Evaluation of a novel radial echoendosonoscope with a piezoelectric-composite transducer: An open-label, multicenter, randomized, parallel-group, noninferiority clinical trial

Sheng Wang[1], Jintao Guo[1], Xiang Liu[1], Nan Ge[1], Guoxin Wang[1], Jinlong Hu[1], Kai Zhang[1], Siyu Sun[1]
[1]Department of Gastroenterology, Shengjing Hospital of China Medical University, Shenyang, Liaoning Province, China

ABSTRACT

Background and Objectives: EUS is widely used in the clinical practice. This study aimed to evaluate the efficacy of a novel echoendoscope regarding image quality, maneuverability, stability of the entire machine system, and safety. **Setting and Design:** We conducted this open-label, multicenter, randomized, parallel-group, noninferiority clinical trial in three tertiary hospitals between November 2018 and April 2019. **Subjects and Methods:** One hundred and thirty patients were included. The stratified segment randomization method was employed. Sixty-five patients in the test group received an EUS examination using the new material radial echoendoscope, and 65 patients in the control group received an EUS examination using the existing endoscope. We recorded the image quality, maneuverability, stability of the entire machine system, and safety. For the main outcome, comprehensive image quality, the groups were compared with the noninferiority test, using the confidence interval method and 10% as the noninferiority threshold. The Pearson Chi-square test was used to compare the incidence of adverse events between the groups. **Results:** Sixty-five patients in the test group and 63 patients in the control group were analyzed. Two patients in control group did not complete an EUS examination due to machine problems. There were no significant differences in image quality, maneuverability of the echoendoscope, stability of the entire machine system, and safety between the groups. **Conclusions:** This new material radial echoendoscope showed good capabilities for image quality, maneuverability, stability of the entire machine system, and safety. Our data suggest that the new echoendoscope may provide an additional option for endoscopic physicians.

Key words: EUS, gastrointestinal diseases, pancreatobiliary diseases

INTRODUCTION

EUS is widely used in clinical practice.[1-3] EUS provides high-resolution, real-time imaging of the gastrointestinal tract and surrounding organs, especially of the bile

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Address for correspondence
Dr. Siyu Sun, Department of Gastroenterology, Shengjing Hospital of China Medical University, Shenyang 110004, Liaoning Province, China. E-mail: sun-siyu@163.com
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duct and pancreas. EUS plays an increasing role in the diagnosis and management of gastrointestinal malignancies, pancreatic diseases, and biliary diseases.[4-8] To meet clinical requirements, many devices have been invented in recent years.[9-12]

The purpose of this open-label, multicenter, randomized, parallel-group, noninferiority clinical trial was to evaluate the efficacy of a new material radial echoendoscope with regard to image quality, maneuverability, stability of the entire machine system, and safety, compared to the existing endoscope.

SUBJECTS AND METHODS

Trial design and participants

This open, multicenter, randomized, parallel-group, noninferiority clinical trial was conducted between November 2018 and April 2019 at three tertiary centers. This study was reviewed and approved by the institutional review board (Yuexie Linbei 20180271), and all patients signed a written informed consent form before participation in the study.

The inclusion criteria were as follows: (1) patients who were clinically required to undergo EUS for the diagnosis or treatment; (2) those aged 18 − 70 years; (3) no sex limit; (4) those who agreed to participate in this trial, and had signed an informed consent form; and (5) the proportion of patients with positive results was not <30%.

The exclusion criteria included (1) patients who did not agree to participate or who did not sign the informed consent form; (2) patients with mental illnesses who were unable to cooperate with the examination; (3) patients who could not tolerate endoscopy due to severe cardiopulmonary disease; (4) patients who were in a critical state, such as shock; (5) patients with suspicious or confirmed upper gastrointestinal perforation; (6) patients with an acute phase of chemical or corrosive injury to the stomach or esophagus; (7) patients who were deemed unsuitable to participate in this trial by the researcher.

Rejection criteria included: (1) Patients who did not meet the selection criteria and were mistakenly included were rejected by the institutional review board, which was subsequently confirmed by the main investigator, as well as other patients who were deemed to be rejected by the investigator; (2) patients who had poor compliance, and had failed to undergo inspections in accordance with the prescribed protocol were also excluded.

