ORIGINAL ARTICLE

Evaluation of the Feasibility and Efficacy of Forward-Viewing Endoscopic Ultrasound

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Background/Aims: We aimed to evaluate the feasibility and efficacy of a forward-viewing linear endoscopic ultrasound (FV-EUS) in diagnostic EUS procedures compared to standard oblique-viewing EUS (OV-EUS). **Methods:** This study was a prospective, randomized study that permitted crossover. Fifty-one patients with subepithelial pancreatobiliary and upper gastrointestinal lesions underwent FV-EUS and OV-EUS sequentially, in random order. The EUS visualization was performed by a novice endosonographer, and the image quality of specific lesions was scored by an expert endosonographer. If fine-needle aspiration (FNA) was indicated, it was performed using both echoendoscopes by an expert endosonographer. **Results:** Both of the EUS procedures had similar visualization times and image quality. In general, the visualization time was inversely related to the diameter of the specific lesions. In subepithelial lesions of the stomach and duodenum, the visualization time (98.8±62.2 seconds vs 139.0±66.6 seconds, p=0.008) and image quality (4.1±1.3 vs 3.3±1.7, p=0.02) of FV-EUS were significantly superior to OV-EUS. FV-EUS-guided FNA of pancreatic masses was successful in seven patients (87.5%). **Conclusions:** FV-EUS may increase the ease of access to gastrointestinal subepithelial lesions compared to conventional OV-EUS. The performance of FV-EUS for evaluating pancreatobiliary diseases and performing interventions was comparable to conventional OV-EUS. **(Gut Liver 2015;9:679-684)**

Key Words: Endoscopic ultrasound guided intervention; Forward-viewing endoscopic ultrasound; Oblique-viewing endoscopic ultrasound

INTRODUCTION

The ability of echoendoscope technology to access extraluminal lesions under direct sonographic visualization increases both the technical success rate and safety profile of procedures. Traditionally, endoscopic ultrasound (EUS) and EUS-guided fine-needle aspiration (EUS-FNA) have been performed with an oblique-viewing (OV) EUS (OV-EUS). However, the maneuverability of the OV-EUS in the duodenum, particularly for sampling the pancreatic head and uncinate process lesions, can be challenging.[1] A recently developed forward-viewing (FV) linear EUS (FV-EUS) features an ultrasonographic field of view almost coaxial to the exit path of the working channel, allowing the use of needles and other devices in a collinear fashion similar to a gastroscope.

Conventional EUS-FNA was introduced in the early 1990s and has since become the gold standard algorithm in evaluating suspicious masses adjacent to the gastrointestinal (GI) tract.[2] Due to the surge in new applications for EUS-guided interventions, a FV-EUS has been developed.

The FV-EUS has an electrical curved linear array of 120° forward endoscopic views. It has a 3.7-mm working channel without an elevator, and thus allows the exit of a FNA needle or any other accessories parallel to the longitudinal axis of the EUS. The EUS frequencies can be varied from 5 to 10 MHz, and the scanning plane direction is parallel to its insertion, with a 90° scanning range. The FV-EUS was originally designed for therapeutic procedures. It has been reported to be useful for EUS-FNA in specific circumstances due to its unique characteristics,[1,3] but the utility of FV-EUS has only been reported anecdotally.[4,5] Therefore, the aim of this study was to evaluate the feasibility and the efficacy of FV-EUS for evaluation of pancreaticobiliary and subepithelial lesions compared to conventional OV-EUS us-

ing a prospective, randomized, and cross-over study design.

MATERIALS AND METHODS

1. Patients

Between December 2012 and March 2013, patients referred for evaluation of pancreaticobiliary diseases and GI subepithelial lesions were prospectively enrolled in the study (Fig. 1). The exclusion criteria were as follows: pregnancy, bleeding tendency (prothrombin time INR >1.5 or platelet <80,000/μL), and critically ill patients. In the study period, 62 patients were enrolled and 11 patients refused participation. Study approval was provided by the Ethics Committees of the Asan Medical Center, University of Ulsan College of Medicine. Written informed consent for participation was obtained from all enrolled patients.

