Original Article

Diagnostic advantages of transrectal ultrasound with gastrointestinal agent instillation for rectal adenoma and early-stage rectal cancer: comparison of conventional transrectal ultrasound techniques

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Background: Despite being a major focus of medical research for decades, rectal cancer remains a major threat to human health. This study aimed to compare and analyze the diagnostic value of transrectal ultrasonography (TRUS) for rectal adenoma and early-stage rectal cancer before and after gastrointestinal agent instillation.

Methods: In this prospective study, patients diagnosed with rectal adenomas and early-stage rectal cancer by ultrasound were randomly selected for inclusion. All patients underwent ultrasound examination at the Outpatient Department of the First Affiliated Hospital of China Medical University and underwent surgical treatment at the First Affiliated Hospital of China Medical University. Patients with a lesion located 13 cm or more from the edge of the anus, or history of surgery, and a history of radiation and chemotherapy were excluded. A gastrointestinal agent was directly instilled into the rectal cavity during conventional TRUS to compare and analyze the display of rectal lesions before and after such instillation and to evaluate the infiltration depth of rectal lesions. These findings were compared to the pathological findings to determine the diagnostic efficacy.

Results: Both the conventional TRUS and TRUS with gastrointestinal agent instillation were able to show the rectal wall structure and rectal lesions; the detection rate of rectal lesions of the former was 75.0%, and that of the latter was 97.1% (P<0.001). Of the 27 rectal adenomas, conventional TRUS detected 10, and TRUS with gastrointestinal agent instillation detected 25 lesions. The accuracy [90.54%; 95% confidence interval (CI): 81.48–96.11%; P=1.05E–08], specificity (87.88%; 95% CI: 71.80–96.60%; P=1.09E–05), and sensitivity (92.68%; 95% CI: 80.08–98.47%; P=1.05E–08) of TRUS in diagnosing early-stage rectal cancer were consistent with the pathological findings (P<0.001). The accuracy (95.95%, 95% CI: 88.61–99.16%; P=3.82E–11), specificity (93.94%, 95% CI: 79.77–99.26%; P=1.31E–07), and sensitivity (97.56%, 95% CI: 87.15–99.94%; P=3.82E–11) of TRUS after gastrointestinal agent infusion in diagnosing early-stage rectal cancer were consistent with the pathological findings (P<0.001). The specificity (87.88%; 95% CI: 71.80–96.60%; P=1.09E–05) of TRUS in diagnosing rectal adenomas was consistent with the pathological finding (P<0.001), but the accuracy (65%; 95% CI: 51.60–76.87%; P=0.25) and sensitivity (37.04%, 95% CI: 19.40–57.63%; P=0.25) were not (P>0.05). Meanwhile, the accuracy (93.33%; 95% CI: 83.80–98.15%; P=5.65E–06), specificity (93.94; 95% CI: 79.77–99.26%; P=1.31E–07), and sensitivity (92.59%; 95% CI: 75.71–99.09%; P=5.65E–06) of TRUS after gastrointestinal agent infusion in diagnosing rectal adenomas were consistent with the pathological findings (P<0.001).

Conclusions: TRUS with gastrointestinal agent instillation had significantly improved accuracy in

diagnosing early-stage rectal cancer and detecting intrarectal adenomatoid lesions.

Keywords: Early-stage rectal cancer; rectal adenoma; transrectal ultrasonography (TRUS); gastrointestinal agent

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Introduction

Rectal cancer is a common malignancy of the digestive tract system that is threatening to human health despite being a long-standing, major focus of medical research (1-3). In clinical practice, the identification of a benign or malignant rectal mass is essential for the determination of the corresponding therapy, and such identification and local T staging of rectal cancer have typically been conducted by clinicians via imaging diagnosis. With advances in imaging technology, ultrasonography can be used to accurately diagnose diseases. Transrectal ultrasonography (TRUS) is widely used to diagnose rectal lesions (4-7) and is applied in the T staging of rectal cancer for accurate identification (8). Both TRUS and magnetic resonance imaging (MRI) are the common and preferred imaging examination methods in the diagnosis of rectal cancer (9-11). However, MRI has lower specificity in distinguishing between rectal adenoma and early rectal cancer as compared to TRUS. Studies on this subject have mostly focused on the local infiltration depth of middle- and late-stage rectal cancer and changes in T staging before and after neoadjuvant chemoradiotherapy (12-14); however, the diagnosis of early-stage rectal cancer and rectal adenoma via intrarectal gastrointestinal agent instillation has not been extensively examined. It has been found that the most effective method for differentiating between benign and malignant rectal polyps is to combine TRUS with the acoustic window system (AWS). The AWS extends the procedure scope and prevents polyp compression, enhancing the capability of TRUS to differentiate between benign and malignant rectal polyps (15-17). After gastrointestinal agent infusion, the intestinal cavity can be filled to prevent compression of the lesion, which is beneficial for better differential diagnosis. Due to the difficulty in displaying rectal lesions through abdominal exploration, we combine gastrointestinal drug infusion with TRUS. In this study, intrarectal gastrointestinal agent instillation was used with the conventional TRUS in clinical practice to diagnose early-stage rectal cancer and rectal adenoma, representing an innovation in this field. We present this article in accordance with the STARD reporting checklist (available at https://qims.amegroups.com/article/view/10.21037/qims-23-1507/rc).

