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Original Article

Comparative clinical evaluation of combine three-dimensional anorectal ultrasound and high-frequency linear array ultrasound versus MRI for diagnosis and postoperative outcomes of anal fistula

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Abstract: Objective: To evaluate and compare the diagnostic accuracy and postoperative outcomes of combined 3D-TRUS and HF-LAU versus MRI in the management of anal fistula. Methods: A retrospective analysis was conducted on 200 patients with anal fistula. Patients were divided into two groups: 105 individuals in the control group, who underwent Magnetic Resonance Imaging (MRI), and 95 individuals in the observation group, who were assessed using both 3D-TRUS and HF-LAU. Pathologic findings served as the reference. Diagnostic performance, including sensitivity, specificity, and the area under the receiver operating characteristic (ROC) curve, was compared between the two groups. Results: The combined 3D-TRUS and HF-LAU method demonstrated superior diagnostic accuracy compared to MRI, with significantly better sensitivity and specificity ($P < 0.05$), with AUCs of 0.95 versus 0.89, respectively. The observation group showed significantly shorter postoperative hospitalization and recovery times, as well as a lower complication rate ($P < 0.05$). Postoperative incontinence and fistula recurrence were notably lower in the observation group ($P = 0.017$). Inflammatory markers showed no significant differences between the two groups ($P > 0.05$). Conclusion: The combined 3D-TRUS and HF-LAU method demonstrated superior diagnostic accuracy for detecting anal fistulas compared to MRI, highlighting its potential as a non-invasive, cost-effective alternative to MRI in settings that require high diagnostic precision.

Keywords: Three-dimensional anorectal ultrasound, high-frequency linear array ultrasound, anal fistula, imaging techniques, ultrasound diagnosis

Introduction

Anal fistula (AF), a common yet complex anorectal condition, presents significant diagnostic and therapeutic challenges. It is characterized by an abnormal connection between the anal canal and perianal skin, often resulting from perianal abscesses or chronic inflammation [1]. While clinical examination remains the cornerstone for initial diagnosis, its accuracy is limited, especially for complex fistulas. As such, advanced imaging techniques are indispensable for precise diagnosis and treatment planning [2, 3]. Currently, magnetic resonance imaging (MRI) and endorectal ultrasound (ERUS) are regarded as the gold standards for evaluating anal fistulas, offering detailed visualization of fistula tracts and their relationships to surrounding structures [4, 5]. However, these methods also have their limitations, including high costs, limited availability, and technical complexity, underscoring the need for more accessible and reliable diagnostic alternatives.

Recent advancements in ultrasonography have improved the diagnosis of anal fistulas, particularly with the advent of high-frequency linear array ultrasound (HF-LAUS) and three-dimensional anorectal ultrasound (3D-TRUS) [6-8]. These technologies have emerged as powerful tools in the clinical evaluation of anal fistulas, each offering distinct advantages that enhance

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the overall diagnostic accuracy. HF-LAUS, with its high-resolution imaging capabilities, allows detailed visualization of the anal sphincters and surrounding tissues, facilitating precise identification of fistula tracts and associated abscesses or fluid collections. This modality is especially valuable for assessing the involvement of the anal sphincter, a key factor in surgical planning aimed at preserving sphincter function and minimizing postoperative incontinence [9]. In addition, HF-LAUS excels in detecting small or early-stage fistulas that may be missed during clinical examination [10]. By comparison, 3D-TRUS provides comprehensive, multidimensional reconstructions of the anal canal and perianal structures. This three-dimensional view is particularly advantageous for evaluating complex fistulas, such as those with multiple branches or transsphincteric involvement, which are difficult to assess using traditional two-dimensional imaging. By offering a complete spatial representation, 3D-TRUS helps clinicians understand the fistula's extent and its relationship to critical anatomical structures like the rectal wall and sphincter muscles, thus facilitating preoperative planning and optimizing surgical strategy [11]. Moreover, the holistic visualization provided by 3D imaging may increase intervention precision and reduce the risk of complications.