2. Observers

Patients were placed in a left lateral decubitus position and all EUS procedures were performed under conscious sedation with intravenous midazolam and propofol according to the judgment of the endoscopist. Both the OV-EUS (GF-UE260-AL5, GF-UCT240; Olympus Medical System, Tokyo, Japan) and the newly developed FV-EUS (GIF-Y-0007-UCT; Olympus Medical System) were used. The sequence in which these techniques were employed was randomly assigned.

For the study protocol, two groups were formed depending on the experience of the examiner. The first examiner (expert) was a highly experienced endosonographer who had performed >4,000 EUS examinations related to pancreaticobiliary disease. The second examiner (novice) was a junior gastroenterology fellow who had performed <50 EUS examinations. Only the information regarding reason for referral was revealed to the examiners. The EUS was entirely performed by the fellow

(novice examiner) without any hands-on assistance from the supervisors. Color Doppler EUS was used to assess involvement of vessels. The visualization time was defined as the time from intubation of the upper esophageal sphincter until visualization of the target lesion. If the time to visualize the lesions took more than 200 seconds, it was considered a failed procedure. The EUS image quality of specific lesions was scored using a five-point scoring system by an expert endosonographer, as follows: 1, no visualization; 2, poor visualization; 3, fair visualization; 4, good visualization; 5, excellent visualization.

The EUS-FNA was performed by the expert endosonographer. Usefulness and feasibility of EUS-FNA were evaluated with each of the following four standards: visual field, targeting, needle puncture, and manipulation. A good visual field was defined by a high quality of image and successful striking of the target by the fine needle, whether or not the visualization of the lesion was well maintained. Precise targeting was defined as the needle passing and adjusting properly. A correct needle puncture was defined as the fine needle sticking accurately to the lesion without altered visualization throughout the procedure. A positive hands-on manipulation was defined as the needle and accessory kit operating easily after needle puncture. All four standards were rated as yes or no.

3. Statistical analysis

Continuous variables were reported as means with standard deviations or medians with interquartile ranges (IQR), while categorical variables were reported as proportions with respective percentages. Differences between categorical variables were tested using Pearson chi-square test or Fisher exact test, and continuous variables were tested using Student two-tailed test (normal distribution) or the Mann-Whitney U test (skewed distribution). To analyze the presence of random effects and
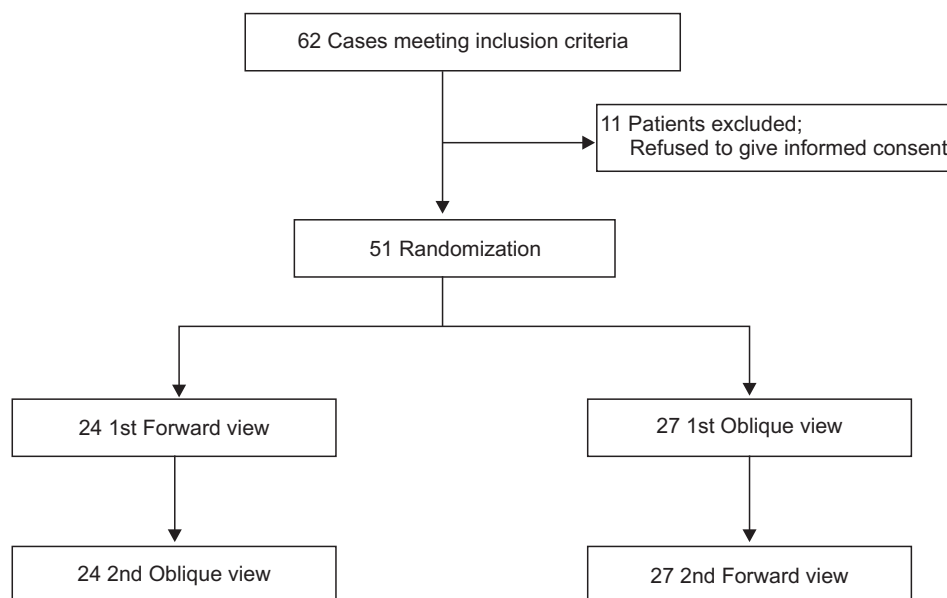

Fig. 1. Flow chart of the study design.