Methods

Study participants

A total of 68 patients admitted to the First Hospital of China Medical University from January 2015 to January 2021 and who preoperatively underwent TRUS were enrolled in this prospective study. We randomly selected patients diagnosed with rectal adenoma or early-stage rectal cancer via ultrasound. The age of the patients ranged from 25 to 82 (median 59 years) years. The cohort included 49 males and 19 females whose rectal lesions were removed in our hospital and whose pathological findings were recorded. None of the patients had any history of anal or rectal surgery, neoadjuvant chemoradiation therapy, or severe intestinal stenosis. Patients with lesions >13 cm distant from the anal margin were excluded. Before the examination, oral and written informed consents were obtained from all patients or their families. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the First Affiliated Hospital of China Medical University Medical Research Ethics Committee (No. AF-SOP-07-1.1-01).

Instruments and examination protocol

All ultrasound examinations were performed using a Hitachi Preirus Ultrasound Unit (Hitachi Medical Corporation, Tokyo, Japan) with a 360° circular-array transducer (model: EUP-R54AW-19; frequency: 5–10 MHz). There were a total of three operators in this study, all of whom have been engaged in ultrasound work for more than 10 years and have mastered TRUS technology. Before the examination, each operator was fully informed of the patients' clinical symptoms and signs but was not aware of other examination results or pathological results. The patients were asked to fast for

Table 1 Characteristics of the patient cohort

Patient information	Pathology, number		
	Pathological types other than rectal adenoma and early-stage rectal cancer (n=33)	Rectal adenoma (n=27)	Early-stage rectal cancer (n=41)
Sex			
Male	20	22	27
Female	13	5	14
Age (years)			
<50	12	5	9
≥50	21	22	32
Location of lesions (cm)			
Low (≤5)	18	10	11
Middle (6–10)	10	15	26
High (11–12)	5	2	4
Number of lesions			
Single	28	10	41
Multiple	5	17	0
Maximum diameter (cm)			
<1	27	20	6
≥1	6	7	35

6–8 h before examination, stay in the left decubitus position, and bend their hips and knees during the examination. First, the patients underwent conventional TRUS, in which the operator applied an appropriate amount of coupling agent to the surface of the probe, placed a disposable latex cover over it, applied coupling agent to the patient's anus, and extended the probe slowly into the intestinal cavity to observe the lesion. Subsequently, the patients underwent an examination with instant gastrointestinal agent (Huzhou East Asia Medical Products Co., Ltd., Huzhou, China) instillation. For the instillation, the operator injected 60–80 mL of the prepared agent into the rectal cavity via a ureteral catheter and syringe, the catheter was pulled out, and then the probe was inserted to observe the lesion in the intestinal cavity. During the examination, the patients were advised to take a deep breath when necessary to relieve their tension and relax the sphincter ani. After the examination, the patients discharged the agent in urine.

Statistical analysis

SPSS 19.0 software (IBM Corp., Armonk, NY, USA) was applied to conduct statistical analysis. The chi-squared test was used to test the detection rate of the conventional TRUS and TRUS with gastrointestinal agent instillation and to determine the consistency between the findings of these methods and the pathological findings. Additionally, the accuracy, sensitivity, and specificity of the two transrectal examination approaches were compared. We calculated the corresponding 95% confidence intervals using MedCalc 19.5.6 software. A two-sided P value <0.001 indicated statistical significance.

Results

Pathological findings and baseline information of patients

There were 130 potentially eligible patients in this study, 29 of whom were excluded. Figure S1 summarizes the reasons for excluding these 29 patients. Ultimately, 101 patients were enrolled, including 33 patients with pathological types other than rectal adenoma and early-stage rectal cancer, 27 patients with rectal adenoma, and 41 patients with early rectal cancer. *Table 1* summarizes the baseline information of the lesions.