Despite the promising capabilities of both HF-LAUS and 3D-TRUS, studies integrating these two modalities into a unified diagnostic approach remains limited. While each technique individually provides substantial diagnostic value, their combined use could enhance overall diagnostic accuracy by leveraging their respective strength [12]. HF-LAUS excels in providing high-resolution, real-time imaging of fistula tracts and sphincter involvement, while 3D-TRUS offers a comprehensive, anatomic overview of the anal canal and surrounding tissues [13, 14]. The integration of these technologies may offer clinicians more detailed and accurate understanding of fistula pathophysiology, thereby improving treatment planning and leading to better clinical outcomes. The current paucity of research on the synergistic use of HF-LAUS and 3D-TRUS highlights a need for further research. Exploring the effective combination of these two modalities represents a promising direction for enhancing diagnostic precision and enabling tailored intervention for anal fistulas [15].

It is also cost-effective, and non-invasive. The synergy between spatial orientation of 3D-TRUS and the high-resolution imaging capability of HF-LAUS may overcome the limitations of traditional diagnostic methods, offering a more robust evaluation, particularly for complex fistulas.

Patinets and Methods

Case selection

This retrospective study included 200 patients diagnosed with AF who were hospitalized at Zhangjiagang TCM Hospital Affiliated to Nanjing University of Chinese Medicine between January 2023 and October 2024. Of these, 105 patients who underwent MRI examination were assigned to the control group, while 95 patients who received both 3D-TRUS and HF-LAUS were assigned to the observation group. All selected patients underwent timely surgical treatment within 3 to 5 days following their respective imaging examinations. Surgical outcomes served as the final diagnostic standard. Preoperative imaging results were compared with postoperative diagnoses to evaluate diagnostic accuracy. The patient selection process is shown in **Figure 1**. The study was approved by the Ethics Committee of Zhangjiagang TCM Hospital Affiliated to Nanjing University of Chinese Medicine.

Inclusion criteria: (1) Patients meeting the diagnostic standard of the *Clinical Diagnosis Guidelines for Anal Fistula (2020 Edition)* [16]; (2) Age between 18 and 75 years; (3) No abnormalities in anal morphology or function; (4) Complete clinical and imaging data.

Exclusion criteria: (1) Concurrent colorectal cancer; (2) Infectious diseases; (3) Traumatic anal fistulas; (4) Pregnant women, infants, and minors; (5) Other serious conditions, including leukemia or pulmonary hypertension; (6) Uncontrolled hypertension; (7) Malignant arrhythmias or presence of a pacemaker.

Data extraction

Data were extracted using a comprehensive approach combining ultrasound imaging and surgical exploration [17]. For ultrasonography, a BK1202 ultrasound diagnostic system was utilized, using a 360° transrectal probe (BK8838, 4-12 MHz) and a high-frequency lin-

