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Accuracy of intestinal ultrasonography in the evaluation of patients with moderate-to-severe ulcerative colitis starting infliximab therapy

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Abstract

Background Intestinal ultrasound (IUS) is accurate in detecting active ulcerative colitis (UC), but its role in repeated monitoring during biologic therapy remains to be established. This study aimed to assess correlations between IUS findings and the Mayo endoscopic score (MES), clinical and biochemical indices, and to evaluate the utility of IUS for monitoring infliximab (IFX) therapy and predicting outcomes.

Methods In this prospective open-label study, patients with moderate-to-severe UC starting IFX were assessed at baseline and at week 14. Flexible sigmoidoscopy, IUS and measurement of fecal calprotectin levels were performed at both time points. Correlations between bowel wall thickness (BWT) and MES, C-reactive protein (CRP), calprotectin, and the Simple Clinical Colitis Activity Index (SCCAI) were analyzed across both visits.

Results Thirty-two patients completed baseline evaluations and 21 completed follow up. Median age was 38 years; 53% were male. Disease extent was left-sided in 41% and extensive in 59%. BWT showed moderate correlations with MES (r=0.43, P=0.0015), and CRP (r=0.40, P=0.007), and a weak correlation with calprotectin (r=0.19, P=0.25). No significant differences in BWT, MES, CRP or calprotectin were observed at either time point. The only significant improvement was in SCCAI, from 7 (4.8-8) to 3 (1-5) (P=0.009). Baseline BWT and MES did not differ significantly between responders and non-responders.

Conclusions BWT measured by IUS correlates with endoscopic and biochemical markers of disease activity. IUS may serve as a reliable, noninvasive alternative to endoscopy for monitoring treatment response in UC.

Keywords Intestinal ultrasound, ulcerative colitis, infliximab, Mayo endoscopic score, bowel wall thickness

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Introduction

Treatment targets for ulcerative colitis (UC) patients include patients' clinical outcomes and endoscopic remission [1]. Endoscopy guides therapy decisions and outcomes, mainly because the evidence it can provide of mucosal evaluation and the treat-to-target mucosal healing (e.g., Mayo endoscopic score [MES] ≤1 activity) is associated with better long-term outcomes [2,3]. During follow up, close monitoring is advocated to assess treatment efficacy and detect early relapse [1,4]. However, repeated endoscopic assessment is challenging, given its high cost and the burden on the patient [5]. Hence, alternative and reliable noninvasive methods to assess disease activity are needed.

Intestinal ultrasound (IUS) is a noninvasive point-of-care procedure that has a favorable safety profile, low cost, and does not require preparation. This makes it an ideal tool for monitoring disease activity, and at the same time enables prompt decision making [6,7]. IUS has been reported to be accurate in the diagnosis of UC, and can also be applied to determine the extent, severity and location of inflammation [8-11]. However, few studies have been performed to compare IUS with endoscopy in UC patients [12-15]. To date, the value of IUS measurements in a tight monitoring scheme during treatment remains to be established.

The primary objective of this study was to investigate the correlation between endoscopic parameters, as measured by the MES, and sonographic parameters of disease activity, mainly presented as bowel wall thickness (BWT).

Patients and methods

Study design

This was a single-center, prospective, open-label, observational study that included patients ≥18 years of age who had been previously diagnosed with UC and started infliximab therapy.

Consecutive patients with moderate-to-severe UC, with disease extent >15 cm proximal to the dentate line, MES ≥2, and a Simple Clinical Colitis Activity Index (SCCAI) >4, who were initiated on infliximab treatment as recommended by their treating physician, were included. All concomitant therapies were allowed. Patients were excluded if their disease was limited to the rectum (proctitis) and when the patients did not provide informed consent. Patients who were positive for cytomegalovirus or *Clostridioides difficile* infection were also excluded, as were pregnant women.

