Newly Developed All in One EUS System: One Cart System, Forward-Viewing Optics Type 360° Electronic Radial Array Echoendoscope and Oblique-Viewing Type Convex Array Echoendoscope

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Abstract Most endosonographers use radial scanning instruments for diagnostic imaging, and use longitudinal scanning instruments primarily for endoscopic ultrasound-guided fine needle aspiration (EUS-FNA). The use of two separate instruments for radial and longitudinal scanning means 2 different echoendoscopes are required, each with its own dedicated US processing unit. Currently available electronic radial echoendoscopes and linear instruments made by the same company require the same other brand US unit. Furthermore, no forward-viewing optics type 360° electronic radial echoendoscope currently exists. We have developed an all-in-one one cart EUS system that saves space and is available for both the forward-viewing type 360° radial electronic echoendoscope and the oblique-viewing type convex echoendoscope. These scopes have a transducer with variable frequency (5.0, 7.5, 10.0, 12.0 MHz) and color and power Doppler flow mapping capabilities. We performed a clinical development test for thirteen patients with sixteen lesions (Radial EUS on 8 lesions and EUS-FNA on 8 lesions) using this new EUS system. These new instruments provided satisfactory US and endoscopic images. The forward-viewing optics of the prototype enhanced intubation and instrument advancement. The radial scanning prototype provided an adequate diagnosis in 8 (100%) out of 8 lesions for EUS. The convex type achieved successful puncture in 8 (100%) out of 8 lesions and collection of adequate specimen for diagnosis of EUS-FNA in 4 (50%) out of 8 lesions. There were no complications in this series. This new system appears to be an attractive alternative for efficient EUS.

Introduction

The growing use of EUS in clinical practice has revolutionized the approach to a variety of GI tract, pancreaticobiliary, and mediastinal diseases. Because of its proven efficacy for diagnosis and staging of malignancy, the demand for EUS has dramatically increased[1)~5)]. Standard EUS is performed with radial US imaging perpendicular to the endoscope shaft, and lateral endoscopic viewing parallel to the shaft and biopsy channel. Radial US imaging is preferred for some diagnostic and staging purposes because of ease of use as well as the production of a full 360°field of view. Mechanical radial imaging has been used to achieve this perpendicular 360°field, but radial imaging does not allow Doppler analysis of vascular flow. A separate image processor from linear imaging echoendoscopes for EUS-FNA is required. This

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necessitates a large financial investment in capital equipment when the goal of a EUS program is to realize the full benefits of the technology and restrict its usage in clinical practice. This thing becomes obstruction of the spread of EUS[4)5)].

A new echoendoscope (XEG-530UR, Fujinon Corporation, Saitama, Japan) has been developed that addresses the problem of multiple technologies. This completely electronic 360°radial array echoendoscope is compatible with the US processor offered by the same manufacturer (Fujinon) for the use with its new linear array instrument (XEG-530UT, Fujinon). Furthermore, this scope has front viewing optics for easy manoeuvrability. The XEG-530 series instrument thus obviates the need to purchase two US processors. This system is put in one cart. We tested a newly developed all-in-one EUS system for daily clinical use.

Materials and Methods

Equipment

The prototype XEG-530UR electronic radial echoendoscope (Fujinon Corporation, Saitama, Japan) has a 360° radial ultrasound image, forward-viewing optics (view angle 140°) with a digital tip diameter of 11.4 mm, a 2.2mm forceps channel, and a working length of 1254mm, 180° up, 90° down, and 100° left/right tip deflection (Fig. 1). The prototype XEG-530UT convex echoendoscope (Fujinon) has a 110° convex ultrasound image, oblique-viewing optics (view angle 140°) with a digital tip diameter of 13.9 mm, a 3.8mm forceps channel, a working length of 1254mm, 160° up, 160° down, and 120° left/right tip deflection (Fig. 2). These scopes have a transducer with variable frequency (5.0, 7.5, 10.0, 12.0 MHz) and color and power Doppler flow mapping capabil-