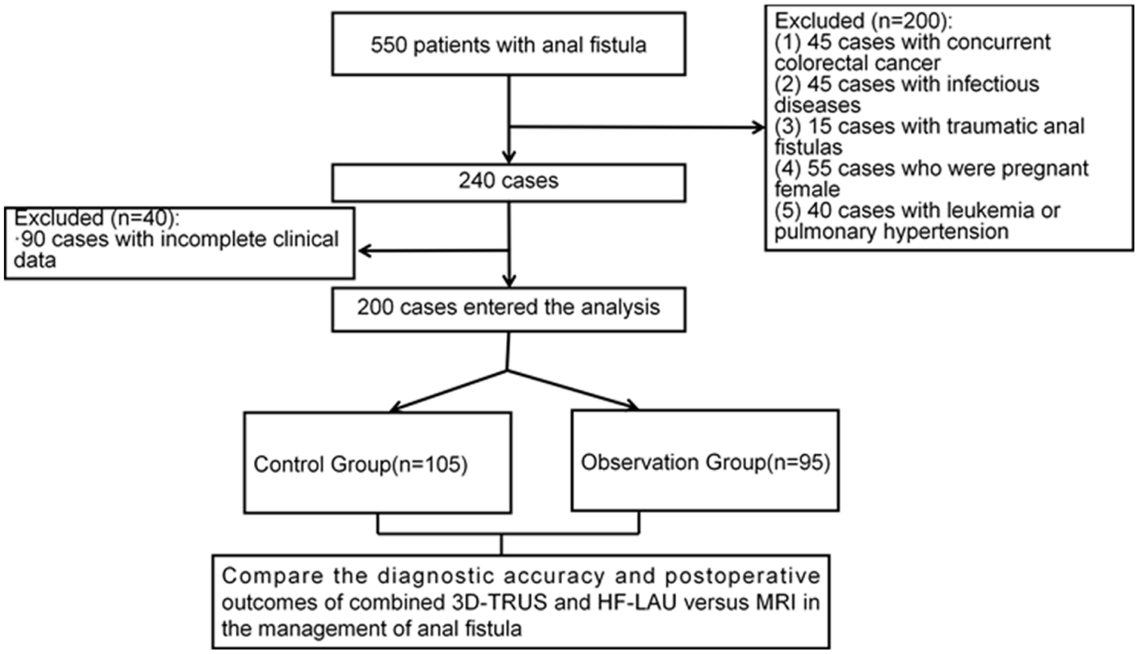

Figure 1. Flow diagram detailing the selection of patients included in this study. 3D-TRUS: Three-Dimensional Anorectal Ultrasound, HF-LAUS: high-frequency linear array ultrasound, MRI: Magnetic Resonance Imaging.

ear array probe (BK8811, 5-12 MHz). Ultrasound gel was applied to the probes, which were covered with a condom for protection. Initially, the high-frequency linear array probe was used for radial scanning of the perianal area to assess the morphology, location, depth, and presence of low-echo tracts connected to the anal canal. Doppler flow imaging (DFI) was employed to visualize blood flow signals around the lesion. Subsequently, the 360° transrectal probe was gently inserted into the anus after instructing the patient to relax and breathe deeply. The probe was advanced into the rectum and oriented at the 12 o'clock position of the lithotomy clock. Scanning was performed from deep to superficial layers along the anal canal to evaluate the anal lumen, wall, and surrounding tissues, identifying the internal opening, number of fistula tracts, their path, and the relationship with the sphincter muscles. Mea-surements were taken relative to the anal verge using the probe's built-in scale. Fistulas were classified according to the Parks classification system (**Figure 2A**, **2B**).

For MRI examination, patients underwent routine scanning without bowel preparation or the use of rectal tubes or markers. Standard imaging sequences included supine, axial, and coronal T1-weighted, T2-weighted, and fat-suppressed sequences, supplemented by additional scans based on the specific clinical condition. Gadolinium-DTPA-enhanced T1-weighted imaging was routinely performed. The slice thickness for all scans was 4 mm (**Figure 2C**, **2D**).

Outcome measures

The primary outcomes of this study focused on the diagnostic performance of the combined 3D-TRUS and HF-LAU approach compared to MRI. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for the detection of the internal opening of anal fistulas, fistula tracts, and associated abscesses. Additionally, the area under the receiver operating characteristic (ROC) curve (AUC) was calculated to compare the diagnostic accuracy of the two methods. Secondary outcomes included postoperative recovery time, complication rates, and recurrence rates, providing further insight into the clinical utility of the imaging methods. The concordance between ultrasound findings and surgical findings was also evaluated, with particular attention to the relationship between ultrasound-based diagnosis and the Parks classification of anal fistulas.