Clinical, biomarkers and time points of assessment

Before treatment initiation, clinical evaluations based on SCCAI and patient recruitment were conducted. Both stool and blood samples were obtained and examined for fecal calprotectin (FC) (μg/g) and C-reactive protein (CRP) (mg/L). Before infliximab induction, endoscopy and IUS were also performed. Further evaluation of the same parameters was performed after 3 months of infliximab therapy. Medical history was collected, including information on disease duration, prior medical treatments, age, sex, and body mass index (BMI).

IUS examination

All IUS examinations were performed by investigators experienced in IUS (DC, with >5 years of experience and >1500 IUS examinations performed), using a GE Logiq S8 ultrasound machine with convex (3.5-5 MHz) and linear probes (7.5-10 MHz). BWT was primarily measured in the sigmoid and descending colon. In each segment, a minimum of 2 measurements were performed in the long axis of the anterior wall, with a minimal distance of 1 cm apart. The thickest measured segment was included in the statistical analysis. In addition, hypervascularization of the bowel wall according to the Limberg score, loss of mural stratification, and mesenteric fat hypertrophy were documented. IUS was performed both at baseline, and after 3 months of therapy initiation.

Endoscopy

Lower endoscopy (colonoscopy or sigmoidoscopy) was performed according to standard procedures at our clinic by an IBD expert. Endoscopic disease activity was scored using the MES [16]. Active inflammation was defined as MES ≥2. Endoscopy was performed both at baseline, and after 3 months of therapy initiation.

Outcomes

Primary outcome

The primary objective of this study was to investigate the correlation between endoscopic parameters, as measured by the MES, and sonographic parameters of disease activity, mainly presented as BWT and color Doppler signal.

Secondary outcomes

Several secondary outcomes were evaluated to provide a comprehensive understanding of the relationship between clinical, endoscopic and sonographic measures of disease severity, and treatment response. First, we assessed the correlation between clinical severity, as evaluated using the SCCAI and both MES and BWT. Second, we examined the correlation between endoscopic and sonographic responses to treatment, defined respectively as a reduction in the MES by at least 1 point from baseline, and a ≥25% reduction in

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BWT from baseline, without new or worsening inflammatory features. Finally, we identified sonographic parameters that were predictive of treatment response, defined as achievement of either endoscopic or sonographic response at follow up, and clinical remission, defined as SCCAI ≤2.

Ethical considerations

This study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki and was approved by the Sheba Medical Center Ethics Committee. Approval was granted under Helsinki protocol SMC-2183-15. All patients provided written informed consent prior to participation in this study.

Statistical analysis

Statistical analysis was performed using SPSS version 25.0. Descriptive statistics were presented as median and interquartile range (IQR) for continuous variables, given the non-normal distribution of the data as assessed by Shapiro-Wilk test, and as frequencies and percentages for categorical variables. For paired comparisons between baseline and follow-up measurements, we employed the Wilcoxon signed-rank test for continuous variables. Correlations between BWT and other clinical parameters (MES, CRP, FC, and SCCAI) were evaluated using Spearman's rank correlation coefficient. To compare BWT between responders and non-responders to infliximab therapy, we utilized the Mann-Whitney *U* test. All statistical tests were 2-tailed, with statistical significance set at $P<0.05$.

Results

Forty patients were initially recruited between May 2017 and July 2023, with 32 patients (80%) included in the final analysis. The reasons for exclusion are shown in the study flow chart (Fig. 1). All included patients had left-sided or extensive colitis

