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Assessing inflammatory bowel disease monitoring procedures in Spain: insights from the IBD-PODCAST study

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Assessing inflammatory bowel disease monitoring procedures in Spain: insights from the IBD-PODCAST study

Introduction & Methods

- Crohn's disease (CD) and ulcerative colitis (UC) are characterized by persistent gastrointestinal inflammation
- Timely, effective management is crucial for improving long-term patient outcomes

To **assess treat-to-target implementation through monitoring practices** in a real-world setting in Spain

396 patients

196 Crohn disease

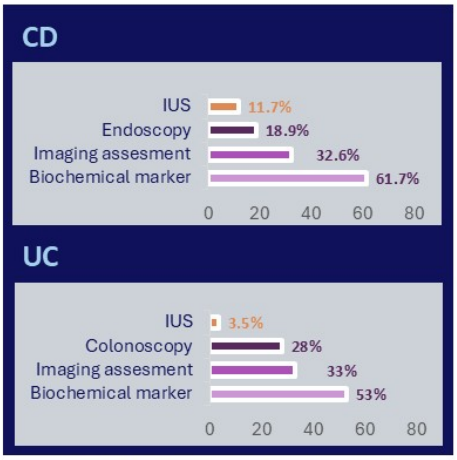
200 Ulcerative colitis

14 centers in Spain

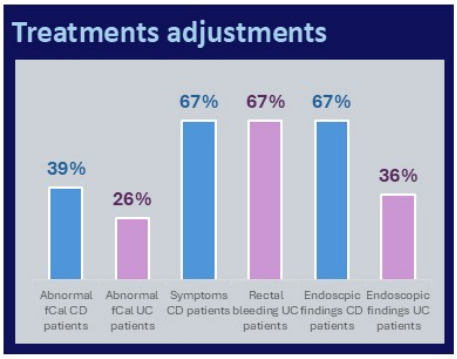
Cross-sectional study

Data collection & Outcomes (Monitoring procedures)

Results: Monitoring practices



Results: Actions taken



CONCLUSION

IBD-PODCAST study examines routine IBD management in Spain and highlights the need for improved monitoring and intervention to optimize patient care and outcomes

CD: Crohn Disease; CRP: C reactive protein; CT: computed tomography ; fCal: fecalprotectin; IBD: inflammatory bowel disease; IUS: intestinal ultrasounds; MRE: magnetic resonance enterography; MRI: magnetic resonance imaging; UC: ulcerative colitis

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Assessing inflammatory bowel disease monitoring procedures in Spain: insights from the IBD-PODCAST study

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Abstract:

Introduction: Crohn's disease (CD) and ulcerative colitis (UC) are characterized by persistent gastrointestinal inflammation. Timely, effective management is crucial for improving long-term patient outcomes.

Materials and methods: As part of the IBD-PODCAST study, this cross-sectional, multicenter, non-interventional study included 396 patients (196 CD, 200 UC) from 14 Spanish hospitals, aiming to assess treat-to-target implementation through monitoring practices in a real-world setting. Biochemical markers (CRP, fCal) measured within ±14 days of index date and imaging tests (endoscopy, IUS, MRI/MRE/CT) during the previous year were collected. Actions taken based on the results were evaluated.

Results: Biochemical markers were requested in more than half the patients and imaging in a third, including endoscopic procedures in 18.9% of CD and 28% of UC cases, and IUS in <12% of patients. Treatment was adjusted in 67% of CD patients with symptoms and 67% of UC patients with rectal bleeding. Only 39% of CD and 26% of UC patients with abnormal fCal had treatment modifications, with 35% and 37% undergoing additional monitoring, respectively. Endoscopic findings prompted adjustments in 87% of CD and 56% of UC patients.

Conclusion: The IBD-PODCAST study examines routine IBD management in Spain, highlighting the need for improved monitoring and intervention to optimize patient care and outcomes.