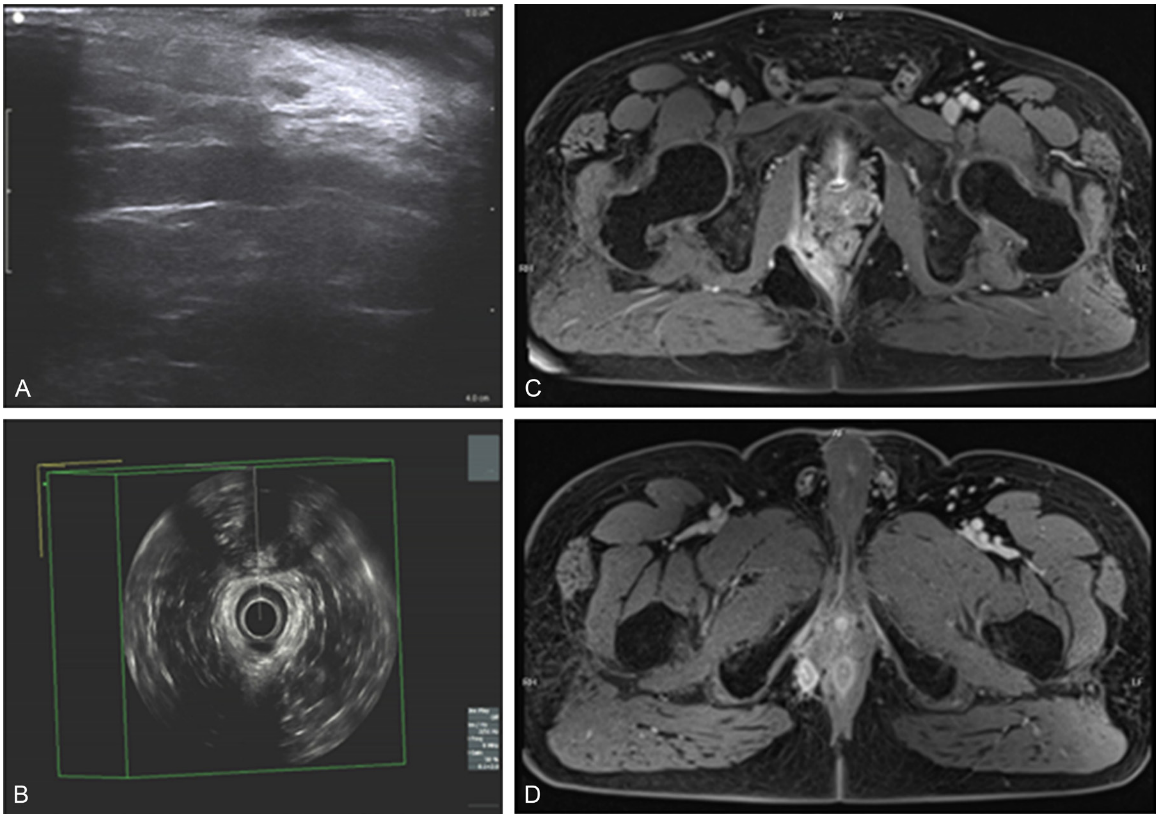

Figure 2. Typical ultrasound images of the two groups. A, B. Three-Dimensional Anorectal Ultrasound (3D-TRUS) images showing detailed visualization of the anal fistula, including the internal opening and fistula tract in the observation group. C, D. Magnetic Resonance Imaging (MRI) images depicting the anatomical structures and fistula tracts in the control group. The imaging modalities were compared for their diagnostic accuracy in detecting the internal opening, fistula tracts, and associated anatomical details in patients with anal fistulas.

Statistical analysis

Statistical analysis was performed using SPSS 20.0. Continuous variables were expressed as mean ± standard deviation (SD), and comparisons between groups were conducted using the independent samples t-test. Categorical variables (n, %) were compared using the chi-square (χ^2) test. Sensitivity (Se), specificity (Sp), PPV, and NPV were calculated for MRI and the combined 3D-TRUS and HF-LAUS examinations. Diagnostic accuracy was assessed by plotting ROC curves, and the AUCs were compared using the DeLong test to ensure robustness. A two-sided *P*-value < 0.05 was considered statistically significant.