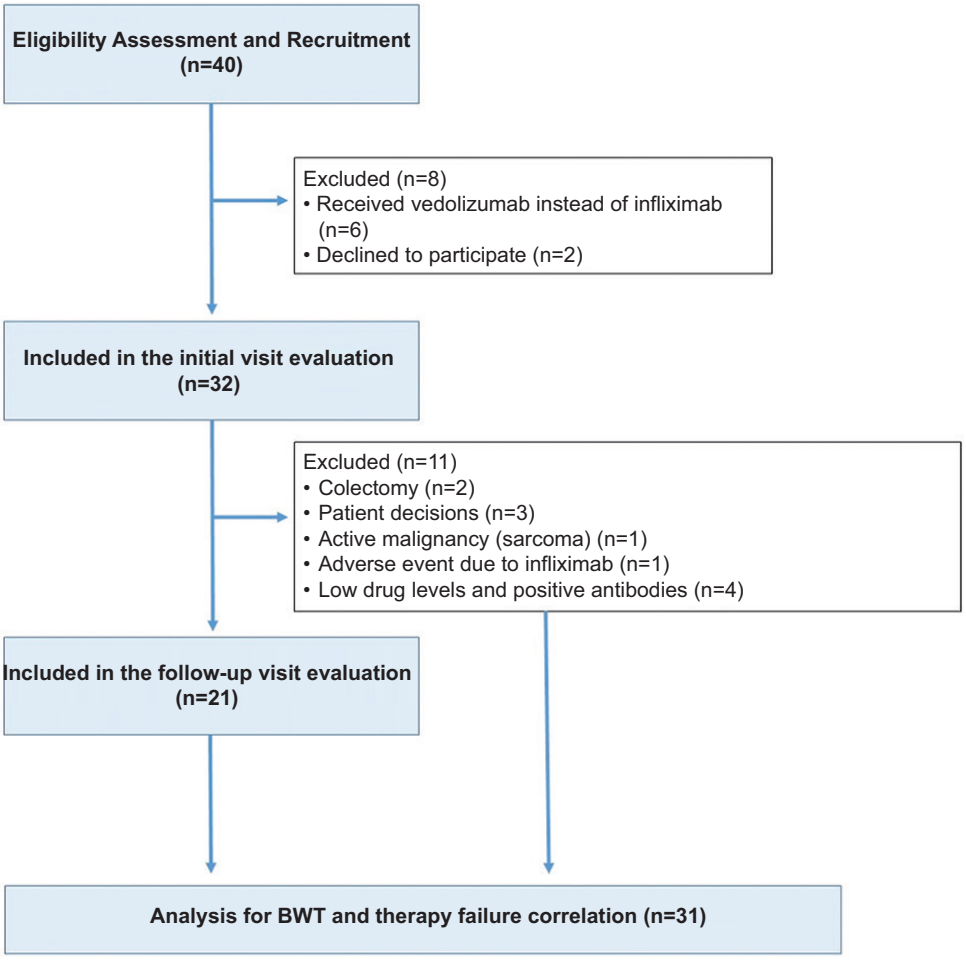

Figure 1 Study flowchart. At study induction, 40 patients were initially recruited, with 32 patients (80%) included in the initial visit analysis. A further 11 participants did not reach the follow-up visit. The final analysis for bowel wall thickness (BWT) and therapy failure included 31 participants

(41% and 59%, respectively). The clinical and demographic characteristics at enrolment of the 32 patients included in the trial are reported in Table 1. The median time interval between endoscopy and IUS was 1.5 days (0-6.25 days).

At baseline, all patients had active disease, with a median SCCAI of 7 (5-8), a median MES of 2 (2-3), CRP level of 9.5 mg/L (4.25-33), and FC levels of 979 µg/g (30-1000).

IUS was performed in all 32 patients at baseline. The sigmoid colon was assessable in all cases. The median BWT at the thickest segment was 5.5 mm (4.4-7.0)

Correlation between BWT, endoscopy, and inflammatory parameters

In a pooled analysis at baseline and after 3 months (median 3 months, IQR 3-4), the correlation between BWT and the MES was evaluated in 49 examinations. The thickest BWT, whether in the sigmoid or descending colon, showed a moderate correlation with the MES (r=0.43, P=0.0015) (Fig. 2). Additionally, BWT demonstrated a moderate correlation with CRP (r=0.40, P=0.007) and a weak correlation with the SCCAI (r=0.28, P=0.03). However, no significant correlation was observed between BWT and FC (r=0.19, P=0.25).

Follow-up evaluation after 3 months

During the follow-up period, 11 of 32 patients (34.3%) did not reach the second assessment, primarily for the following reasons: patient decision to stop the treatment (3 patients, 33%), colectomy (2 patients, 18.1%), non-response (3 patients, 33%), adverse events (1 patient, 9%), infection (1 patient, 9%), and active solid malignancy (sarcoma, 1 patient, 9%).