to introduce correlations of repeated measures, a linear mixed model and cumulative logit analysis model with generalized estimating equation were tested. A p-value of <0.05 was regarded as statistically significant and data were analyzed with the SPSS software version 19.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

1. Visualization of EUS

A total of 51 patients were analyzed (Fig. 1). The mean age was 60.4±11.5 years; 49% were male. The examination was undertaken at the following sites: pancreatic head (n=14), pancre-

atic body or tail (n=14), gallbladder (n=6), gastric subepithelial lesion (n=6), duodenal subepithelial lesion (n=10), and common bile duct (n=1). The mean size of the lesions was 20±14.1 mm in largest dimension (Table 1).

The total mean visualization time of OV-EUS and FV-EUS was 119.8±56.5 and 108.9±54.0 seconds, respectively. If OV-EUS or FV-EUS was performed first, the mean visualization times of OV-EUS and FV-EUS were 129.8±58.4 and 121.5±51.4 seconds, respectively. If OV-EUS or FV-EUS was performed second, the corresponding mean visualization times were 108.6±53.4 and 97.7±54.9 seconds, respectively. When applying a linear mixed model, there was no time difference in visualization (p=0.144).

Specifically, the mean visualization times for pancreas head lesions of FV-EUS and OV-EUS were 115.5±44.7 and 104.6±39.6 seconds, respectively (p=0.310), and for pancreas body and tail lesions they were 99.6±51.8 and 89.4±40.4 seconds, respectively (p=0.245). The visualization times of FV-EUS and OV-EUS for subepithelial lesions of the stomach and duodenum were 98.8±62.2 and 139.0±66.6 seconds, respectively (p=0.008), and for gallbladder lesions were 150.8±53.5 and 136.7±54.3 seconds, respectively (p=0.104) (Table 2).

Considering visualization, OV-EUS showed 58.1% (n=25) of excellent visualization, 37.2% (n=16) of good visualization, and 4.7% (n=2) with fair visualization. The FV-EUS showed 52.2% (n=24) of excellent visualization, 45.7% (n=21) of good visualization and 2.1% (n=1) with fair visualization (Table 3). The cumulative logic model with generalized estimating equation showed FV-EUS was not inferior to OV-EUS (odds ratio [OR],

Table 1. Patient and Lesion Characteristics

Characteristic	Value
No. of patients	51
Age, yr	60.4±11.5
Sex, male/female	25/26 (49/51)
Largest diameter on EUS, mean±SD (IQR), mm	20±14.1 (10.3–26.8)
Organs/structures	
Pancreatic head	14
Pancreatic body/tail	14
Gallbladder	6
Stomach, duodenum subepithelial tumor	16
Common bile duct	1

Data are presented as mean±SD or number (%) unless otherwise indicated.
EUS, endoscopic ultrasound; IQR, interquartile range.

Table 2. Visualization Time in FV-EUS and Conventional OV-EUS

Organ/structure	FV-EUS	OV-EUS	p-value
Pancreatic head	115.5±44.7 (75.0–162.5)	104.6±39.6 (52.5–145.5)	0.310
Pancreas body/tail	99.6±51.8 (57.0–142.5)	89.4±40.4 (55.5–127.5)	0.245
GI SET	98.8±62.2 (30.3–150)	139.0±66.6 (83.8–200)	0.008
Gallbladder	150.8±53.5 (98.75–200)	136.7±54.3 (100–170)	0.104

Data are presented as mean±SD (interquartile range).
FV-EUS, forward-view endoscopic ultrasound; OV-EUS, oblique-view endoscopic ultrasound; GI SET, gastrointestinal (stomach and duodenum) subepithelial tumor.

Table 3. Baseline Image-Quality Characteristics

	Method	Nonvisualized	Fair	Good	Excellent
First exam	OV-EUS	5 (18.5)	0	10 (37.0)	12 (44.5)
	FV-EUS	3 (12.5)	1 (4.2)	8 (33.3)	12 (50.0)
Second exam	OV-EUS	3 (12.5)	2 (8.3)	6 (25.0)	13 (54.2)
	FV-EUS	2 (7.4)	0	13 (48.1)	12 (44.5)
Total	OV-EUS	8 (15.7)	2 (3.9)	16 (31.4)	25 (49.0)
	FV-EUS	5 (9.8)	1 (2.0)	21 (41.2)	24 (47.0)

Data are presented as number (%).
OV-EUS, oblique-view endoscopic ultrasound; FV-EUS, forward-view endoscopic ultrasound.