Examination process

During the examination process, we used the EG-530UR2 echoendoscope (Fuji Company, Tokyo, Japan) for those in the control group, and the EG-UR5 echoendoscope (Sonoscape company, Shenzhen, China) for those in the test group [Figure 1]. The operators were not blinded with regard to the devices. A comparison between the existing and new radial echoendoscope is shown in Table 1.

1. Endoscopic images were recorded of the cardia, gastric angle, antrum, and duodenum. EUS images were recorded of the esophagus, stomach, duodenum, gall bladder, bile duct, pancreas, and the left lobe of the liver. Images of the left lobe of the liver were used for color Doppler image quality assessment
2. The maneuverability of the echoendoscope was

Table 1. Comparison between existing and new radial echoendoscope

Index	EG-UR5 echoendoscope	EG-530UR2 echoendoscope
Optical system		
Field of view	140l	140l
Direction of view	Forward view	Forward view
Outer diameter (mm)		
Distal end	Φista	Φista
Insertion tube	Φnser	Φnser
Channel inner diameter (mm)	Φmm)	Φmm)
Working length (mm)	1250	1250
Angulation range	U: 180tio 90 180ti 1001	U: 180tio 90 180tion r
Ultrasound scanning range	360r	360r
Balloon function	Yes	Yes

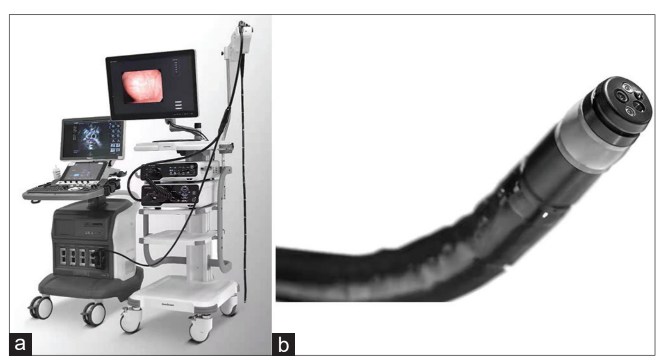

Figure 1. (a) The entire new radial echoendoscope system (b) The distal end of the new echoendoscope

evaluated by the investigator with respect to the bending angle, locking, water supply, air supply, and suction performance
3. The stability of the system was evaluated from the occurrence of unstable events such as failure to start the machine, abnormal interruption, no image display or severe image interference, appearance damage, or functional failure of the endoscope after cleaning and disinfection
4. The safety of the entire machine was evaluated according to the number of adverse events such as leakage, insufficient surface of the echoendoscope, and visualization of scratches on patients.

Sample size
This study was a noninferiority test and the image quality was the main evaluation index. According to the previous clinical applications of the control echoendosonoscope and related literature, the excellent and good image quality rate of the echoendosonoscope system is generally above 95%. Therefore, this study assumed that the comprehensive image quality of the control machine (EG-530UR2 echoendosonoscope system [Fuji Company, Tokyo, Japan]) was above 95%, and the excellent and good image quality rate of the test machine (EG-UR5 echoendosonoscope system [Sonoscape Company, Shenzhen, China]) was similar to that of the control machine. The calculations were performed using the noninferiority test such that α was set at 0.05, a 1-β at 0.80, and the noninferiority threshold was 10%. These calculations revealed that each group required 59 patients (118 patients in total). Considering a dropout rate of 10%, a total of 130 patients were required.

Randomization
The stratified segment randomization method was employed. Stratified by the center and providing the number of seeds and the length of the sections, according to the test and control groups at a 1:1 ratio, a random grouping arrangement of 130 subjects was generated using the statistical software SAS version 9.2 (SAS Institute, Cary, NC, USA). The serial number 001–130 corresponding to the inspection machines was allocated (random code table) and the serial number also corresponded to the subject number. The random code table was kept by a designated person at each center. After the subjects selected a number from the packed box, the researcher shared the subject's number with the designated person, who then issued whether the selected subject would be assigned to the test machine or the control machine according to the random code table.