In terms of improvements assessed at the initial and 3-month follow up after infliximab induction, no significant differences were observed in BWT, MES, CRP orFC levels (5.5 mm vs. 4.4 mm, P=0.2; 2 (2-3) vs. 2 (1-3), P=0.4; 9.4 vs. 9.6, P=0.4; 979 vs. 394, P=0.1, respectively). The only significant improvement was observed in the SCCAI, which improved from 7 (range 4.8-8) to 3 (range 1-5), with a P-value of 0.009 (Fig. 3). After 3 months, 66.6% (14/21) achieved a clinical response, and 47.6% (10/21) achieved clinical remission.

Correlation of BWT index and therapy outcome

Overall, data regarding therapy outcomes were available for all patients followed up in our department (21 patients with available follow-up data at the second assessment, and 11 patients who did not reach this assessment time point as per the study protocol). Excluding a sarcoma case, 31 patients were evaluated for the correlation between BWT and therapy outcome. Nine of these 31 patients (29%) responded to the therapy and continued with infliximab, while 22 of 31 (71%) did not respond. There was no significant difference between the median baseline BWT in the responder group and the non-responder group (5.5 mm [4.2-6.7] vs. 5.5 mm [4.6-7.3], P=0.5) (Fig. 4).

Table 1 Demographic and baseline characteristics of the analyzed population at baseline (n=32)

Characteristics	Value
Age, years, median (IQR)	38 (28.25-60.7)
Male sex, n (%)	17 (53.2)
Disease duration, years, median (IQR)	7 (6-9.7)
Disease extent	
Left sided colitis (E2), n (%)	13 (41)
Extensive colitis (E3), n (%)	19 (59)
Smoking, n (%)	4 (12.5)
EIM, n (%)	9 (28.1)
Disease activity	
Mayo endoscopic score, median (IQR)	2 (2-3)
SCCAI, median (IQR)	7 (4.5-8)
Maximal BWT, median (IQR)	5.5 (4.5-7)

IQR, interquartile range; n, number of patients; EIM, extraintestinal manifestations; SCCAI, simple clinical colitis activity index; BWT, bowel wall thickness

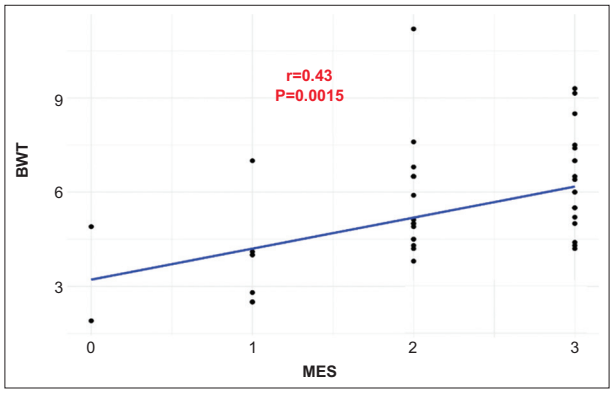

Figure 2 Correlation analysis between Mayo endoscopic score (MES) and ultrasonography bowel wall thickness (BWT) in patients with ulcerative colitis. r represents the correlation coefficient and P the P-value

To further assess the predictive value of BWT, both baseline BWT and change in BWT were analyzed for their ability to predict therapeutic response in patients receiving infliximab. Logistic regression analysis revealed limited predictive power for both parameters in identifying successful treatment outcomes.