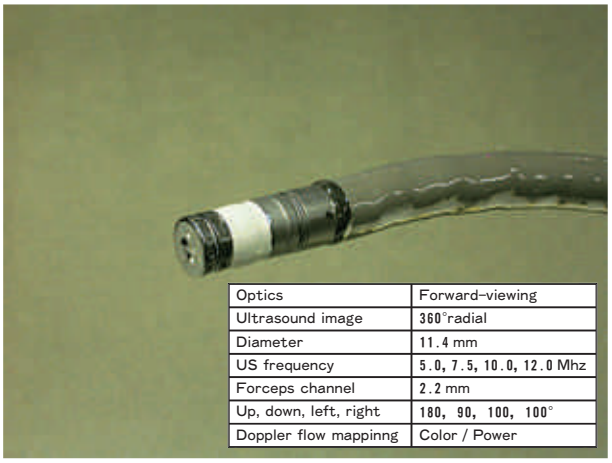

Fig. 1 Distal tip of Fujinon XEG-530UR prototype electronic radial echoendoscope.

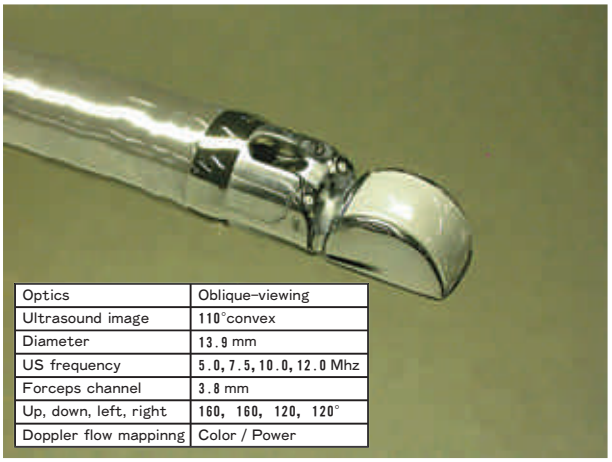

Fig. 2 Distal tip of Fujinon XEG-530UT prototype convex array echoendoscope.

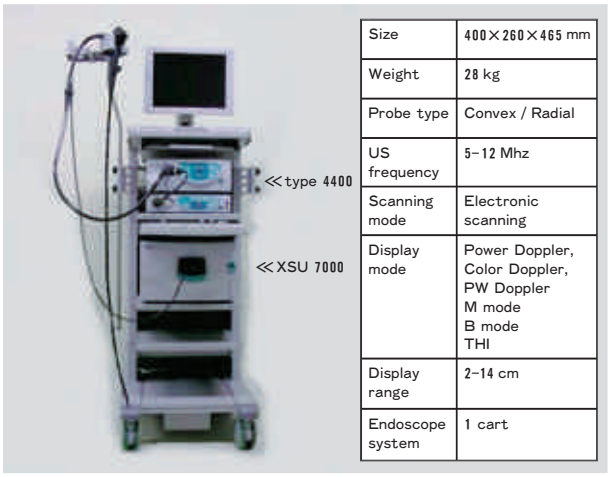

Fig. 3 Endoscopic system (<< type 4400) and ultrasound system (<< XSU-7000) are on single unified cart.

ities. They provide endoscopic and ultrasound images with Fujinon type 4400 endoscopic and XSU-7000 ultrasound processors in a one cart system (Fig. 3). Acoustic coupling is achieved by means of a balloon filled with water attached to the tip and/or luminal water infusion. All FNA procedures were performed using the Olympus needle (NA-11J-KB), consisting of a 180 cm long steel needle 0.8 mm in diameter (22G) with a stylet passing through a metal catheter with an outer diameter of 1.6mm, which is power-shot style that advances to a maximum of 4 cm immediately with the push of a button. Standard EUS imaging and EUS-FNA techniques were used to examine normal and abnormal findings.

Patients

On four days (May 30, June 30, July 28, and September 8 2006), we performed a clinical development study for the Fujinon new EUS system which included electronic radial EUS on 5 patients (8 lesions) and EUS-FNA on eight patients (8 lesions) (Table 1). One attending endosonographer (KA) performed all EUS and EUS-FNA procedures. All procedures were performed under conscious sedation. We evaluated the instrument performance characteristics of the new system. Written, informed consent for EUS and for participation in the trial was obtained from all patients. The study protocol was approved by the institutional review board of our hospital.