Outcomes
The main outcome was the quality of the endoscopic images. Endoscopic image quality was evaluated for the following: cardia, gastric angle, antrum, and duodenum, based on clarity, color reproducibility, and brightness uniformity [Supplementary Table 1] Ultrasound image quality was evaluated for the following: esophagus, stomach, duodenum, gall bladder, bile duct, pancreas, and the left lobe of the liver, based on contour, degree of image delicacy, duct structure, among others [Supplementary Table 2.1-2.7] When all sub-indices of all observable judgment points were evaluated as excellent, the endoscopic image quality was evaluated as excellent. When one or more observation points were evaluated as good, the endoscopic image quality was evaluated as good. When one or more observation points were evaluated as poor, the endoscopic image quality was evaluated as poor. The comprehensive image quality evaluation method was based on the quality of the images of both endoscopy and ultrasound. Only when the results of both the endoscopic image quality evaluation and the ultrasound image quality evaluation reached "excellent" or "good," could the comprehensive image quality evaluation result be judged as "excellent" or "good." When the evaluation results of the two parties were inconsistent, the comprehensive image quality evaluation result was based on the lower evaluation. A comprehensive image quality rate of excellent/good was calculated according to the number of cases rated excellent plus the number of cases rated good/the entire number of cases examined × 100%.

The secondary outcomes were the maneuverability of the echoendoscope, system stability, and safety of the entire machine, the evaluation of which is detail in Supplementary Table 3. With regard to the maneuverability of the echoendoscope, if any item in the table was poorly evaluated, it was judged to be poor.

Statistical analysis
Statistical analyses were performed using the Statistical Software Packages SPSS version 19 and SAS version 9.4 (SAS Institute, Chicago, IL, USA). Demographic and baseline data were analyzed using the Chi-square test and two sample *t*-test. The total dropoff rate and the dropoff rate due to adverse events

were compared using the Pearson Chi-square test. For the main outcome, comprehensive image quality, the two groups were compared with the noninferiority test, using the confidence interval method and 10% as the noninferiority threshold. The Pearson Chi-square test was used to compare the incidence of adverse events between the two groups. In all analyses, $P < 0.05$ was considered to indicate statistical significance.

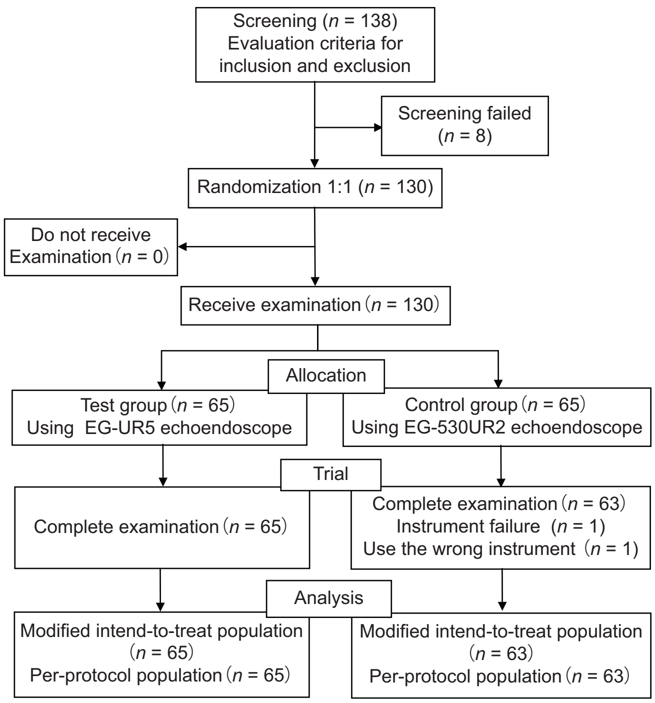

Figure 2. Consort diagram

RESULTS

The scheme for enrolment and randomization throughout the study is shown in Figure 2. A total of 138 patients were screened at three centers between November 2018 and April 2019, and 130 participants were randomized into the two groups. The test and control groups consisted of 65 patients each. Only 63 patients in the control group were analyzed because two patients did not complete the EUS examination due to machine problems. The demographic and clinical characteristics of the patients at baseline were mostly balanced between the groups [Table 2].

For endoscopic image evaluation, one cardia could not be observed due to esophagus surgery in the test group. The gastric angle could not be observed in two patients in the test group and ten patients in the control group. The overall image quality of the test machine endoscope was 100% (65/65), and the overall image quality of the control machine endoscope was 100% (63/63), the rate difference was 0.0%, and the 95% confidence interval for the rate difference was 0.0%–0.0%. The overall image quality of the endoscope was evaluated as excellent, good, and poor in proportions of 46.2% (30/65), 53.8% (35/65), and 0% (0/65) in the test group and 69.8% (44/63), 30.2% (19/63), and 0% (0/63) in the control group. There were no significant differences noted between