Discussion

This single-center prospective study examined the utility of IUS for monitoring biologic therapy in a moderate-to-

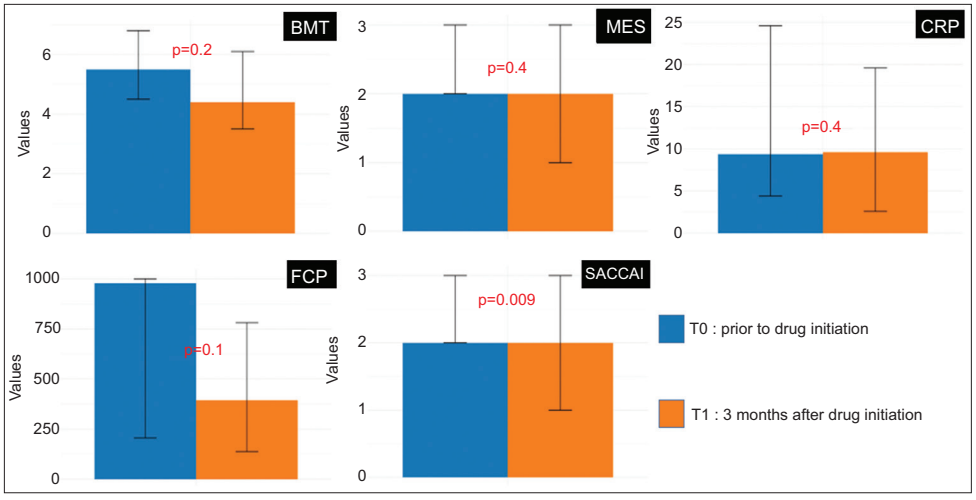

Figure 3 Comparison of each parameter before infliximab induction (T0) and 3 months after therapy initiation (T1). No significant differences were observed at both time points in terms of bowel wall thickness (BWT), Mayo endoscopic score (MES), C-reactive protein (CRP) or fecal calprotectin (FC). The only notable improvement was observed in the Simple Clinical Colitis Activity Index (SCCAI)

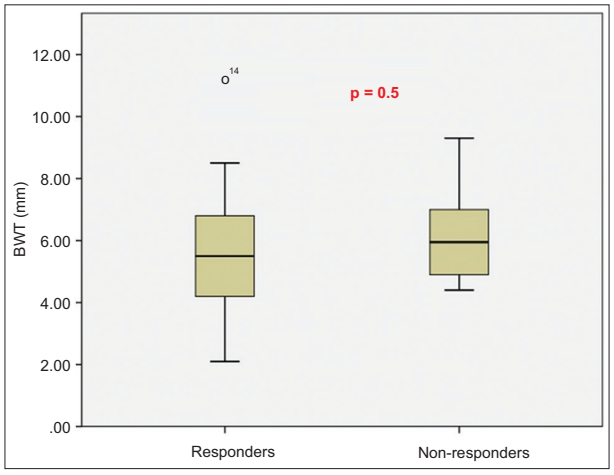

Figure 4 Box-and-whisker plot comparing bowel wall thickness (BWT) measurements between responders and non-responders to therapy. There was no statistically significant difference in BWT between responders and non-responders

severe UC population starting infliximab therapy. We aimed to establish correlations between BWT, measured by IUS, and the MES, as well as other clinical and biochemical severity indices, such as CRP, FC, and the SCCAI. The results provide several insights into the role of IUS in UC management during biologic therapy.

Our findings demonstrate a significant correlation between BWT and MES. This correlation suggests that IUS could potentially serve as a noninvasive alternative to lower endoscopy for assessing disease activity in UC patients. This is consistent with previous studies that demonstrated the diagnostic accuracy of IUS in detecting active UC [17-19]. Furthermore, BWT has been identified as the most important IUS parameter in UC assessment and has a moderate-to-strong correlation with MES, suggesting that noninvasive monitoring with IUS could be a good alternative to endoscopy for assessing therapy response [8,17,20].