TRUS findings of the normal rectum

The ultrasonic probe used in TRUS and the instrument used

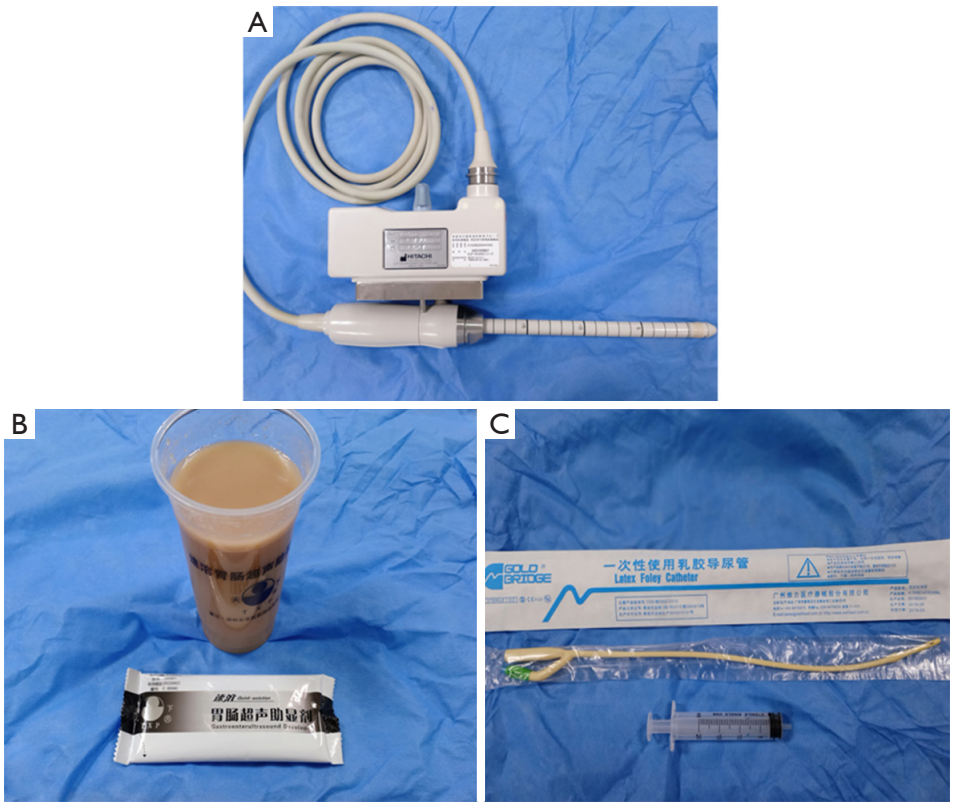

Figure 1 Ultrasonic probes and consumables. (A) 360° TRUS probe. (B) Instant gastrointestinal agent. (C) Urethral catheter and syringe for cavity injection. TRUS, transrectal ultrasonography.

for gastrointestinal agent injection are shown in *Figure 1*. TRUS provided a clear observation of the five-layer structure of the intestinal wall. These five layers, from the innermost to the outermost, respectively, were the interface layer (hyperechoic), mucosal muscle layer (hypoechoic), submucosal layer (hyperechoic), muscularis propria (hypoechoic), and serosal layer (hyperechoic). During ultrasonic probing, the interface layer is often an interface echo between the mucosa and probe or rectum contents. During the conventional TRUS, the probe was closely adhered to the mucosa (*Figure 2A*,*2B*), while during TRUS with gastrointestinal agent instillation, the interface layer was clearly shown (*Figure 2C*,*2D*).

Ultrasonography findings of rectal adenoma and early-stage rectal cancer

On ultrasonography, both rectal adenoma and early-stage rectal cancer appeared with a low echo, clear boundary, bulging into the intestinal cavity, and a blood flow of varying abundance. Rectal adenoma was present only in the mucosal layer, while early-stage rectal cancer was found infiltrating into the mucosal muscle layer and submucosal layer. Although it was difficult for the conventional TRUS to detect small rectal adenomas, TRUS with gastrointestinal agent instillation was able to show these lesions (*Figures 3*,*4*). For early-stage rectal cancer, both the TRUS examinations revealed the degree of the lesion; however, for most lesions, TRUS also detected the infiltration depth (*Figure 5*), while for a few early-stage rectal cancers, even TRUS with gastrointestinal agent instillation could not detect the infiltration depth (*Figure 6*).

Diagnostic efficacy of the two TRUS examinations

Of the 101 patients examined, 68 were diagnosed with rectal adenoma or early-stage rectal cancer via ultrasound. For 68 rectal lesions, the detection rate of conventional TRUS was 75.0% while that of TRUS with gastrointestinal agent instillation was 97.1%, representing a statistically significant difference (P<0.001). Conventional TRUS failed to detect 17 rectal lesions, which were adenomas.