Keywords: Crohn's disease. Ulcerative colitis. Treat-to-target. Monitoring procedures. Endoscopy. fCal. CRP. IUS.

Introduction

Patients with inflammatory bowel diseases (IBD), such as Crohn's disease (CD) and ulcerative colitis (UC) experience a significant disease burden (1) , as has been confirmed specifically in the Spanish cohort of the IBD-PODCAST study (2), highlighting the need for appropriate management in the Spanish IBD population.

Medical professionals managing CD and UC have traditionally focused on symptom regression, and current recommendations, such as the STRIDE II consensus, consider clinical response and clinical remission as immediate and intermediate treatment targets, respectively (3, 4). Endoscopic lesions and predictive biomarkers have been observed up to 8 years before symptom onset (5, 6), stressing the significance of the underlying inflammation. In this sense, normalization of C-reactive protein (CRP) and fecal calprotectin (fCal) have been additionally included as intermediate targets, endoscopic healing is acknowledged as a long-term treatment target. Finally absence of disability and normalized health-related QoL (HRQoL) are long-term treatment goals (3).

The emergence of innovative advanced therapies may help to achieve more ambitious goals, such as mucosal healing, associated with durable clinical remission and less flares, hospitalizations, and surgeries (7).

Increasing evidence supports early effective treatment to prevent disease progression and complications, as observed in the PROFILE trial (8). Similar findings from studies in children highlight the need for early treatment (9, 10), since IBD compromises normal growth. To implement "treat-to-target" (T2T) strategies, timely treatment decisions based on regular monitoring are key for long-term outcomes. Although the CALM and STARDUST studies yielded mixed results regarding tight control, both were limited to treatment optimization strategies, not considering the alternative of treatment switching(11-15).

Non-invasive monitoring tools, such as intestinal ultrasound (IUS), represent the potential for faster assessment and early optimization (16). In the IBD-PODCAST study, many patients presented suboptimal disease control [3], both globally and in local

cohorts, including Canadian (17) and Spanish patients (2). The Spanish IBD units' quality certification program (CUE) highlights the importance of effective monitoring to improve long-term outcomes(18). Similarly, the European Crohn's and Colitis Organization (ECCO) outlined care standards based on evidence, expert consensus, and patient perspectives (19).

The objective of this sub-analysis of the IBD-PODCAST study in Spain was to evaluate whether the abnormalities found during patient monitoring led to changes in their management, specifically if a T2T strategy is applied when continuous monitoring data are available.

Materials and Methods

Study design and patients

The IBD-PODCAST study is a cross-sectional, multicenter, non-interventional study of patients with IBD. All data regarding study design and participants are described in detail in the first manuscript and the global cohort (1, 2). Patients fulfilling selection criteria were enrolled consecutively at each site on the day of their routine clinic visit until the target sample size was reached. A sample size of 200 patients with CD and 200 patients with UC was estimated, considering that sites expected to see a mean (standard deviation [SD]) of 460 (252.97) CD patients and 510 (329.05) UC patients in the year of the study.

Assessments

Outcome assessments were performed separately for CD and UC. Baseline patient and disease characteristics, treatment history, and objective assessment of red flags were collected from patient medical records.

For monitoring purposes, data were extracted from medical records that included objective assessments conducted as part of routine clinical practice. The two

monitoring procedures collected were a) endoscopy/colonoscopy and imaging assessment via imaging techniques, including magnetic resonance imaging (MRI), magnetic resonance enterography (MRE), computed tomography (CT), and intestinal ultrasound (IUS), all available within the last 12 months preceding patient enrolment in the study; and b) biochemical assessment using the laboratory biomarkers fecal calprotectin (fCal) or C-reactive protein (CRP), available within ±14 days of the index date. Additionally, data regarding treatment modifications (including intensifications and switches to other treatment) and any subsequent additional monitoring procedures prescribed following these follow-up evaluations were also collected for analysis.