0.83; 95% confidence interval [CI], 0.43 to 1.62; p=0.59).

In detail, the mean scores of image quality for pancreas head lesions of FV-EUS and OV-EUS were 4.4±0.6 and 4.4±0.6, respectively (p=1.00), and for pancreas body and tail lesions were 4.6±0.5 and 4.6±1.1, respectively (p=0.71). The image quality scores of FV-EUS and OV-EUS for subepithelial lesions of the stomach and duodenum were 4.1±1.3 and 3.3±1.7, respectively (p=0.02) (Fig. 2), and for gallbladder lesions were 3.3±1.9 and 4.2±1.6, respectively (p=0.1) (Table 4).

One pancreatic body mass lesion was visualized only with FV-EUS, and one gallbladder lesion was visualized only with OV-EUS. The lesions were relatively small such that it was not easy for the novice endosonographer to trace the cystic duct of gallbladder. FV-EUS allows for better recognition of several features of chronic pancreatitis such as hyperechoic margins of the pancreatic duct, subtle lobularity of the parenchyma, small cystic changes in the parenchyma, and side branch duct ectasia than OV-EUS.

Among 16 cases of subepithelial lesion, two stomach subepithelial lesions and one duodenum subepithelial lesion failed to be visualized with the OV-EUS, whereas all subepithelial lesions were visualized with FV-EUS. One common bile duct mass lesion failed to be visualized by the novice endosonographer due to the difficulty in anatomical tracing (Table 5).

2. EUS-FNA

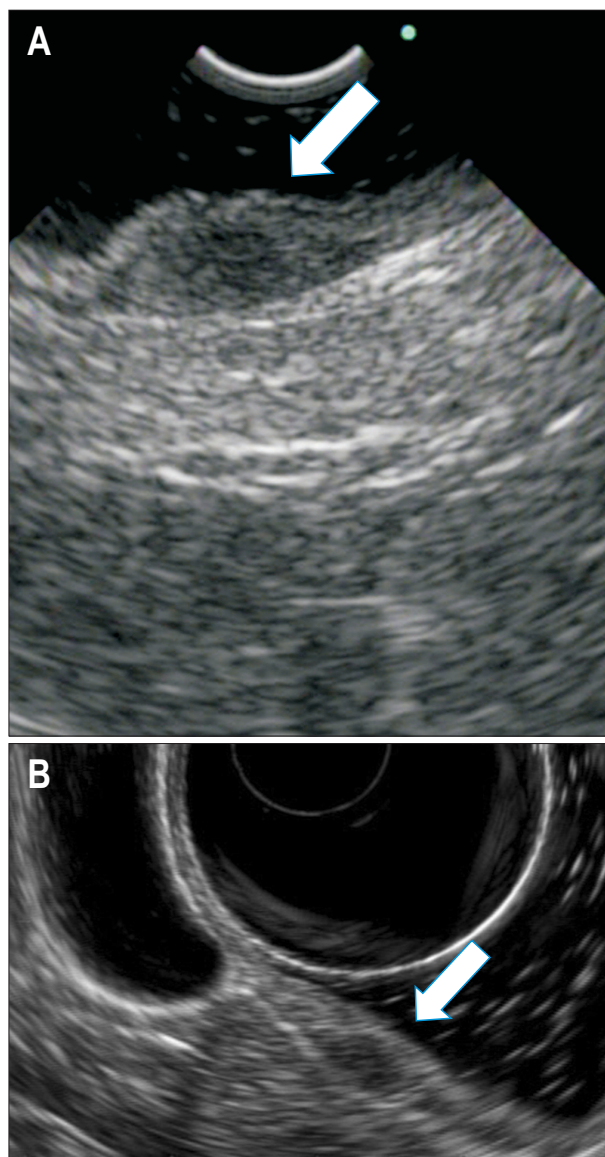EUS-guided interventions were conducted in 12 patients

Fig. 2. Endoscopic ultrasound images of a duodenal subepithelial lesion with a forward-view endoscopic ultrasound (A) and an oblique-view endoscopic ultrasound (B). The forward-view endoscopic ultrasound yielded superior image quality.