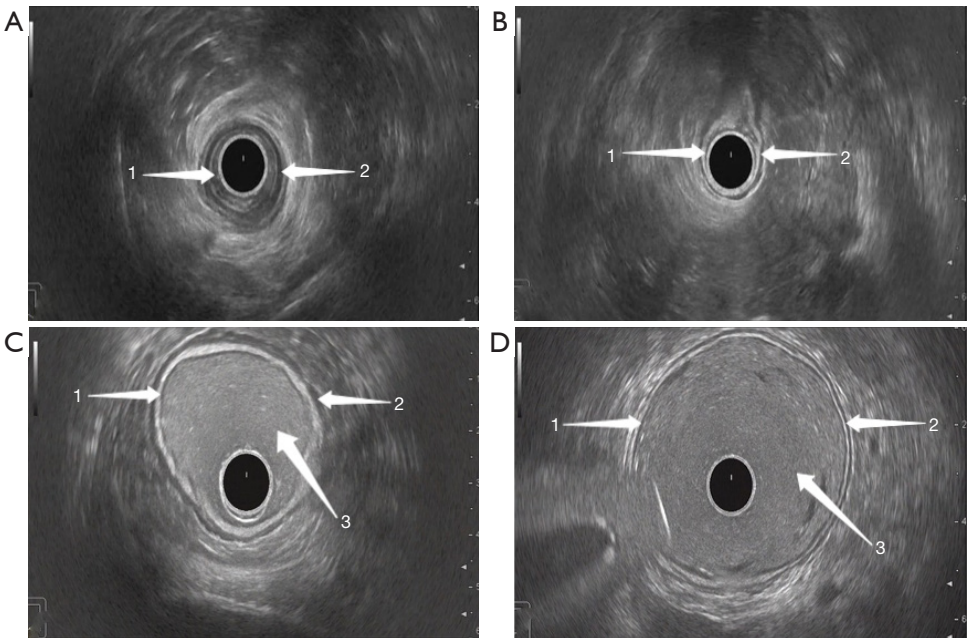

Figure 2 The rectal wall of TRUS before and after administration of the gastrointestinal agent. (A) The normal lower segment of the rectum. (B) The normal upper middle segment of the rectum. (C) The normal middle segment of the rectum, with the intestinal wall and submucosal layer being thicker after gastrointestinal agent instillation. (D) The normal middle segment of the rectum, with the intestinal wall and submucosal layer being thinner after gastrointestinal agent instillation. 1: mucosal muscle layer (hypoechoic); 2: muscularis propria (hypoechoic); 3: gastrointestinal agent. TRUS, transrectal ultrasonography.

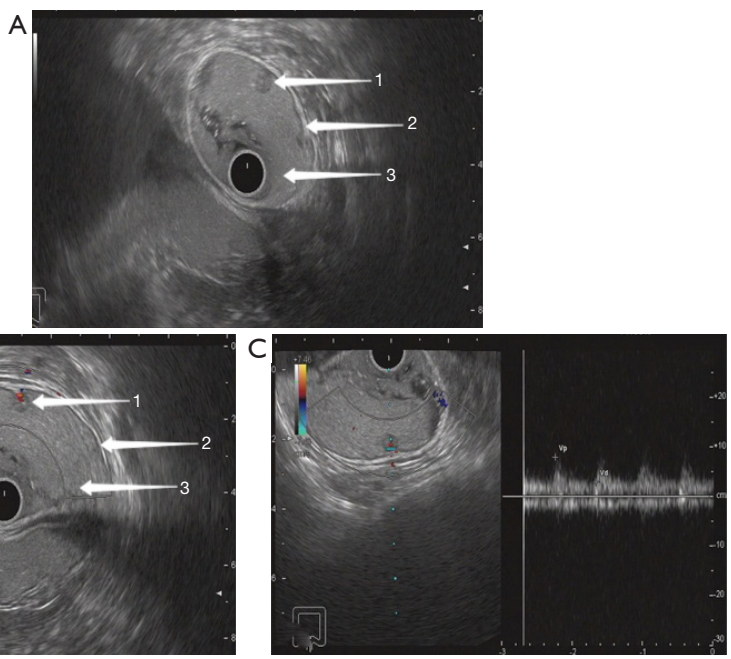

Figure 3 Rectal adenoma of the same patient on TRUS with gastrointestinal agent instillation. (A) Two-dimensional ultrasonogram. (B) Color Doppler ultrasonogram. (C) Spectral Doppler ultrasonogram. 1: rectal adenoma; 2: submucosal layer (hyperechoic); 3: gastrointestinal agent. TRUS, transrectal ultrasonography.