For CD and UC patients, failure to achieve endoscopic remission or findings of active disease on MRI/MRE/CT or IUS, as well as abnormal fCal and CRP levels, were considered indicative of inflammatory activity. Symptomatic disease activity was determined using red flags indicating lack of clinical remission according to STRIDE-II, as described previously (1, 2).

Study objectives

The primary objective of this post-hoc descriptive analysis was to assess the implementation of T2T strategies in daily clinical practice by describing IBD disease monitoring procedures in Spain.

The secondary objectives were 1) to estimate the proportion of patients on treatment with targeted immunomodulators (TIMs); 2) to estimate the proportion of patients in the study population with known inflammatory status who fall into the following disease activity subgroups: (i) symptomatic + inflammatory active, (ii) asymptomatic + inflammatory active, (iii) symptomatic + inflammatory inactive, and (iv) asymptomatic + inflammatory inactive; and 3) to describe actions taken by the physician in Spanish IBD clinical practice in regard to newly identified suboptimal control at the patient visit (treatment adjustment or monitoring strategies).

Statistical analyses

Baseline demographics and clinical variables were summarized as means and SD and frequency data (proportion), as applicable.

Results

Characteristics of the CD and UC study population

A total of 396 patients (196 CD and 200 UC) from 14 Spanish sites were included in the analysis. Clinical characteristics of the study population are summarized in **Table 1**.

In terms of the Harvey-Bradshaw index (HBI), 7.7% of CD patients presented a HBI score >4, 5.1% presented a HBI abdominal pain (AP) score >3, and 3.6% had a HBI stool frequency (SF) score >1. Mayo stool frequency was elevated in 17.5% of UC patients, and 7.5% reported rectal bleeding in the last 3 days. Most patients were in the long-term treatment window, according to STRIDE II (87.8% of CD and 90.5% of UC patients) (2).

Assessment of suboptimal control: overlapping red flags

Even if symptoms might suggest low active disease rates, further analysis of disease control based on STRIDE II recommendations among long-term treatment patients found suboptimal control in 57.6% (99/172) of patients with CD and in 43.6% (79/181) of patients with UC. These results are in line with the pooled analysis of the overall international population (N = 2185) (1). Impaired QoL emerged as the most common red flag indicative of suboptimal control in both CD and UC patients. However, beyond QoL, a significant percentage of patients exhibited additional red flags. Among long-term suboptimally controlled CD patients, 22.2% presented a single QoL red flag, while

in 33.3% of cases, QoL overlapped with another red flag, and in 44.4% of patients, suboptimal control was identified by red flags other than QoL. Regarding long-term suboptimally controlled UC patients, 29.1% presented a single QoL red flag, 41.8% experienced impaired QoL overlapping with another red flag, and in 29.1% of patients, suboptimal control was due to red flags other than QoL (see **Figure 1**).

Treatments

Of the total number of CD patients (*N* = 196), 28.1% were TIM-naïve at the index date, while 35.2% were first-line TIM users, and 36.7% used TIMs as second-line therapy (see **Figure 2 and Table 2**). Among TIM-experienced CD patients (*N* = 141), the most common TIMs were adalimumab (originator and biosimilar, 31.9%), infliximab (24.1%), and ustekinumab (22.7%).

In UC patients (*N* = 200), 58% were TIM-naïve, 18% were first-line TIM users, and 24% were second-line users (**Figure 2**). Among TIM-experienced UC patients (*N* = 84), the most common TIMs were vedolizumab (31.0%), infliximab (25.0%), and adalimumab (originator and biosimilar, 15.5%).

It is worth noting that 13.3% of CD patients and 6.5% of UC patients did not receive any IBD-specific treatment. Additionally, only one-third of the study population had previous treatment (including current treatment) with two or more TIMs.