Results

Comparison of clinical characteristics between the two groups

The baseline clinical characteristics of the two groups are summarized in **Table 1**. No significant differences were observed between the two groups in terms of age, gender distribution, body mass index (BMI), course of disease, previous surgeries, smoking history, comorbidities (e.g., diabetes, hypertension, hyperlipidemia, and coronary artery disease) (all P > 0.05). Overall, the clinical characteristics were well-balanced between the two groups, with no major disparities in key factors that could influence the study's outcomes.

Diagnostic accuracy for detecting anal fistula

The diagnostic accuracy for detecting anal fistulas was assessed using the Area Under the Receiver Operating Characteristic Curve (AUC) to compare the performance of MRI and the combined 3D-TRUS + HF-LAU approach. The results demonstrated that the observation group had a significantly higher AUC of 0.95, indicating superior diagnostic accuracy compared to the MRI method, which had an AUC of 0.89. The ROC curve analysis further emphasized the enhanced discriminative ability of the

Table 1. Comparison of clinical characteristics between the two groups

Parameter	Control Group (n = 105)	Observation Group (n = 95)	t/X^2	*P Value*
Age (Mean ± SD)	48.03 ± 10.76	47.72 ± 9.14	0.220	0.826
Gender (Male %)	70	80	3.167	0.075
Disease Duration (Months)	23.69 ± 4.80	24.21 ± 5.28	0.736	0.463
Comorbidities (%)	30	35	1.555	0.212
Previous Surgeries (%)	25	20	0.217	0.641
BMI (Mean ± SD)	25.38 ± 2.53	25.04 ± 3.72	0.763	0.446
Smoking History (%)	35	36	0.453	0.501
Diabetes (%)	10	15	1.790	0.181
Hypertension (%)	30	35	1.555	0.212
Hyperlipidemia (%)	35	40	1.637	0.201
Coronary Artery Disease (%)	10	15	1.790	0.181

Note: BMI: body mass index.

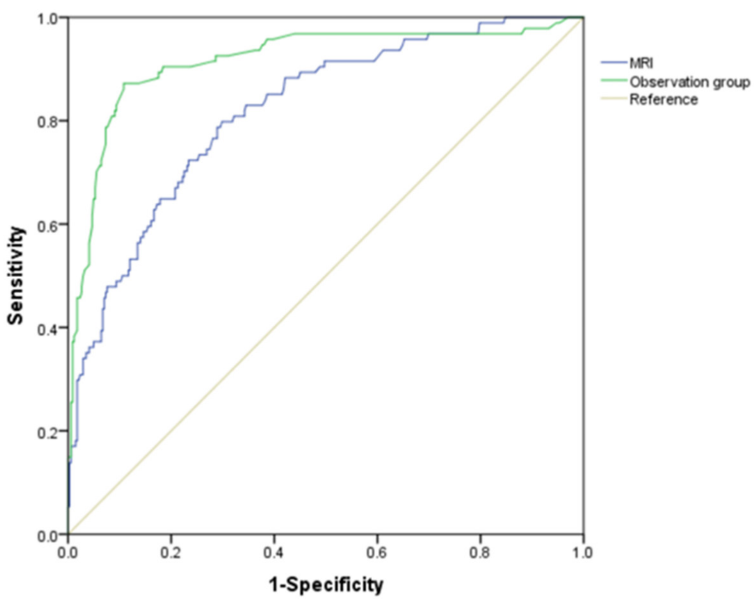

Figure 3. The ROC analysis. Note: ROC: Receiver Operating Characteristic.

combined approach (**Figure 3**), as it achieved better sensitivity and specificity in detecting the internal opening of anal fistulas. This was reflected in the calculated diagnostic metrics (sensitivity: 92%, specificity: 89%, PPV: 91%, and NPV: 93%) for the observation group, compared to MRI, which showed slightly lower values across the same metrics (sensitivity: 87%, specificity: 84%, PPV: 85%, and NPV: 88%) (**Table 2**). The significant differences in these values ($P < 0.05$) demonstrate that the 3D-TRUS + HF-LAU method provides a more accurate, non-invasive, and cost-effective alternative to MRI, especially in clinical settings requiring high diagnostic precision.