Table 4. Mean Imaging Quality Scores* with FV-EUS and Conventional OV-EUS

Organ/structure	FV-EUS	OV-EUS	p-value
Pancreatic head	4.4±0.6	4.4±0.6	1.00
Pancreatic lesion	4.6±0.5	4.6±1.1	0.71
Subepithelial tumor	4.1±1.3	3.3±1.7	0.02
Gallbladder	3.3±1.9	4.2±1.6	0.1

Data are presented as mean±SD.
FV-EUS, forward-view endoscopic ultrasound; OV-EUS, oblique-view endoscopic ultrasound.
*1, no visualization; 2, poor visualization; 3, fair visualization; 4, good visualization; 5, excellent visualization.

Table 5. Visualization of Pancreaticobiliary Lesions with an Forward-View Echoendoscope and a Conventional Echoendoscope by a Novice Endosonographer

Location	Total no. of patients	Visualization on both FV- and OV-EUS	Visualization on OV-EUS only	Visualization on FV-EUS only	Invisualization on both FV- and OV-EUS
Pancreatic head	14	14	-	-	-
Pancreatic body and tail	14	13	-	1	-
Gallbladder	6	4	1	-	1
Subepithelial tumor	16	13	-	3	-
Common bile duct	1	-	-	-	1

FV-EUS, forward-view endoscopic ultrasound; OV-EUS, oblique-view endoscopic ultrasound.

Table 6. Details of the Feasibility of Forward-Viewing Endoscopic Ultrasonography-Guided Fine-Needle Aspiration by an Expert Endosonographer

Patient	Age, yr	Sex	Indication	Location	Size, mm	Access route	FNA needle, gauge	Feasibility				Impression of FV-EUS	FV-EUS-FNA cytology
								Visual field	Targeting	Needle puncture	Manipulation		
1	70	M	Pancreatic mass	Pancreatic body	40×30	Stomach	22	Yes	Yes	Yes	Yes	Pancreatic cancer	Adenocarcinoma
2	57	M	Pancreatic mass	Pancreatic head	27×25	Duodenal bulb	22	Yes	Yes	Yes	Yes	Inflammatory pseudotumor	Absence of neoplastic cells
3	39	F	Pancreatic cyst	Pancreatic head	23×20	Duodenal bulb	22	Yes	Yes	Yes	Yes	Pancreatic SPN	Absence of neoplastic cells
4	65	F	Bile duct mass	Distal CBD	13×9	Stomach	22	Yes	No	No	No	Bile duct cancer	Absence of neoplastic cells
5	67	M	Pancreatic mass	Pancreatic head	22×13	Duodenal bulb	22	Yes	Yes	Yes	Yes	Pancreas cancer with splenic artery encasement	Adenocarcinoma
6	70	M	Pancreatic mass	Pancreatic body	26×19	Stomach	22	Yes	Yes	Yes	Yes	Pancreatic cancer	Adenocarcinoma
7	67	M	Pancreatic cyst	Pancreatic tail	47×35	Stomach	22	Yes	Yes	Yes	Yes	Pancreatic pseudocyst	Absence of neoplastic cells
8	77	M	Pancreatic mass	Pancreatic head	34×17	Duodenal bulb	22	Yes	Yes	Yes	Yes	Neuroendocrine tumor	Neuroendocrine neoplasm

FNA, fine-needle aspiration; FV-EUS, forward-view endoscopic ultrasound; M, male; F, female; SPN, solid-pseudopapillary neoplasm; CBD, common bile duct.