Disease activity and inflammatory status

Among the CD (*N* = 16) and UC (*N* = 37) global symptomatic population, inflammatory activity was assessed in 43.8% of CD patients and in 64.9% of UC patients, all of them presenting active inflammation according to corresponding red flags. In asymptomatic patients, the proportion of patients with positive inflammatory activity assessment was 23.3% (42/180) in CD and 19.9% (33/163) in UC patients (see **Figure 3**).

Notably, more than half of the symptomatic CD population (9/16; 56.2%) and over one third of symptomatic UC patients (13/37; 35.1%) had unknown inflammatory status, while this proportion was higher among asymptomatic CD (129/180; 71.7%) and UC patients (130/163; 78.3%).

Monitoring at index

Biochemical markers

Of the total CD population (*N* = 196), CRP testing was conducted in 57.1% of patients, 22.3% of whom had a value >0.5 mg/dL, and in 43.5% of UC patients (*N* = 200), 21.8% of whom had a value >0.5 mg/dL. FCal testing was performed in 44.9% of CD and in 47.5% of UC patients, observing that 26.1% of CD and 36.8% of UC patients had a value >250 mg/dL, respectively. Determination of CRP or fCal was performed in 61.7% of CD patients and 53% of UC patients; 73.5% of CD patients and 68.5% of UC patients underwent either biochemical testing (CRP or fCal) or imaging assessment; and 19.9% of CD patients and 17.5% of UC patients underwent both biochemical testing (CRP or fCal) and imaging assessment. Additionally, hemoglobin was measured in 60.7% of CD and in 49.5% UC of patients, with 2.5% of CD patients and 4% of UC patients presenting IBD-related anemia (see **Table 1**).

Annual imaging assessment

Of the total population, 32.6% of CD patients (*N* = 196) and 33% of UC patients (*N* = 200) underwent objective monitoring via imaging assessment within 12 months. The most frequent imaging technique over this period was endoscopy/colonoscopy, which was utilized in 18.9% of CD patients and 28% of UC patients, of which 17 CD (45.9%) and 34 UC patients (60.7%) presented endoscopic findings indicating active disease. IUS was more frequently performed in CD than in UC patients, with rates of 11.7% and 3.5%, respectively. Among them, IUS findings suggestive of active disease were detected in 12 CD (52.2%) and 4 UC patients (57.1%). MRI/MRE/CT were performed in 6.2% of CD patients and 3% of UC patients, with 6 (50%) and 2 (33.3%) of these

patients exhibiting findings consistent with active disease, respectively.

Action taken and responses

No actions were taken in 55/96 CD (57%) and 36/88 UC patients (41%) with relevant clinical parameters at the time of the visit. The single clinical parameters most likely leading to an action by the physician (unadjusted) were HBI score >4 and lack of significant clinical improvements for CD patients, and steroid use, rectal bleeding, lack of significant clinical improvements and stool frequency for UC patients. Treatment adjustments were primarily prompted by lack of significant clinical improvement (77.8%) and HBI scores >4 (66.7%) in CD patients, while rectal bleeding (66.7%) and anemia (50%) were significant factors in UC patients. Additional monitoring was primarily considered necessary when there was a HBI score >4 (80%) or lack of significant improvement (77.8%) in CD patients, and steroid usage (100%) and rectal bleeding (86.7%) in UC patients.

At the index date, 15 CD patients (7.7%) had a HBI score >4, with no further action taken in 13% of them. Among 35 UC patients (17.5%) with increased stool frequency, no further action was taken in 28%. However, all 15 UC patients presenting with rectal bleeding had treatment adjustments or additional monitoring (see **Figure 4a**).

Following evaluation of inflammatory status by biomarkers CRP and fCal, no further action was taken in the case of 76% of CD patients and 74% of UC patients with abnormal CRP values. Regarding abnormal fCal values, no further action was taken in 26% of CD patients and 37% of UC patients (**Figure 4b**).