Relationship between imaging methods and postoperative recovery time

The postoperative outcomes of the two groups are summarized in **Table 3**. The observation group demonstrated significantly better postoperative outcomes compared to the control group. Specifically, the observation group had a shorter postoperative hospitalization time (4.23 ± 1.13 days vs. 5.08 ± 1.34 days, $P < 0.001$), and a shorter postoperative recovery time (7.54 ± 1.58 weeks vs. 8.68 ± 1.95 weeks, $P < 0.001$). Additionally, the observation group exhibited a lower complication rate (3.2% vs. 12.3%, P = 0.016).

Relationship between postoperative complications and diagnostic method

The comparison of postoperative complications between the two diagnostic groups revealed no significant differences in postoperative bleeding (4.5% vs. 3.2%, P = 0.470), wound infection (2.1% vs. 1.8%, P = 0.651), or fistula recurrence (3.3% vs. 2.1%, P = 0.651). However, the observation group, which used the combined 3D-TRUS and HF-LAUS method, demonstrated a significantly lower incidence of postoperative incontinence compared to the control group (2.1% vs. 10.1%, P = 0.017). Additionally, the observation group exhibited a

Table 2. Diagnostic accuracy for detecting anal fistula

Diagnostic Metric	Control Group (n = 105)	Observation Group (n = 95)	X^2 Value	*P* Value
Sensitivity	87%	92%	4.56	0.033
Specificity	84%	89%	3.21	0.073
Positive Predictive Value	85%	91%	5.02	0.025
Negative Predictive Value	88%	93%	4.83	0.028

Table 3. Relationship between imaging methods and postoperative recovery time

Imaging Method	Postoperative Hospitalization Time (Days)	Postoperative Recovery Time (Weeks)	Postoperative Complication Rate (%)
Control group	5.08 ± 1.34	8.68 ± 1.95	12.3
Observation Group	4.23 ± 1.13	7.54 ± 1.58	3.2
t/X^2	4.796	4.502	5.838
P	0.000	0.000	0.016

Table 4. Relationship between postoperative complications and diagnostic methods

Complication Type	Control group	Observation Group (%)	X^2	*P* Value
Postoperative Bleeding	4.5	3.2	0.521	0.470
Wound Infection	2.1	1.8	0.205	0.651
Postoperative Incontinence	10.1	2.1	5.674	0.017
Fistula Recurrence	3.3	2.1	0.205	0.651
Infection	5.2	3.1	0.521	0.470
Wound Healing Issues	2.5	1.3	1.020	0.312
Postoperative Fistula	10.2	1.5	5.674	0.017
Abdominal Distension	4.1	3.0	0.148	0.700

significantly lower rate of postoperative fistulas compared to the MRI group (1.5% vs. 10.2%, P = 0.017). No significant differences were observed for other complications such as infection (3.1% vs. 5.2%, P = 0.470), wound healing issues (1.3% vs. 2.5%, P = 0.312), or abdominal distension (3.0% vs. 4.1%, P = 0.700) (**Table 4**). Overall, while most postoperative complications were comparable between the two diagnostic approaches, the combined 3D-TRUS and HF-LAUS method was associated with a significantly lower risk of postoperative incontinence and a lower incidence of postoperative fistulas.