Table 2. The demographic and clinical characteristics of the patients

Index	Description	Allocation		Statistics	*P*
		Test group	Control group		
Gender (%)	Male	40 (61.5)	31 (49.2)	1.970	0.160
	Female	25 (38.5)	32 (50.8)		
	Total	65 (100.0)	63 (100.0)		
Age (year)	x̄±s	53.0r) l g	53.1±10.7	−0.092	0.927
	Minimum-maximum	27.0-70.0	25.0-69.0		
	P25-P75	44.0-61.0	45.0-62.0		
	Median	55.0	54.0		
	x̄±s (missing)	65 (0)	63 (0)		
Height (cm)	x̄±s	167.4tg. 7	164.5±7.2	2.094	0.038
	Minimum-maximum	150.0-188.0	150.0-181.0		
	P25-P75	160.0-173.0	160.0-170.0		
	Median	168.0	163.0		
	n (missing)	65 (0)	63 (0)		
Weight (kg)	x̄±s	66.7htg. 2	63.2±10.3	1.515	0.132
	Minimum-maximum	41.5-106.0	43.0-90.0		
	P25-P75	55.0-74.0	57.0-67.0		
	Median	65.0	62.0		
	n (missing)	65 (0)	63 (0)		

The index "gender" adopts Pearson Chi-square test, and the other indexes adopt two independent sample *t*-test

Table 3. The evaluation result of endoscopic image quality

Position	Index	Evaluation	Groups		Difference between test group and control group (%)	95% CI	χ^2/exact probability	*P*
			Test group	Control group				
Cardia	Clarity	Excellent	36 (56.3)	50 (79.4)	0.0	0.0-0.0	-	1.000
		Good	28 (43.7)	13 (20.6)				
		Poor	0	0				
		Total	64 (100.0)	63 (100.0)				
	Color reproduction	Excellent	46 (71.9)	46 (73.0)	0.0	0.0-0.0	-	1.000
		Good	18 (28.1)	17 (27.0)				
		Poor	0	0				
		Total	64 (100.0)	63 (100.0)				
	Brightness uniformity	Excellent	59 (92.2)	58 (92.1)	0.0	0.0-0.0	-	1.000
		Good	5 (7.8)	5 (7.9)				
		Poor	0	0				
		Total	64 (100.0)	63 (100.0)				
Gastric angle	Clarity	Excellent	43 (68.3)	36 (67.9)	0.0	0.0-0.0	-	1.000
		Good	20 (31.7)	17 (32.1)				
		Poor	0	0				
		Total	63 (100.0)	53 (100.0)				
	Color reproduction	Excellent	46 (73.0)	37 (69.8)	0.0	0.0-0.0	-	1.000
		Good	17 (27.0)	16 (30.2)				
		Poor	0	0				
		Total	63 (100.0)	53 (100.0)				
	Brightness uniformity	Excellent	59 (93.7)	49 (92.5)	0.0	0.0-0.0	-	1.000
		Good	4 (6.3)	4 (7.5)				
		Poor	0	0				
		Total	63 (100.0)	53 (100.0)				
Gastric antrum	Clarity	Excellent	47 (72.3)	52 (82.5)	0.0	0.0-0.0		1.000
		Good	18 (27.7)	11 (17.5)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Color reproduction	Excellent	45 (69.2)	45 (71.4)	0.0	0.0-0.0	-	0.000
		Good	20 (30.8)	18 (28.6)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Brightness uniformity	Excellent	61 (93.8)	61 (96.8)	0.0	0.0-0.0	-	0.000
		Good	4 (6.2)	2 (3.2)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
The first part of duodenum	Clarity	Excellent	50 (76.9)	52 (82.5)	0.0	0.0-0.0		1.000
		Good	15 (23.1)	11 (17.5)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Color reproduction	Excellent	47 (72.3)	46 (73.0)	0.0	0.0-0.0	-	1.000
		Good	18 (27.7)	17 (27.0)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Brightness uniformity	Excellent	63 (96.9)	59 (93.7)	0.0	0.0-0.0	-	1.000
		Good	2 (3.1)	4 (6.3)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Total		Excellent	30 (46.2)	44 (69.8)	0.0	0.0-0.0	-	1.000
		Good	35 (53.8)	19 (30.2)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				