Data recording and analysis

The maneuverability, video imaging quality, quality of the gray scale images of the target lesions and visualization of the needle during EUS-FNA were graded by the endosonographer on a data sheet at the conclusion of each procedure. These parameters were rated on a 3-point scale (poor, fair, good). Information was also recorded on the power Doppler capability, including the diagnostic utility.

Results

Thirteen patients (5 men, 8 women; median age 71 years, range 57-80 years) with sixteen lesions underwent EUS or EUS-FNA for various indications (Table 1). Maneuverability and performance of XEG-530UR and XEG-530UT electronic scanning videoendoscopes is shown in Table 2. These new instruments provided satisfactory US and endoscopic images (Fig. 4-6). The forward-viewing optics of XEG-530UR was specifically cited as facilitating intuba-

Table 1 Clinical data of sixteen lesions examined by XEG-530UR and XEG-530UT

Indications	Diagnosis (No of lesions)	No. of lesions
EUS using XEG-530UR		8 (Total)
Staging for early gastric cancer	T1N0	1
Esophageal submucosal tumor	Gastrointestinal mesenchymal tumor	1
Gastric submucosal tumor	Lipoma	1
Small pancreatic head mass	Small pancreatic cancer suspected	1
Pancreatic cystic mass	Intraductal papillary mucinous tumor of the pancreas	2
Gastric ulcerated lesion	Gastric ulcer	1
Gall bladder tumor	Tumor like debris of the gall bladder	1
EUS-FNA using XEG-530UT		8 (Total)
Rectal submucosal mass	Rectal implantation cyst	2
Gastric submucosal tumor	Gastrointestinal stromal tumor (2), Not diagnostic* (3)	5
Esophageal submucosal tumor	Not diagnostic*	1

* : Not diagnostic due to inadequate specimen

Table 2 Maneuverability and performance of XEG-530UR and XEG-530UT electric scanning videoechoendoscopes

	Poor (%)	Fair (%)	Good (%)	n
XEG-530UR				5
Esophageal intubation	0 (0)	0 (0)	5 (100)	5
Duodenal intubation	0 (0)	0 (0)	3 (100)	3
General maneuverability	0 (0)	0 (0)	5 (100)	5
Video image quality	0 (0)	0 (0)	5 (100)	5
Lesion visibility	0 (0)	0 (0)	5 (100)	5
XEG-530UT				8
Esophageal intubation	0 (0)	4 (67)	2 (33)	6
General maneuverability	0 (0)	8 (100)	0 (0)	8
Video image quality	0 (0)	0 (0)	8 (100)	8
Lesion visibility	0 (0)	0 (0)	8 (100)	8
Needle visibility	0 (0)	0 (0)	8 (100)	8

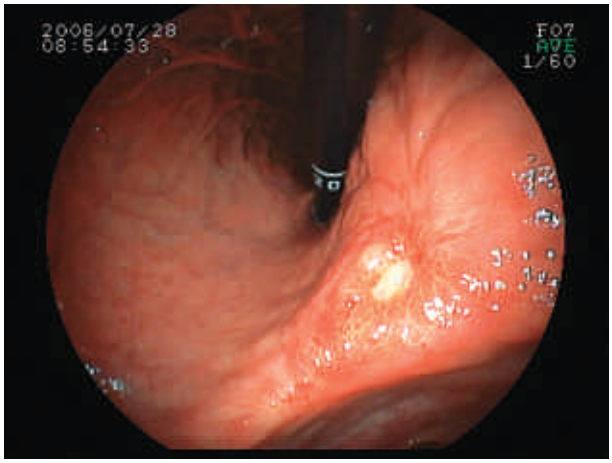

Fig. 4 Endoscopic view of gastric ulcer at the lesser curvature of the angulus by XEG-530UR.