and mainly included FNA of a pancreatic mass by an expert endosonographer. EUS-FNA was performed with disposable 22-gauge needles (Echotip Ultra; Cook Medical Inc., Winston-Salem, NC, USA) inserted through the 3.7-mm working channel of the EUS. The clinical and procedural data of FV-EUS-guided FNA are summarized in Table 6. Visualization of the primary lesion by FV-EUS was obtained in all of the eight cases, and FV-EUS-guided FNA was performed successfully in seven patients (87.5%). There were no procedure-related adverse events. Procedural indications included pancreatic mass detected on computed tomography (CT) or transabdominal ultrasonography (n=5), pancreatic cyst seen on CT (n=2), and intrabile duct mass noted on CT (n=1). The lesions were located in the pancreatic head in four patients, in the pancreatic body in two patients, in the pancreatic tail in one patient and in the distal common bile duct in one patient. EUS-FNA using both FV- and OV-EUS failed to obtain diagnostic samples in the patient with a distal bile duct mass due to surgically altered anatomy and major vessel interposition. For this patient, percutaneous transhepatic biliary drainage was inserted and a biopsy was taken using choledochoscopy.

DISCUSSION

In this report, we have presented our initial experience in the evaluation of pancreatobiliary and subepithelial lesions with an FV-EUS, which has been developed with the aim of potentially expanding the therapeutic applications of EUS and EUS-guided interventions.

The access to the target lesion was faster in the FV-EUS than in the OV group, especially in subepithelial lesions. Overall, there was no significant difference in image quality between the two groups, but in subepithelial lesions, the FV-EUS cohort showed superior image quality. Once in contact with the intestinal wall, the smaller transducer of the FV-EUS, compared to that of the OV-EUS, allows scanning in a perpendicular direction relative to the insertion direction, which could be advantageous for clinical evaluation.[4] Lesions in the pancreatic body and tail appeared easier to locate with a FV-EUS, whereas for pancreatic head and cystic duct lesions of diameter <20 mm, the image quality of FV-EUS was inferior to OV-EUS.

A major drawback of conventional OV-EUS is that endoscopic accessories must access the targeted lesions at an acute angle when they are deployed through the biopsy channel. This exerts force on the needle, which can often unintentionally result in the EUS being pushed away from the intestinal wall, leading to technical failure. Moreover, the tip of the EUS must always be maintained straight to permit an easy path for accessories, and this can be technically difficult to achieve, particularly when the EUS is in an acutely angulated position, such as in the gastric cardia, the duodenum, or the rectosigmoid junction.[6] Another major disadvantage of the OV-EUS is that it requires reorienta-

tion when switching from a sonographic to an endoscopic view, because the intestinal wall frequently opposes the EUS during interventions under sonographic guidance.[7]

On the contrary, FV-EUS enables a field of examination that is almost parallel to the endoscopic view, which makes it easier to deploy the needle and allows a greater penetrating force with a precise orientation of the needle.[5] The needle could also be advanced through the working channel in the retroflexed position and handled easily by simply applying up and down deflection. In addition, FV-EUS has improved in upward function, which could be bent up to 180°, compared to 130° for OV-EUS. This allows direct targeting of lesions in an easier position with the frontal exit of the needle.[4]

The FV-EUS scope maneuverability and stability, and the ease of performing FNA, were satisfactory and comparable to that of previous studies evaluating the yield of EUS-FNA. The limitations of the FV-EUS are that is has a narrower field of view than the OV-EUS,[5] it does not have an elevator or a balloon, and the outer diameter of the distal end and the insertion tube are smaller. However, from our experience, it is possible to satisfactorily visualize and obtain high diagnostic yields. The forward-array image and the availability of Doppler imaging also allowed safer FNA procedures. We also found there were no limitations in targeting with FV-EUS.

In summary, our experience with FV-EUS for evaluation of pancreatobiliary and GI subepithelial diseases seems to be comparable to conventional OV-EUS. The narrow image does not preclude basic diagnostic maneuvers. Moreover, visualization was obtained faster with FV-EUS and it significantly increased the ease of access to GI subepithelial tumors. These FV-EUS features allowed facile procedures to be performed by a novice endosonographer. FV-EUS-guided FNA also showed no limitations in the hands of an expert endosonographer. This suggests that FV-EUS and FV-EUS-guided FNA could be useful adjuncts to conventional OV-EUS and OV-EUS-FNA.

CONFLICTS OF INTEREST

ACKNOWLEDGEMENTS

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