CI: Confidence interval

Table 4. The evaluation result of ultrasound image quality

Position	Index	Evaluation	Groups		Difference between test group and control group	95% CI	χ^2/exact probability	*P*
			Test group	Control group				
Esophagus	Shape contour	Excellent	59 (90.8)	58 (92.1)	0.0	0.0-0.0	-	1.000
		Good	6 (9.2)	5 (7.9)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Degree of delicacy	Excellent	57 (87.7)	57 (90.5)	0.0	0.0-0.0	-	1.000
		Good	8 (12.3)	6 (9.5)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Stomach	Shape contour	Excellent	63 (96.9)	60 (95.2)	0.0	0.0-0.0	-	1.000
		Good	2 (3.1)	3 (4.8)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Degree of delicacy	Excellent	61 (93.8)	60 (95.2)	0.0	0.0-0.0	-	1.000
		Good	4 (6.2)	3 (4.8)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Duodenum	Shape contour	Excellent	60 (92.3)	59 (93.7)	0.0	0.0-0.0	-	1.000
		Good	5 (7.7)	4 (6.3)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Degree of delicacy	Excellent	60 (92.3)	58 (92.1)	0.0	0.0-0.0	-	1.000
		Good	5 (7.7)	5 (7.9)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Gallbladder and bile duct	The wall of gall bladder	Excellent	64 (98.5)	60 (95.2)	0.0	0.0-0.0	-	1.000
		Good	1 (1.5)	3 (4.8)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	The cavity of gall bladder	Excellent	65 (100.0)	62 (98.4)	0.0	0.0-0.0	-	1.000
		Good	0	1 (1.6)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Bile duct	Excellent	63 (96.9)	58 (92.1)	0.0	0.0-0.0	-	1.000
		Good	2 (3.1)	5 (7.9)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Pancreas	Shape contour	Excellent	62 (95.4)	60 (95.2)	0.0	0.0-0.0	-	1.000
		Good	3 (4.6)	3 (4.8)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Degree of delicacy	Excellent	60 (92.3)	58 (92.1)	0.0	0.0-0.0	-	1.000
		Good	5 (7.7)	5 (7.9)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	The main pancreatic duct	Excellent	59 (90.8)	55 (87.3)	0.0	0.0-0.0	-	1.000
		Good	6 (9.2)	8 (12.7)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				

Contd..

Table 4. Contd...

Position	Index	Evaluation	Groups		Difference between test group and control group	95% CI	χ^2/exact probability	*P*
			Test group	Control group				
Left lobe of liver (ultrasound image)	Shape contour	Excellent	61 (93.8)	60 (95.2)	0.0	0.0-0.0	-	1.000
		Good	4 (6.2)	3 (4.8)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Degree of delicacy	Excellent	54 (83.1)	57 (90.5)	0.0	0.0-0.0	-	1.000
		Good	11 (16.9)	6 (9.5)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Ducts	Excellent	57 (87.7)	58 (92.1)	0.0	0.0-0.0	-	1.000
		Good	8 (12.3)	5 (7.9)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Left lobe of liver (color Doppler image)	Vascular filling	Excellent	59 (90.8)	27 (42.9)	0.0	0.0-0.0	-	1.000
		Good	6 (9.2)	36 (57.1)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	brightness	Excellent	64 (98.5)	62 (98.4)	0.0	0.0-0.0	-	1.000
		Good	1 (1.5)	1 (1.6)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Color distribution	Excellent	60 (92.3)	54 (85.7)	0.0	0.0-0.0	-	1.000
		Good	5 (7.7)	9 (14.3)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
	Real-time blood flow	Excellent	64 (98.5)	59 (93.7)	0.0	0.0-0.0	-	1.000
		Good	1 (1.5)	4 (6.3)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				
Total		Excellent	50 (76.9)	22 (34.9)	0.0%	0.0~0.0	-	1.000
		Good	15 (23.1)	41 (65.1)				
		Poor	0	0				
		Total	65 (100.0)	63 (100.0)				

CI: Confidence interval

the groups (P = 1.0). The details of the image quality of the echoendoscope are shown in Table 3.

The overall ultrasound image quality was evaluated as excellent, good, and poor in proportions of 76.9% (50/65), 23.1% (15/65), and 0% (0/65) in the test group, and 34.9% (22/63), 65.1% (41/63), and 0% (0/63) in the control group. There were no significant differences noted between the groups (P = 1.0). The details of the overall ultrasound image quality are shown in Table 4.

Evaluation of the maneuverability of the echoendoscope was excellent in the test and control groups. One unstable event of the machine system (1.5%) occurred in the test group, and the 95% confidence interval was 0.0%–4.5%. One unstable event of the machine system (1.5%) occurred in the control group and the 95% confidence interval was 0.0%–4.5%. There were no significant differences noted between the groups (P = 1.0).

