells for the sample to be deemed adequate[48]. However, no such requirement exists for GI and pancreatic lesions to assess sample adequacy. Based on cytopathologist review, 50 or more cell clusters with at least two cells in each cluster was chosen as the most reliable alternate indicator of tissue adequacy. We speculate that 50 or more cell clusters with at least 2 cells in each cluster would enable the cytopathologist to make a diagnosis with high confidence in distinguishing benign from malignant lesions. This, however, needs further evaluation and validation in future studies.

Table 1 Baseline characteristics of patients included in this study (*n* = 226)

Baseline characteristic	22G RB needle (*n* = 128)	22G FG needle (*n* = 98)	*P* value
	n (%) or (mean ± SD)	*n* (%) or (mean ± SD)	
Location of lesion			
Gut wall lesions[1]	17 (13)	13 (13.3)	0.55
Pancreatic lesions	65 (51)	58 (59.2)	
Lymph node	23 (18)	15 (15.3)	
Extramural lesions[2]	23 (18)	12 (12.2)	
Lesion nature			
Solid	124 (97)	92 (94)	0.34
Mixed	4 (3)	6 (6)	
Lesion size (mm)	35.0 (20.9)	36.0 (16.0)	0.67
Age (year)	66.3 (12.4)	68.1 (11.6)	0.29
Gender			
Female	58 (45)	39 (40)	0.42
Male	70 (55)	59 (60)	
Presence of trainee			
Yes	39 (30)	40 (41)	0.12
No	89 (70)	58 (59)	
Number of passes	3.1 (0.8)	3.2 (0.7)	0.77
Contrast sonovue			
Yes	1 (1)	4 (4)	0.17
No	127 (99)	94 (96)	

[1]Gut wall lesions include oesophageal, gastric, duodenal or rectal wall lesions.
[2]Extramural lesions-does not include pancreatic lesions and lymph node. RB: Reverse bevel; FG: Franseen geometry.

The independent association between lesion size and higher number of cell clusters corroborates previous study findings. A retrospective study on 583 patients reported a strong correlation between diagnostic yield and the size of the lesion[5]. Another retrospective study involving 271 patients reported that the size of the lesion was an independent factor for tissue acquisition[8]. These indicate that care is needed with smaller lesions and the type of needle used, a modifiable factor, become even more important in smaller lesions.

Three passes is being considered sufficient when using 22G for tissue acquisition. Three or more number of passes with FNA needle has been shown to have a satisfactory sensitivity, specificity, positive predictive value, negative predictive value and accuracy of 84.3%, 97%, 99%, 64%, and 84%, respectively[21]. Given that the FNB needle requires significantly lower passes for adequate tissue acquisition[18], it is not unreasonable to speculate that the number of passes made in this study was more than adequate for tissue acquisition in both needle groups (mean > 3 in both FG and RB needle groups), and therefore could be the reason why it was not an independent predictor of adequate tissue acquisition. This is further supported by a previous retrospective study which showed adequate yield of histological material with lower number of passes[45].

A randomized control trial (RCT) comparing FG needle and fork tip needle reported a diagnostic cell block yield of 92% and 96%, respectively with no statistical significance between the two needles[49]. Another RCT comparing FG and FNA needles reported a diagnostic cell block yield of 97.8% for FG needle[42]. An observational study comparing 20G forward bevel needle and 22G FG needle found no difference in histological diagnosis rate, but FG needle achieved longer mean cumulative length of tissue core biopsies per needle pass[50]. A prospective study comparing FG needle with standard FNA (expect, Boston scientific) needle reported increased rate of tissue

Table 2 Factors associated with tissue adequacy-univariable and multivariable logistic regression analysis

Factors	Univariable analysis			Multivariable analysis	
	Insufficient tissue (C1) (*n* = 29)	Sufficient tissue (C2-C5) (*n* = 197)	*P* value	OR (95%CI)	*P* value
	n (%) or (mean ± SD)	*n* (%) or (mean ± SD)			
FNB needle used[a]					
22G RB needle	22 (76)	106 (59)	0.03	3.01 (1.15-7.86)	0.02
22G FG needle	7 (24)	91 (41)			
Gender					
Female	12 (41)	85 (43)	1.00		
Male	17 (59)	112 (57)			
Age (years)	66.7 (16.4)	67.2 (11.4)	0.88		
Presence of trainee					
Yes	7 (24)	72 (37)	0.22		
No	22 (76)	125 (63)			
Location of lesion[a]					
Gut wall lesions[1]	6 (20)	24 (12)	< 0.01	2.64 (0.85-8.19)	0.09
Pancreatic lesions	8 (28)	115 (58)		9.42 (3.51–25.33)	< 0.01
Lymph node	15 (52)	23 (12)		1.18 (0.00–669.44)	0.99
Extramural lesions[2]	0 (0)	35 (18)		1.00	
Lesion size (mm)	30.1 (20.4)	36.2 (18.6)	0.11		
Lesion nature					
Solid	27 (94)	189 (96)	0.62		
Mixed	2 (6)	8 (4)			
Number of passes made	3.1 (0.7)	3.1 (0.8)	0.61		
Sonovue contrast					
Yes	1 (97)	4 (2)	0.50		
No	28 (3)	193 (98)			