Additionally, BWT showed significant correlations with other markers of disease activity, including CRP and the SCCAI. These correlations further support the potential of IUS as a comprehensive tool for monitoring UC activity. However, the lack of a significant correlation between BWT and FC is noteworthy. This discrepancy might be explained by the inherent differences between the 2 modalities. BWT, measured via intestinal ultrasound, reflects mural changes—such as edema, fibrosis and vascular engorgement—across the bowel wall, while FC is a biomarker of mucosal neutrophils. The absence of a correlation in this study might reflect the complexity of inflammation in UC, where different biomarkers may represent distinct aspects of the disease process, and FC may not always accurately reflect the full spectrum of disease activity. It may also fail to capture structural changes in the bowel wall. Goodsall *et al* [21] similarly observed that, while both FC and BWT were useful in assessing UC activity, they did not always correlate strongly, reinforcing the idea that these tools capture different, and potentially complementary, aspects of disease behavior. In the present study, we focused on BWT as the primary ultrasonographic parameter for disease assessment. This decision was guided by the robust evidence supporting BWT as a reliable and reproducible marker of disease activity in UC. Prior studies have demonstrated moderate to strong correlations between BWT and endoscopic scores, as well as its utility in monitoring treatment response and guiding clinical decisions [8,11,17,20]. Although incorporating a composite score might have enhanced diagnostic precision, we aimed to maintain methodological consistency and minimize interobserver variability by using

BWT alone. Notably, we also documented an enhanced color Doppler signal in 75% of cases at baseline, providing complementary support for active inflammation in this cohort.

Our findings differ from those of recent prospective studies that demonstrated early improvements in IUS parameters, particularly BWT, during biologic treatment. For instance, the TRUST&UC study observed a significant reduction in BWT as early as 2-6 weeks after therapy initiation, with sustained improvement by week 12, which was associated with clinical and endoscopic remission [22]. Similarly, Alocca *et al* [23] reported that early BWT reduction predicted a sustained therapeutic response. These findings highlight the importance of longitudinal IUS assessment to fully capture the kinetics of mucosal healing.

In our study, the only significant improvement after 3 months of infliximab therapy was noted in the SCCAI, which decreased from a median of 7 to 3 (P=0.009). In contrast, BWT, MES, CRP and FC levels did not show measurable changes. This discrepancy may be due to the relatively short follow-up period of 3 months, which may not be sufficient to capture the therapeutic effects of infliximab. Additionally, the high dropout rate, with 34.3% of patients not completing the follow-up assessment, may have introduced bias and reduced the power of the study to detect significant changes. Furthermore, this discrepancy between clinical improvement and other parameters suggests that clinical symptoms may improve more rapidly than mucosal healing or inflammatory markers. It also highlights the importance of using multiple assessment tools in monitoring the UC treatment response.

Our study had several limitations. Firstly, the small sample size, particularly after the loss of follow up for some patients, limits the generalizability of the findings and may have reduced the statistical power to detect certain associations. Secondly, the short follow-up period of 3 months may have been insufficient to capture long-term therapeutic outcomes or changes in disease activity, which could provide more comprehensive insights into the utility of IUS over time. Additionally, the high rate of treatment discontinuation for various reasons may have impacted the assessment of long-term treatment outcomes. Moreover, the single-center study design might have introduced biases related to specific practices or patient populations, which may not be applicable in other settings. Future studies with larger, more diverse populations and longer follow-up periods are needed to confirm these findings and further establish the role of IUS in the management of UC.

In conclusion, the observed correlations between BWT and other disease activity measures suggest that IUS may serve as a reliable, noninvasive alternative to lower endoscopy for assessing disease activity. This study further supports the role of IUS as a patient-friendly tool for monitoring treatment response in patients with UC receiving biologic therapy.

Summary Box

What is already known:

- Intestinal ultrasound (IUS) is an accurate, noninvasive tool for detecting active inflammation in ulcerative colitis (UC)
- Bowel wall thickness (BWT) is the most widely used IUS parameter to assess disease activity in UC
- Endoscopic evaluation remains the gold standard for monitoring response to biologic therapy in UC
- Data on the role of repeated IUS measurements during biologic treatment in UC are limited

What the new findings are:

- BWT measured by IUS showed a significant correlation with the Mayo endoscopic score during infliximab therapy in UC
- While BWT and fecal calprotectin did not correlate strongly, their complementary roles may enhance disease monitoring when used in combination
- These findings support the use of IUS as a noninvasive tool for monitoring biologic therapy in UC, especially in the early treatment phase

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