One adverse event, a left hypopharyngeal injury, occurred in a patient in the control group (1.5%); the patient received conservative treatment. No adverse events occurred in the test group. There were no significant differences noted between the groups (P = 1.0).

DISCUSSION

We evaluated a new material radial echoendoscope. In our study, the image quality, endoscope maneuverability, stability, and the safety of the entire new radial echoendoscope system were not inferior to the existing echoendoscope system.

The characteristics of the echoendoscope system are vital for the EUS examination procedure.[10,13] There are radial, linear, and forward-viewing echoendoscopes.[14-16] The linear and forward-view echoendoscope allows the performance of EUS-FNA[17,18] and EUS guided interventions[19-21] and is gaining increasing popularity over the radial echoendoscope. However, the radial echoendoscope renders complete and straightforward views of lesions in the gastrointestinal wall and the common bile duct, which is vital in clinical practice.[22-28]

The ultrasound image quality of the echoendoscope is an important factor for formulating an accurate diagnosis. The new echoendoscope combined multi-matching layer acoustic matching technology with self-made piezoelectric-composite material. This ultrasound system could obtain clearer ultrasound images, deeper penetration depth, and stronger contrast.

Piezoelectric composite material is a new material that contains at least one piezoelectric material and other nonpiezoelectric materials that are combined in a specific manner. Compared with single-phase piezoelectric materials and piezoelectric polymers, the new material has a high piezoelectric constant, high thickness electromechanical coupling coefficient, low mechanical quality factor, and low acoustic impedance,[29] which is suitable for creating transducers with high sensitivity, broadband, and a narrow pulse. The multi-matching layers acoustic matching technology reduces the attenuation of the ultrasonic waves in the transmission process, and reduces heat loss, while enabling the ultrasonic energy to smoothly enter human tissue and improves the penetrating power.[30]

We evaluated the image quality of endoscopy and ultrasound. Our comprehensive image quality evaluation method was based on both the image quality of endoscopy and ultrasound, and that the comprehensive image quality excellent/good rate was 100% in the test group. There were no significant differences between the test and control groups. For the image quality of endoscopy, the new system demonstrated good characteristics for clarity, color reproducibility, and brightness uniformity. Notably, operators could clearly observe the structures in the images. For ultrasound images, the new system could observe the gastrointestinal tract and surrounding organs clearly, and for color Doppler, allowed clear visualization of the vascular structures. The diagnosis of lesions did not serve as an index for the evaluation of ultrasound image quality, but the new system allowed clear observation of the lesions to formulate a diagnosis and guide clinical treatment in the test group.

Maneuverability of the echoendoscope used for those in the test group, including the bending angle, locking, water and gas supply, and suction, was good, and there were no significant differences between the test and control groups. The operator could perform successful intubations at the first attempt. Ultrasound scans of all targeted regions were performed smoothly. The gastric angle could not be observed in two patients in the test group; however, the gastric angle could not be observed in ten patients in the control group. This should be improved with further development of instruments.

Both test and control groups experienced one unstable event of the echoendoscope system, and there was no significant difference between the groups. In the test group, the malfunction was caused by misplacement of a sealing ring during cleaning and disinfection of the endoscope, which could be avoided by correct operation. There were no adverse events in the test group and one adverse event, a left hypopharyngeal injury, occurred in the control group, which was conservatively treated.

There were limitations in our study. First, the operators were not blinded with regard to the devices. Second, the analysis of the echoendoscope's maneuverability and image quality was subjective and prone to evaluation bias, although the procedures were all performed by experienced endosonographers in three different tertiary hospitals to prevent this bias.

CONCLUSIONS

There were no significant differences between the new radial echoendoscope machine and the existing one with regard to image quality, maneuverability, stability of the entire machine system, and safety. The findings of this study suggest that the new radial echoendoscope system could be used in clinical practice.

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Conflicts of interest

Siyu Sun is the Editor-in-Chief of the journal. The article was subject to the journal's standard procedures, with peer review handled independently of the editor and his research groups.