[a]Parameters with a $P < 0.10$ on univariable analysis were included in the multivariable analysis and these parameters are indicated by an asterisk.
[1]Gut wall lesions include oesophageal, gastric, duodenal or rectal wall lesions.
[2]Extramural lesions do not include pancreatic lesions and lymph node. Tissue adequacy: C1: Insufficient; C2: Benign; C3: Atypical; C4: Suspicious; C5: Malignant. FNB: Fine needle biopsy; RB: Reverse bevel; FG: Franseen geometry.

acquisition with FG needle[43]. In par with previous literature, the cytological yield of FG needle in our study was 93%. Such high tissue yield with newer needles is likely ameliorate the need for ROSE in the future.

A major limitation of this study is its retrospective nature and the potential for inherent selection bias. It was difficult to ascertain if a particular needle was chosen due to stock availability, personal preference, or due to lesion characteristics. However, given that the baseline characteristics were similar between the two needle groups, it is less likely that the above mentioned factors would have impacted the study significantly. Further, the blinding of cytopathologist to the needle used and the original report is likely to mitigate the bias and improve the reproducibility of this study.

In conclusion, tissue adequacy of 22G FG FNB needle was superior to 22G RB FNB. Further, the type of needle seems to be the only modifiable factors that impacts adequate tissue acquisition. Multicentre prospective trials are needed to further evaluate the utility of different needle types.

Table 3 Factors associated with number of cell groups-univariable and multivariable logistic regression analysis

Factors	Univariable analysis			Multivariable analysis	
	< 50 cell clusters (*n* = 138)	≥ 50 cell clusters (*n* = 88)	*P* value	OR (95%CI)	*P* value
	n (%) or (mean ± SD)	*n* (%) or (mean ± SD)			
FNB needle used[a]					
22G RB needle	85 (62)	43 (49)	0.07	1.79 (1.02 - 3.12)	0.04
22G FG needle	53 (38)	45 (51)			
Gender					
Female	65 (47)	32 (36)	0.13		
Male	73 (53)	56 (64)			
Age (yr)	66.8 (12.3)	67.5 (11.7)	0.67		
Presence of trainee					
Yes	44 (32)	35 (40)	0.25		
No	94 (68)	53 (60)			
Location of lesion					
Gut wall lesions[1]	20 (14)	10 (11)	0.39		
Pancreatic lesions	78 (57)	45 (51)			
Lymph node	23 (17)	15 (17)			
Extramural lesions[2]	17 (12)	18 (21)			
Lesion size (mm)[a]	33.1 (16.9)	39.0 (21.2)	0.02	1.02 (1.00 – 1.03)	0.02
Lesion nature[a]					
Solid	129 (93)	87 (99)	0.09	0.13 (0.02 - 1.10)	0.06
Mixed	9 (7)	1 (1)			
Number of passes made	3.1 (0.8)	3.2 (0.8)	0.65		
Sonovue contrast					
Yes	3 (2)	2 (2)	1.00		
No	135 (98)	86 (98)			

[a]Parameters with a $P < 0.10$ on univariable analysis were included in the multivariable analysis and these parameters are indicated by an asterisk.
[1]Gut wall lesions include oesophageal, gastric, duodenal or rectal wall lesions.
[2]Extramural lesions do not include pancreatic lesions and lymph node. FNB: Fine needle biopsy; RB: Reverse bevel; FG: Franseen geometry.

ARTICLE HIGHLIGHTS

Research background

Many factors can affect endoscopic ultrasound fine needle biopsy (EUS-FNB) procedures tissue acquisition efficacy, with needle type and design being one of the possible factors.

Research motivation

Currently, there is no direct comparison of tissue acquisition efficacy between reverse bevel (RB) and Franseen geometry (FG) needles.

Research objectives

To look any for different in tissue acquisition performance between RB and FG needles, which can potentially be a modifiable factor to improve EUS-FNB accuracy in making a confident diagnosis.

Research methods

A retrospective study of all EUS-FNA/FNB procedures by either 22G RB needle or 22G FG needle between January 2016 and February 2019. All cytology slides were reviewed by an independent gastrointestinal cytopathologist blinded to the needle used and the initial cytology report. The primary and secondary outcomes were to assess the sample adequacy using Euro-cytology criteria and the number of cell clusters, respectively.

Research results

A total of 226 procedures were included. RB needle was used in 128 procedures and FG needle in 98 procedures. The baseline characteristics of both groups were comparable. On multivariable analysis, FG needle ($P = 0.02$) and location of the lesion ($P < 0.01$) were independently associated with adequate. Further, the use of FG needle ($P = 0.04$) and the size of the lesion ($P = 0.02$) were independently associated with acquisition of increased number of cell clusters.

Research conclusions

FG needle is superior to RB needle in acquiring adequate tissue and attaining higher number of cell clusters for solid and mixed lesions.

Research perspectives

Multicentre prospective trials are needed to further evaluate the utility of different needle types.

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