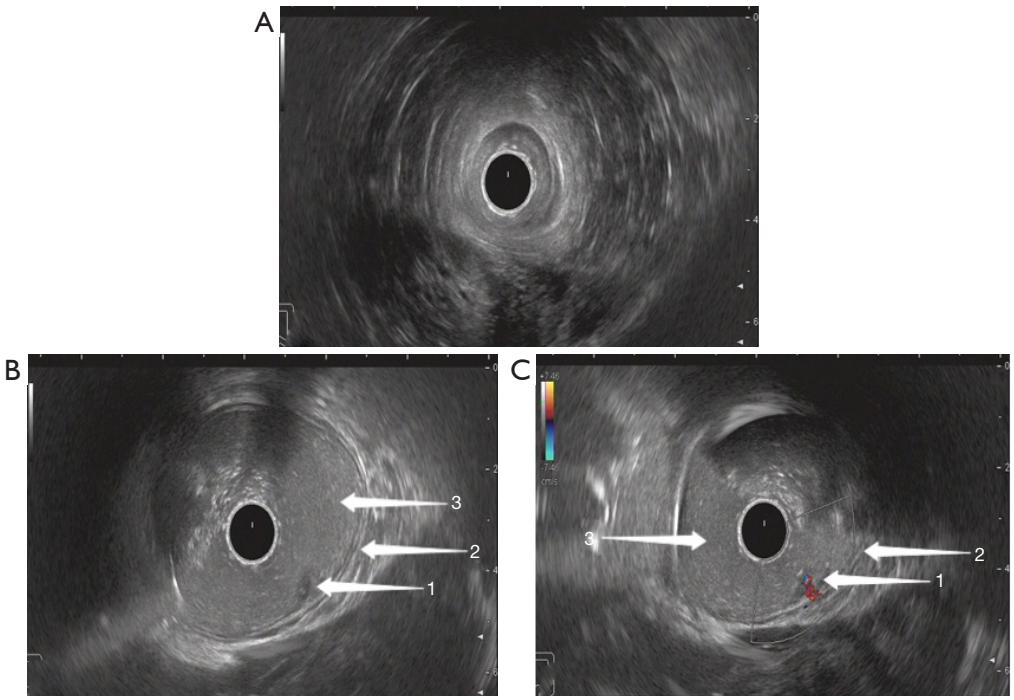

Figure 4 Rectal adenoma of the same patient in on TRUS. (A) No rectal lesion in conventional TRUS. (B,C) Two-dimensional and color Doppler ultrasonograms of rectal adenoma on TRUS with gastrointestinal agent instillation. 1: rectal adenoma; 2: submucosal layer (hyperechoic); 3: gastrointestinal agent. TRUS, transrectal ultrasonography.

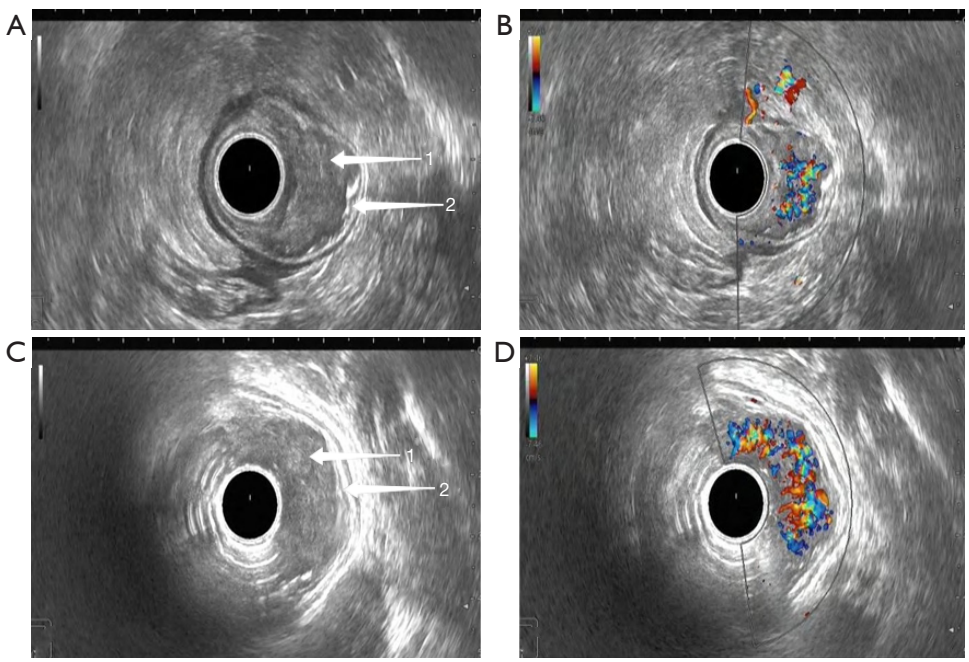

Figure 5 Early-stage rectal cancer on conventional TRUS of the same patient. (A,C) 2D ultrasonograms of early-stage rectal cancer on conventional TRUS. (B,D) Color Doppler ultrasonograms of early-stage rectal cancer on conventional TRUS. 1: early-stage rectal cancer; 2: submucosal layer (hyperechoic). TRUS, transrectal ultrasonography; 2D, two-dimensional.