Comparison of inflammatory indexes between the two groups

Figure 4 compares the inflammatory markers between the two groups. No significant differences were found for any of the measured inflammatory markers (P > 0.05). Specifically, C-reactive protein (CRP) levels were (75.46 ± 8.52) mg/L in the control group and (76.20 ± 8.93) mg/L in the observation group (P = 0.554). Procalcitonin (PCT) levels were (0.42 ± 0.03) ng/mL in the control group and (0.42 ± 0.04) ng/mL in the observation group (P = 0.62). Neutrophil (Neu) percentages were (64.26 ± 7.14) % in the control group and (64.93 ± 8.60) % in the observation group (P = 0.547). White blood cell (WBC) counts were (7.55 ± 0.11) × 10^9/L in the control group and (7.53 ± 0.13) × 10^9/L in the observation group (P = 0.31). These findings suggest that the choice of diagnostic method (3D-TRUS + HF-LAUS vs. MRI) did not significantly influence inflammatory responses, and both groups exhibited comparable inflammatory profiles.

Discussion

The diagnosis of anal fistula remains a clinical challenge, particularly in distinguishing complex fistulas from other anorectal conditions. Imaging techniques such as MRI, endoscopy, and ultrasound have been increasingly used to improve diagnostic accuracy. Among these,

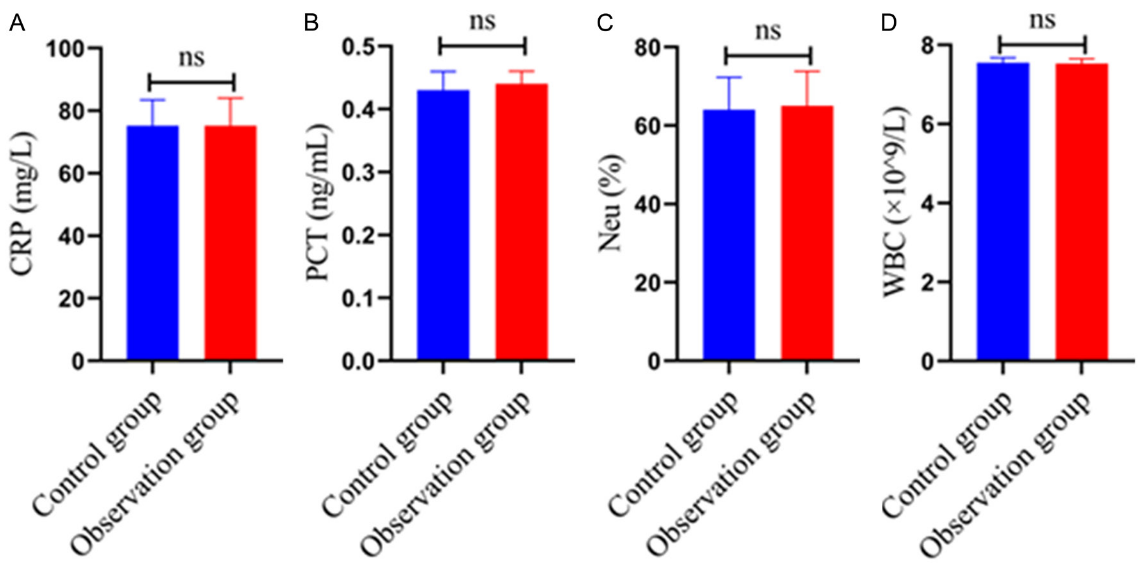

Figure 4. Comparison of inflammatory indices between the two groups. A. CRP, B. PCT, C. Neu, D. WBC. Note: CRP: C-reactive protein, PCT: procalcitonin, Neu: neutrophils, WBC: white blood cells. ns, no significance.

3D-TRUS combined with HF-LAU has gained attention for its promising results in the evaluation of anal fistulas. This study aimed to evaluate the clinical application of this combined approach and compare its diagnostic performance with MRI.

In terms of diagnostic accuracy, the observed advantage of the combined 3D-TRUS and HF-LAU method over MRI aligns with previous studies that have underscored the potential of 3D imaging in improving diagnostic performance [18-21]. The ability of HF-LAU to provide high-resolution, real-time imaging further enhances this diagnostic capability, offering a more detailed assessment of fistula structures [22]. The mechanism behind this improvement lies in the better spatial resolution and higher contrast achieved by combining these two modalities, which enables a more accurate identification of anal fistulas, a crucial aspect of guiding treatment decisions.