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Supplementary Table 1. The evaluation criteria of endoscopic image quality

Index	Evaluation criteria
Clarity	Excellent: The surface structure and vascular lines are clear and easy to identify Good: The clarity of surface structure and blood vessel lines is acceptable and recognizable Poor: The surface structure and blood vessel lines are not clear and difficult to identify
Color reproduction	Excellent: Good color reproduction, no color difference Good: The color has a slight color cast, and there is a slight color difference Poor: Color distortion, obvious color difference
Brightness uniformity	Excellent: High brightness, good uniformity, no dark areas are observed Good: Medium brightness, fair uniformity, with slight dark areas Poor: Low brightness, poor uniformity, and obvious dark areas

Supplementary Table 2.1. The evaluation of endoscopic ultrasound image quality of esophagus

Index	Evaluation criteria
Shape contour	Excellent: The boundaries of each layer are clear and easy to identify Good: The boundaries of each layer are clear and identifiable Poor: The boundaries of each layer are unclear and unrecognizable
Degree of delicacy	Excellent: Good delicate Good: Delicate Poor: Rough

Supplementary Table 2.2. The evaluation of endoscopic ultrasound image quality of stomach

Index	Evaluation criteria
Shape contour	Excellent: The boundaries of each layer are clear and easy to identify Good: The boundaries of each layer are clear and identifiable Poor: The boundaries of each layer are unclear and unrecognizable
Degree of delicacy	Excellent: Good delicate Good: Delicate Poor: Rough

Supplementary Table 2.3. The evaluation of endoscopic ultrasound image quality of the duodenum

Index	Evaluation criteria
Shape contour	Excellent: The boundaries of each layer are clear and easy to identify Good: The boundaries of each layer are clear and identifiable Poor: The boundaries of each layer are unclear and unrecognizable
Degree of delicacy	Excellent: Good delicate Good: Delicate Poor: Rough

Supplementary Table 2.4. The evaluation of endoscopic ultrasound image quality of the gall bladder and bile duct

Index	Evaluation criteria
The wall of gallbladder	Excellent: The inner membrane is clear and easy to identify Good: The inner membrane is clear and identifiable Poor: The inner membrane is not clear and unrecognizable
The cavity of gallbladder	Excellent: Good and clear image Good: The image clear Poor: The image is not clear
Bile duct	Excellent: Good and clear images in the extrahepatic bile duct Good: Clear images in the extrahepatic bile duct Poor: The image in the extrahepatic bile duct cannot be displayed

Supplementary Table 2.5. The evaluation of endoscopic ultrasound image quality of the pancreas

Index	Evaluation criteria
Shape contour	Excellent: The boundaries of each layer are clear and easy to identify Good: The boundaries of each layer are clear and identifiable Poor: The boundaries of each layer are unclear and unrecognizable
Degree of delicacy	Excellent: Good delicate Good: Delicate Poor: Rough
Pancreatic duct	Excellent: Clear display Good: Can be displayed Poor: Not clear

Supplementary Table 2.6. The evaluation of endoscopic ultrasound image quality of the left lobe of the liver

Index	Evaluation criteria
Shape contour	Excellent: The boundaries of each layer are clear and easy to identify Good: The boundaries of each layer are clear and identifiable Poor: The boundaries of each layer are unclear and unrecognizable
Degree of delicacy	Excellent: Good delicate Good: Delicate Poor: Rough
Bile duct	Excellent: Clearly show the four-level branch of bile duct Good: Clearly show the three-level branch of bile duct Poor: The bile duct structure is fuzzy

Supplementary Table 2.7. The evaluation of endoscopic ultrasound image quality of color Doppler of portal vein

Index	Evaluation criteria
Vascular filling	Excellent: Fully filled Good: Partially filled Poor: Not full
Brightness	Excellent: Bright Good: Dim Poor: No display
Color distribution	Excellent: Uniform Good: Relatively uniform Poor: Not uniform
Real-time blood flow	Excellent: Synchronization Good: Delay Poor: Not synchronized

Supplementary Table 3. The evaluation of maneuverability of echoendoscope

Index	Evaluation criterion
Bending angle	Excellent: Normal function, good operation, in line with clinical use requirements Poor: Cannot be used normally or does not meet the requirements of clinical use
Locking	Excellent: Normal function, good operation, in line with clinical use requirements Poor: Cannot be used normally or does not meet the requirements of clinical use
Water and gas supply	Excellent: Smooth water and air supply and can be used normally Poor: Poor patency, affecting normal use
Suction function	Excellent: Unobstructed suction, no backspray when sucking liquid Poor: Poor patency performance or Backspray phenomenon during liquid absorption