After endoscopic/colonoscopy assessment, no further action was taken in 47% of CD patients and 44% of UC patients with findings indicating active disease. In the presence of IUS findings, no action was taken in 42% of CD patients and 100% of UC patients. Lastly, no further action was taken in 50% of both CD and UC patients with MRI/MRE/CT findings suggestive of active disease (**Figure 4c**).

Discussion

The early and sustained control of inflammation via biomarkers or imaging can lead to the normalization of QoL in the long-term. Despite in this cohort partial disease control was primarily attributed to impaired QoL, over 70% of patients presented overlapping or distinct red flags. Treat-to-target strategies have been shown to improve the intermediate and long-term evolution of IBD by reducing chronic damage (14, 20). To implement them, continuous monitoring of biomarkers and ultrasound, radiological, and endoscopic parameters is necessary to assess the inflammatory activity of the disease (3, 21, 22). The IBD-PODCAST study cross-sectionally evaluated a significant population of 2185 patients with IBD in ten different countries, and some of its findings have been previously reported (1, 2, 17). In this sub-analysis, we evaluated how disease monitoring was conducted in the Spanish cohort (2), and specifically whether the results led to actions being taken or not.

IBD monitoring is based on the determination of biomarkers such as CRP and fCal, endoscopy, radiological studies (3, 21) and, increasingly, ultrasound (20). The monitoring results from the IBD-PODCAST Spanish cohort are generally consistent with those from the overall international population (1, 2, 23). A significant proportion of patients underwent objective monitoring using biochemical markers, with over half having a current CRP or fCal test. These rates are almost similar to those reported in previous real-life monitoring studies (24, 25). However, imaging monitoring within the previous 12 months was conducted in less than a third of CD and UC patients. Endoscopy/colonoscopy was the predominant procedure, in line with rates reported in previous studies (25). Nevertheless, low implementation of IUS in Spain was observed, with barely one in ten patients assessed using this technique.

Additionally, limited disease monitoring data in our population may also result in undetected inflammation and absence of mucosal healing, thereby increasing the potential risk of disease-related complications (21, 25). One reason for the lack of

inflammation assessment could be that the symptoms reported by patients did not suggest an inflammatory cause. Nevertheless, periodic evaluation of the underlying inflammation should still be conducted. In fact, in our population, the lack of information on the inflammatory status of subgroups of asymptomatic CD and UC patients classified as adequately controlled suggests that these patients could be at risk.

Monitoring can only impact disease progression if therapeutic approaches are adjusted when abnormalities are detected. Despite suboptimal control, 57% of CD and 41% of UC patients in this study did not have treatment changes, with adjustments often linked to symptoms rather than active inflammation identified through monitoring procedures. Gastroenterologists mainly base decisions on clinical symptoms, rarely relying on biological or imaging findings unless there's clinical deterioration. The lack of treatment adjustments is striking, considering that around 70% of patients are naïve to TIMs or use them as first-line therapy. Barriers to treatment switching may include the still low rates of mucosal healing and biomarker normalization with available therapies, uncertainty about the outcomes of treatment switch in asymptomatic patients, and concerns over side effects. Recent emergence of therapies inducing mucosal healing, and improved monitoring tools could help achieve better long-term outcomes and exceed traditional treatment goals (26, 27).

Despite its limitations due to its cross-sectional design (2), our study provides insights into current CD and UC monitoring practices in Spain, highlighting strengths and areas for improvement. The lack of biochemical data may be partly due to the study's narrow window (2).However, endoscopy and other imaging procedures (MRI/MRE, CT, or IUS) were also scarcely performed. Another limitation might be the low number of patients with known inflammatory status, which may affect interpretation. Real-life variables may also have influenced outcomes.

Although monitoring followed international trends, abnormalities prompted treatment changes in only a minority of cases. While reasons are unclear, a more proactive approach and treatment adjustments based on monitoring data could address many

suboptimal situations.

In conclusion, this analysis of IBD-PODCAST in Spain identified insufficient therapeutic response to monitoring demands and the need for better use of objective monitoring tools to improve patient outcomes and quality of life.