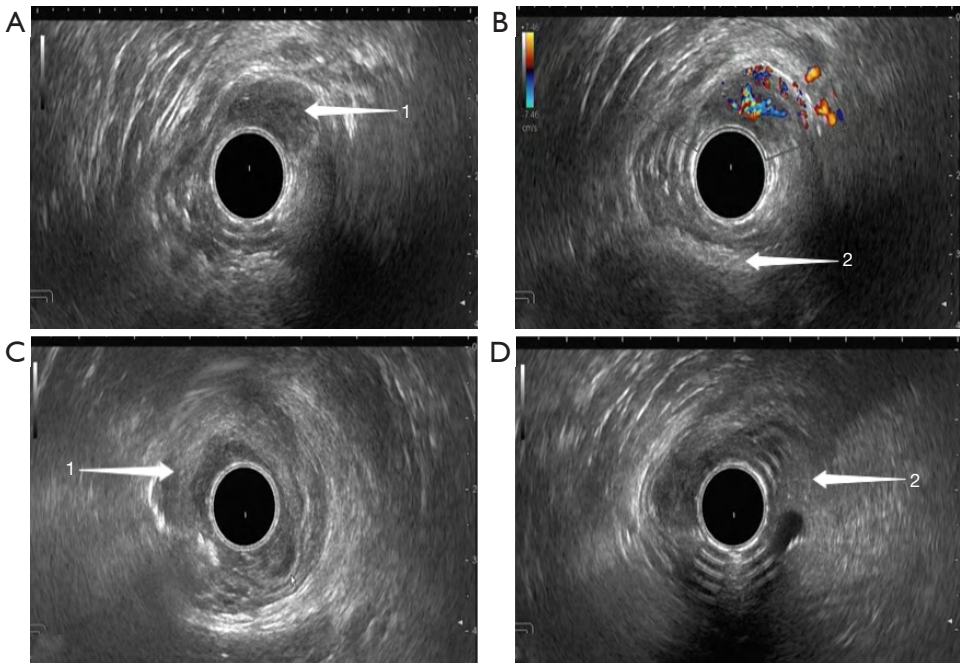

Figure 6 Early-stage rectal cancer on TRUS of the same patient. (A,C) The layers of the rectal wall cannot be clearly discerned on conventional TRUS. (B,D) The layers of the rectal wall cannot be clearly discerned on TRUS with gastrointestinal agent instillation. 1: early-stage rectal cancer; 2: gastrointestinal agent and rectum contents (excrement and gas, etc.). TRUS, transrectal ultrasonography.

Table 2 Evaluation of the diagnostic effect of two the TRUS examination types for early-stage rectal cancer and rectal adenoma

TRUS	Accuracy		Specificity		Sensitivity	
	Value (95% CI), %	P	Value (95% CI), %	P	Value (95% CI), %	P
Early-stage rectal cancer						
Conventional method	90.54 (81.48–96.11)	<0.001	87.88 (71.80–96.60)	<0.001	92.68 (80.08–98.47)	<0.001
Gastrointestinal agent method	95.95 (88.61–99.16)	<0.001	93.94 (79.77–99.26)	<0.001	97.56 ((87.15–99.94)	<0.001
Rectal adenoma						
Conventional method	65 (51.60–76.87)	>0.05	87.88 (71.80–96.60)	<0.001	37.04 (19.40–57.63)	>0.05
Gastrointestinal agent method	93.33 (83.80–98.15)	<0.001	93.94 (79.77–99.26)	<0.001	92.59 (75.71–99.09)	<0.001

TRUS, transrectal ultrasonography; CI, confidence interval.

Of these, 15 were detected by TRUS with gastrointestinal agent instillation, and 2 were not detected at all. Regarding the consistency between ultrasonography and pathological findings, a difference was detected between TRUS and TRUS with gastrointestinal agent instillation. The accuracy [90.54%; 95% confidence interval (CI): 81.48–96.11%; P=1.05E–08], specificity (87.88%; 95% CI: 71.80–96.60%; P=1.09E–05), and sensitivity (92.68%; 95% CI: 80.08–98.47%; P=1.05E–08) of TRUS in diagnosing early-stage rectal cancer were consistent with the pathological findings (P<0.001) (*Table 2*). *Table 3* shows the cross-tabulation of the TRUS and early-stage rectal cancer pathological results. The accuracy (95.95; 95% CI: 88.61–99.16%; P=3.82E–11), specificity (93.94%; 95% CI: 79.77–99.26%; P=1.31E–07), and sensitivity (97.56; 95% CI: 87.15–99.94%; P=3.82E–11) of TRUS after gastrointestinal agent infusion in diagnosing early-stage rectal cancer were consistent with the pathological findings (P<0.001) (*Table 2*). *Table 4* shows the cross-tabulation of the results of TRUS after gastrointestinal agent infusion for early-

Table 3 A cross-tabulation of TRUS and pathological results for early-stage rectal cancer

Early-stage rectal cancer	Pathology		Total
	Positive	Negative	
TRUS			
+	38	4	42
–	3	29	32
Total	41	33	74

Positive, early-stage rectal cancer; negative, pathological type other than rectal adenoma and early-stage rectal cancer. +, ultrasound diagnosis of early rectal cancer; –, ultrasound diagnosis other than rectal cancer. TRUS, transrectal ultrasonography.