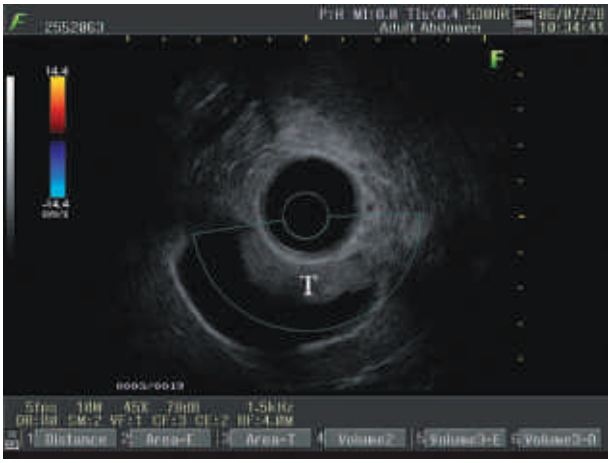

Fig. 5 Transduodenal EUS image by XEG-530UR showing tumor like sludge (T) of the gall bladder. Color Doppler image in fan-shaped area reveals no blood flow.

Fig. 6 EUS view obtained with XEG-530UT showing FNA of the gastroinestinal stromal tumor of the stomach (<< needle tip).

tion and advancement of the electronic instrument as compared with the oblique-viewing convex type echoendoscope XEG-530UT. In particular, XEG-530UR could be used for routine esophagogastroduodenoscopy (Fig. 4). The Doppler imaging was very helpful in distinguishing blood vessels from other structures. Furthermore, it was useful in differentiating a tumor from the tumor-like sludge of the gall bladder (Fig. 5). XEG-530UR provided adequate EUS diagnosis in all 8 lesions. EUS-FNA using the prototype XEG-530UT

was easily performed as well as that using conventional instrument. Real-time visualization of the needle during EUS-FNA was rated as good in all lesions (Fig. 6). Successful puncture of the lesion was obtained in all 8 patients (100%). The collection rate of adequate specimens was 50 % (4 of 8 patients), and histological diagnosis was successfully performed in all 4 adequate specimens. The reasons for inadequate sampling were hardness and small size (less than 2 cm) of the intramural tumors. There were no complications.

Discussion

In accurate EUS evaluation for gastroenterological diseases, both radial scanning instruments for diagnostic EUS imaging and longitudinal scanning instruments primarily for EUS-FNA were required to realize the full benefits of the technology[1)~6)]. At present, EUS requires a range of dedicated echoendoscopes (one for EUS, one for EUS-FNA) with specialized image processing and display consoles that require more space than standard endoscopy[4)5)]. The extended learning curve mainly due to the difficult maneuverability of the oblique viewing optics type echoendoscope and the high cost of the equipment are major obstacles. Technologic improvements have made videoendoscopy equipment more compact and ergonomic and have facilitated its routine use within and outside the endoscopy suite[4)]. For similar reasons, new compact EUS systems are being designed that enhance convenience and affordability. This device can be placed on the same cart with a light source and videoprocessor, thereby optimizing the use of limited space. Furthermore, it is useful to perform diagnostic and interventional EUS procedures in different procedure rooms within an endoscopy unit and in other areas of a hospital (radiology, emergency, operating room).

Despite the improved optics of video echoendoscopes, up to 18% of patients may still require concurrent diagnostic videoendoscopy at the time of conventional EUS[7)]. In the study, the video image quality of the new instruments was judged as good. Furthermore, the forward-viewing optics of the investigational device is clearly advantageous ; it facilitates intubation and eliminates the need for endoscopy with a standard endoscope as all luminal structures are examined adequately. In this study, the new electronic radial echoendoscope could be used for routine EGD. Thus, it may be able to eliminate diagnostic EGD before EUS in some patients. Whether the forward-viewing optics reduce the risk of cervical perforation associated with passage of the oblique-viewing mechanical radial instruments is uncertain[8)]. Large-scale studies would be required to confirm that intubation with the front-viewing electronic instrument is safer.

The gray scale images obtained with the new compact EUS system were judged as good in our study. Image quality is largely subjective and bias remains unavoidable. A detailed comparative study would be required to determine whether accuracy for tumor staging with a new electronic scanning echoendoscope is superior to that achievable with a conventional mechanical one. The power Doppler feature of the new system provided good color filling of vasculature with minimal dispersion into areas of nonvascular tissue. This imaging modality allowed rapid differentiation of blood vessels from other structures and was helpful in diagnosing for all patients in the present study.