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Table 1. Clinical characteristics and monitoring of the overall CD and UC study population

Clinical characteristics	CD overall (N = 196)	UC overall (N = 200)
HBI Score (CD patients)*		
Number of patients with HBI score >4, n (%)	15 (7.7)	
Number of patients with HBI AP subscore >3	10 (5.1)	NA
Number of patients with HBI SF subscore >1	7 (3.6)	
Mayo Score (UC patients)*		
Number of patients with Mayo SF subscore >0	NA	35 (17.5)
Number of patients with Mayo RB subscore >0		15 (7.5)
Extraintestinal manifestations[‡], n (%)	34 (17.3)	24 (12.0)
Axial arthritis	12 (6.1)	5 (2.5)
Peripheral arthritis	10 (5.1)	12 (6.0)
Psoriasis	10 (5.1)	4 (2.0)
Ankylosing spondylitis	7 (3.6)	3 (1.5)
Hidradenitis suppurativa	2 (1.0)	0 (0.0)
Erythema nodosum	0 (0.0)	2 (1.0)
Comorbidities[†], n (%)	102 (52.0)	96 (48.0)
Arterial hypertension	28 (14.3)	32 (16.0)
Dyslipidemia	27 (13.8)	29 (14.5)

Type 2 diabetes mellitus	14 (7.1)	19 (9.5)
Anemia	15 (7.7)	8 (4.0)
Cardiovascular diseases	12 (6.1)	11 (5.5)
Mental disorder (depression, anxiety, substance abuse)	8 (4.1)	13 (6.5)
Patients with bowel urgency based on P-SCCAI, if available, n (%)[‡]	24/93 (25.8)	55/193 (28.5)
FACIT-F at index, mean (SD)	81.5 (19.81)	82.6 (20.08)
Laboratory markers		
Current CRP lab test, n (%)	112 (57.1)	87 (43.5)
CRP >0.5 mg/dL	25/112 (22.3)	19/87 (43.5)
Current fCal lab test[§]**, n (%)**	88 (44.9)	95 (47.5)
fCal >250 µg/g	23/88 (26.1)	35/95 (36.8)
Current hemoglobin lab test[§]**, n (%)**	119 (60.7)	99 (49.5)
Patients with IBD-related anemia	3/119 (2.5)	4/99 (4)
Imaging		
Endoscopy/colonoscopy[‖]**, n (%)**	37 (18.9)	56 (28)
Lack of endoscopic remission	17/37 (45.9)	34/56 (60.7)
MRI/MRE/CT[‖]**, n (%)**	12 (6.2)	6 (3)

MRI/MRE/CT indicating active disease	6/12 (50)	2/6 (33.3)
IUS‖, n (%)	23 (11.7)	7 (3.5)
IUS indicating active disease	12/23 (52.2)	4/7 (57.1)
Concurrent monitoring		
Current CRP or fCal lab test§, n (%)	121 (61.7)	106 (53)
Biochemical§ or imaging‖, n (%)	144 (73.5)	137 (68.5)
Biochemical§ and imaging‖, n (%)	39 (19.9)	35 (17.5)

AP: abdominal pain; CD: Crohn´s disease; CRP, C-reactive protein; fCal, fecal calprotectin; HBI: Harvey Bradshaw index; N: total number of patients in this group; RB: rectal bleeding; SD: standard deviation; SF: stool frequency; UC; ulcerative colitis. n, number of patients.

* For CD, symptoms were defined as a stool frequency score >3, a Harvey-Bradshaw Index (HBI) abdominal pain subscore >1, or a global HBI score >4. For UC, symptoms were defined as a Mayo Stool frequency subscore >0 or a rectal bleeding subscore >0 Estimation of the proportion patients with bowel urgency was an exploratory outcome for UC patients only.

‡ patients with at least one extraintestinal manifestation

† patients with at least one current comorbidity

§ Measured within ±14 days

‖ Imaging performed in the last 12 months.