Table 4 A cross-tabulation of TRUS after gastrointestinal agent infusion and pathological results in early-stage rectal cancer

Early-stage rectal cancer	Pathology		Total
	Positive	Negative	
TRUS after gastrointestinal agent infusion			
+	40	2	42
–	1	31	32
Total	41	33	74

Positive, early-stage rectal cancers; negative, pathological type other than rectal adenoma and early-stage rectal cancer. +, ultrasound diagnosis of early rectal cancer; –, ultrasound diagnosis other than rectal cancer. TRUS, transrectal ultrasonography.

Table 5 A cross-tabulation of TRUS and pathological results in rectal adenoma

Rectal adenomas	Pathology		Total
	Positive	Negative	
TRUS			
+	10	4	14
–	17	29	46
Total	27	33	60

Positive, rectal adenoma; negative, pathological type other than rectal adenoma and early-stage rectal cancer. +, ultrasound diagnosis of rectal adenoma; –, ultrasound diagnosis other than rectal adenoma. TRUS, transrectal ultrasonography.

Table 6 A cross-tabulation of TRUS after gastrointestinal agent infusion and pathological results for rectal adenoma

Rectal adenomas	Pathology		Total
	Positive	Negative	
TRUS after gastrointestinal agent infusion			
+	25	2	27
–	2	31	33
Total	27	33	60

Positive, rectal adenoma; negative, pathological type other than rectal adenoma and early-stage rectal cancer. +, ultrasound diagnosis of rectal adenoma; –, ultrasound diagnosis other than rectal adenoma. TRUS, transrectal ultrasonography.

stage rectal cancer and those of pathology. The specificity (87.88%; 95% CI: 71.80–96.60%; P=1.09E–05) of TRUS in diagnosing rectal adenomas was consistent with the pathological finding (P<0.001). The accuracy (65%; 95% CI: 51.60–76.87%; P=0.25) and sensitivity (37.04%; 95% CI: 19.40–57.63%; P=0.25) of TRUS in diagnosing rectal adenomas were not statistically significant compared to the pathological results (P>0.05) (*Table 2*). *Table 5* shows the cross-tabulation of TRUS and rectal adenomas pathological results. The accuracy (93.33%; 95% CI: 83.80–98.15%; P=5.65E–06), specificity (93.94%; 95% CI: 79.77–99.26%; P=1.31E–07), and sensitivity (92.59%; 95% CI: 75.71–99.09%; P=5.65E–06) of TRUS after gastrointestinal agent infusion in diagnosing rectal adenomas were consistent with the pathological findings (P<0.001) (*Table 2*). *Table 6* shows the cross-tabulation of TRUS after gastrointestinal agent infusion and the rectal adenomas pathological results. Overall, TRUS with gastrointestinal agent instillation was significantly better in the detection and diagnosis of rectal adenoma and early-stage rectal cancer than was conventional TRUS.

Discussion

TRUS has been widely used in the diagnosis of anal and rectal lesions (18,19). One study outlined endorectal/endoanal ultrasound (ERUS/EAUS) and perineal ultrasound (PNUS), with their most crucial indications being rectal tumors and inflammatory diseases (20). The accurate preoperative determination of the local infiltration depth of rectal cancer can guide the determination of optimal therapies in clinical practice. TRUS and MRI are the existing effective methods that can determine the local infiltration depth of rectal cancer (21,22), and has its

respective advantages. In some cases, conventional TRUS cannot meet the needs of clinical diagnosis. The probe of the conventional TRUS closely adheres to the rectal mucosa after it is extended into the rectum, and some gas and feces are detected in the intestinal cavity (whether perfused or not before examination), often causing lesions in the mucosal layer or small lesions in the intestinal wall to be missed or misdiagnosed. In emaciated or obese patients, the probe may not fully reach the lesion or might fail to detect them. In such cases, the advantages of TRUS with gastrointestinal agent instillation are even more apparent.

In previous studies, drinking water and coupling agent were injected into the rectal cavity to observe rectal lesions and diagnose T staging (23,24), which indicated that intrarectal instillation enables observation and accurate diagnosis of the lesion. Our study further investigated gastrointestinal instillation using instant gastrointestinal agents. When the rectal cavity was filled with the agent, the rectum could be filled up (as air inflation during an enteroscopy). The gastrointestinal agent disperses gas residues and feces in the rectal cavity, allowing for the observation of intrarectal lesions and the smooth extension of the probe. This method is superior to the injection of water or coupling agent into the rectum because the water may flows too quickly while the coupling agents may flow too slowly. Therefore, both water and coupling agents can cause discomfort in patients. Consequently, the use of gastrointestinal agent is advantageous as it is tolerable, does not harm the body, flows satisfactorily, provides a better contrast window for intrarectal lesions, disperses gas and feces inside the rectal cavity, and is discharged smoothly after examination. Moreover, the results of this study demonstrated that TRUS with gastrointestinal agent instillation has a higher detection rate, sensitivity, and accuracy for rectal lesions than does conventional TRUS, thereby effectively reducing the missed rate and misdiagnosis rate of rectal lesions.