EUS-FNA has emerged as a minimally

invasive technique that allows identification and sampling of various gastrointestinal intramural and extraintestinal mass lesions[9]. The accuracy of EUS-FNA for sampling lymph nodes and extraluminal masses such as pancreatic tumors and cysts has been shown to be greater than 80%[10)11)]. However, previous studies[11)12)] found that EUS-FNA was less useful in the diagnosis of GI tract lesions, and particularly submucosal tumors. A multicenter study that included a series of 115 GI tract lesions reported that the sensitivity, specificity, and accuracy of EUS-FNA in diagnosing neoplastic GI tract lesions were 61%, 79%, and 67%, respectively[11)]. Furthermore, it is difficult to obtain adequate tissue sample from the small and hard mass using currently available needles. The results of the present study show that the adequate sampling rate of the new compact EUS system is relatively low (50%). The main reasons for inadequate sampling were the hardness and small size (less than 2cm) of the intramural tumor (small GI tract submucosal tumor). However, the puncture success rate of the lesions in this study was 100% (5/5). We think that our low sampling rate was due to the nature of the lesion and needle technique, not due to our new EUS system. Further technical and mechanical refinements of the needles are required to solve this problem. The number of patients in the current study is small, and it was not designed to assess the accuracy of the new system in the evaluation of any specific disease. Thus, any assessment regarding the performance of the system with respect to any particular disease is necessarily preliminary. Nevertheless, needle visualization, targeting, and passage through the instrument were rated as good in all patients. This would support the premise that this new compact EUS system is attractive for EUS-FNA.

In conclusion, the Fujinon new EUS system evaluated is compact and efficient. Although direct comparative trials with conventional systems would be needed to determine which features are advantageous, the results of the present study indicate that the new compact EUS system is feasible and may afford some improvement in efficiency.

Disclosure

The Newly developed all in one EUS system was provided to the study investigators without charge by Fujinon Corporation.

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(和文抄録)

新開発したオールインワン超音波内視鏡システム：ワンカートシステム，前方直視型 360°放射状電子走査超音波内視鏡及び斜視型コンベックス超音波内視鏡

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多くの超音波内視鏡検査医は診断用には放射状走査型超音波内視鏡を，超音波内視鏡ガイド下穿刺吸引生検には縦方向走査型超音波内視鏡を用いている．二つの異なる放射状走査と縦方向走査の超音波内視鏡検査を行うためには，二つの異なる別々の超音波内視鏡とそれぞれの専用の観測装置が必要である．最近入手可能な同じ会社で製造された放射状走査型超音波内視鏡と縦方向走査型超音波内視鏡は他社の同一の超音波観測装置が必要である．さらに内視鏡視野が直視型で 360°観察可能な放射状電子走査型超音波内視鏡は存在しない．我々は内視鏡視野が直視型で 360°観察可能な放射状電子走査型超音波内視鏡と内視鏡視野が斜視型のコンベックス型超音波内視鏡の両方が使用可能で，全ての装置が一つのカートに収まる省スペースな超音波内視鏡システムを開発した．これらの超音波内視鏡は 5.0，7.5，10.0，12.0 MHz の四つの周波数が選べるうえ，カラー及びパワードップラー表示が可能である．13 人 16 病変(放射状走査型超音波内視鏡検査　8 病変，超音波内視鏡ガイド下穿刺吸引生検　8 病変) に対してこの新型超音波内視鏡システムを用いた開発臨床試験を行った．これらの新しい超音波内視鏡を用い良好な超音波及び内視鏡画像が得られた．内視鏡視野が直視型である原型機は内視鏡の挿入性と操作性を高めた．放射状走査型超音波内視鏡原型機を用いた超音波内視鏡検査では，8 病巣全て (100%) において適切な診断がなされた．コンベックス型超音波内視鏡原型機を用いた超音波内視鏡ガイド下穿刺生検では，8 病巣全ての穿刺に成功し，8 病巣中 4 病巣 (50%) において診断に足る適正な検体の採取ができた．この研究において合併症は認めなかった．この新しいシステムは効率的な超音波内視鏡検査を行うのに魅力的な選択肢の一つと思われる．