The study also found that 3D-TRUS in combination with HF-LAU significantly improved postoperative outcomes, including reduced hospitalization time and faster recovery. These results are consistent with the findings of Roca et al. [23], who reported that more accurate preoperative imaging leads to better surgical planning and reduced complications. The ability to accurately map fistula tracts and surrounding tissues allows for more precise surgical interventions, minimizing tissue damage and reducing recovery time. The mechanism behind these benefits may be related to the ability of the 3D-TRUS + HF-LAU method to offer real-time feedback during the diagnostic and preoperative phases, improving surgical precision and enabling better postoperative management [24]. The reduced complication rate observed in the observation group is particularly noteworthy, with lower incidences of postoperative incontinence and fistula recurrence compared to the control group. These findings suggest that enhanced diagnostic accuracy not only improves treatment outcomes but also reduces the risk of adverse postoperative events, which aligns with the current studies [25-27].

The comparison of inflammatory markers between the two groups yielded no significant differences, indicating that the choice of diagnostic method did not influence the inflammatory response or the body's healing process post-surgery. This result is in line with the study by Nguyen et al. [28], which also found no significant impact of imaging modalities on inflammatory markers following surgery. These findings suggest that the observed improvements in postoperative outcomes, such as faster recovery and reduced complications, are likely attributable to the accuracy and effectiveness of the combined imaging approach in preoperative planning rather than changes in the inflammatory response.

While the results of this study are promising, there are several limitations that must be addressed by future research. First, this was a single-center, retrospective study with a relatively small sample size. Larger, multicenter, prospective studies are needed to validate these findings and assess the generalizability of the results. Future studies should also consider the long-term outcomes associated with the use of 3D-TRUS and HF-LAU in the management of anal fistulas, particularly in terms of recurrence rates and postoperative quality of life. Another limitation was the lack of direct comparison between 3D-TRUS + HF-LAU and other diagnostic modalities, such as endoscopy or biomarker analysis. Combining imaging techniques with other diagnostic tools may further enhance the diagnostic use of these methods and provide a more comprehensive approach to the evaluation of anal fistulas. For example, integrating 3D-TRUS and HF-LAU with endoscopic examination could provide a more detailed assessment of the fistula's relationship with the mucosal surface and any associated abscesses. Additionally, the use of biomarkers such as C-reactive protein (CRP) and procalcitonin (PCT) could provide complementary information about the inflammatory status of the patient and help guide clinical decision-making.

In conclusion, the combined use of 3D-TRUS and HF-LAU offers a superior diagnostic approach for evaluating anal fistulas, providing higher diagnostic accuracy compared to MRI. These technologies are non-invasive, cost-effective, and widely accessible, making them an attractive alternative to MRI, particularly in resource-limited settings. The enhanced diagnostic precision offered by 3D-TRUS and HF-LAU has the potential to improve surgical planning, reduce postoperative complications, and ultimately improve patient outcomes. Further research, including larger multicenter trials and long-term follow-up studies, is necessary to fully validate the clinical benefits of this combined approach and establish its role in comprehensive management of anal fistulas.

Disclosure of conflict of interest

None.

Abbreviations

3D-TRUS, Three-Dimensional Anorectal Ultrasound; MRI, Magnetic Resonance Imaging; HF-LAU, High-Frequency Linear Array Ultrasound; PPV, Positive Predictive Value; NPV, Negative Predictive Value; ROC, Receiver Operating Characteristic; AF, Anal Fistula; ERUS, Endorectal Ultrasound; DFI, Doppler Flow Imaging; Se, Sensitivity; Sp, Specificity; BMI, Body Mass Index; CRP, C-reactive Protein; PCT, Procalcitonin; WBC, White Blood Cell Count.

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