Furthermore, in this study, conventional TRUS did not detect small rectal adenomas, while TRUS with gastrointestinal agent instillation had a significantly improved detection rate of rectal adenomas and enabled accurate diagnosis. However, TRUS with gastrointestinal agent instillation failed to detect two rectal adenomas because they were extremely small (diameter 0.2–0.3 cm and adenomatous polyps according to pathological findings) and because there was silted-up feces in the rectum. In most cases, the early-stage rectal cancers were large lesions that were identified in both examinations. However, early-stage rectal cancers with irremovable feces in the intestinal cavity were only diagnosed with TRUS and gastrointestinal agent instillation. The conventional TRUS misdiagnosed eight cases in this study (including 5 overstaged as T2 and three misdiagnosed as adenoma). The three cases misdiagnosed as adenomas had a shallow infiltration depth and a small cancerous range (pathological results showed tubular adenoma with localized malignancy). Of the five cases of ultrasound overstaging, four were diagnosed by TRUS with gastrointestinal agent instillation, which yielded results consistent with the pathological findings (which showed T1 stage rectal cancer). One case, diagnosed by TRUS with gastrointestinal agent instillation as T2 stage rectal cancer, was inconsistent with the pathological findings (which showed T1 stage rectal cancer). The reason for this erroneous ultrasound staging was the presence of a significant inflammatory infiltrate and the location of the lesion in the upper rectum. Therefore, TRUS with gastrointestinal agent instillation could diagnose lesions rather accurately when used with enteroscopy.

Some limitations to this study should be mentioned. First, there was a relatively small number of cases, only a few high rectal lesions were detected by the 360° circular-array probe up to 18 cm depth, and only a few patients facilitated the extension of the probe into the depth of 18 cm in practical application. Second, some studies have evaluated the diagnostic performance of endorectal ultrasound and shear-wave elastography in patients with complex rectal adenoma or early rectal cancer (25). Therefore, in future clinical research, we also plan to examine the use of shear-wave elastography and recruit more cases.

Conclusions

Conventional TRUS can accurately diagnose early rectal cancer. TRUS with gastrointestinal agent instillation further enhances the diagnostic accuracy of early rectal cancer, reducing the missed rate and misdiagnosis rate. It is also advantageous due to its convenient and broad application, low cost, and simple operation. Therefore, its extensive use in clinical practice is warranted.

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://qims.amegroups.com/article/view/10.21037/qims-23-1507/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-23-1507/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Before the examination, oral and written informed consents were obtained from all patients or their families. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the First Affiliated Hospital of China Medical University Medical Research Ethics Committee (No. AF-SOP-07-1.1-01).

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Supplementary

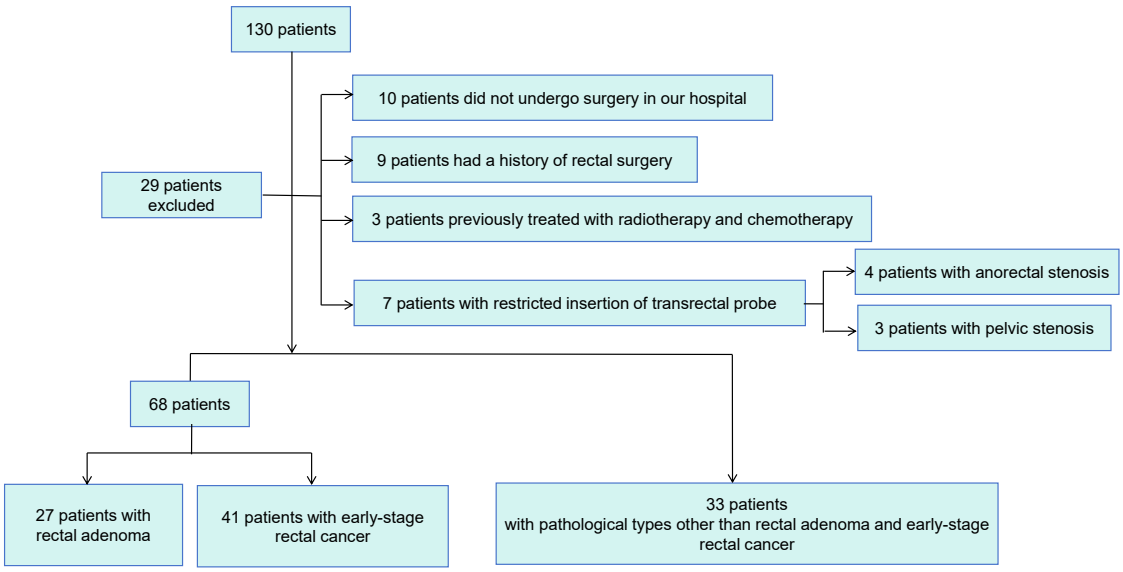

Figure S1 Flow diagram for rectal cancer patients.

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