Table 2. Treatment characteristics of the overall CD and UC study population

	CD overall (N = 196)	UC overall (N = 200)
Treatment		
Treatment phase, n (%)		
Short-term	11 (5.6)	14 (7.0)
Intermediate-term	13 (6.6)	5 (2.5)
Long-term	172 (87.8)	181 (90.5)
Current CD/UC specific treatments, n (%)	170 (86.7)	187 (93.5)
Yes	26 (13.3)	13 (6.5)
No		
Current[§], n (%)		
TIM[*,‡]	121 (61.7)	79 (39.5)
Other therapies[†]	107 (54.6)	191 (95.5)
Treatment with TIM, n (%)		
TIM-naïve	55 (28.1)	116 (58)
TIM first line	69 (35.2)	36 (18)
TIM-experienced (>1 line)	72 (36.7)	48 (24)
Steroid overuse		
Current prednisolone used at ≥10 mg/d for >6 weeks, n (%)	2 (1.0)	3 (1.5)
Patient received more than one steroid course in the last 12 months, n (%)		
Yes	16 (8.2)	29 (14.5)
No	180 (91.8)	171 (85.5)

Patients may be receiving TIM, non-TIM and other treatments simultaneously. Data reflect patients who have at least one of the treatments on the index date.

* includes TIM first-time users, total number of patients with at least one TIM. A total of 20 patients (10 with suboptimal control disease ICD and 10 with optimal control disease) in the CD group and 5 (4 with suboptimal control disease and 1 with optimal control disease) in the UC group were not currently on TIM but had previously taken it.

‡ includes anti-TNF, vedolizumab, ustekinumab, tofacitinib, filgotinib, upadacitinib, ozanimod

† Other therapies included: systemic steroids, budesonide, thiopurines, methotrexate (CD only), oral 5-ASA

§ Patients and percentages may add up to more than 100% as patients may receive more than one treatment.

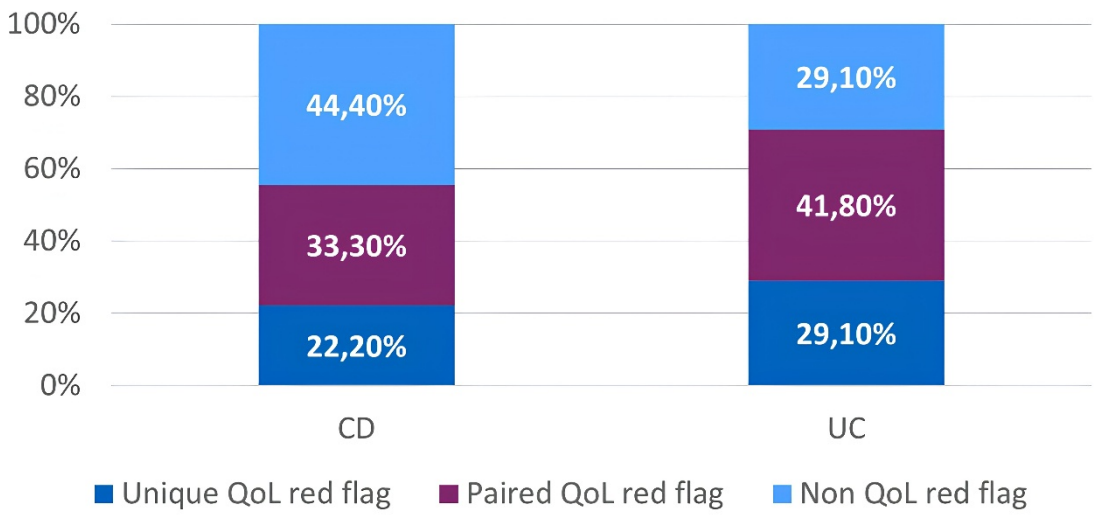

Figure 1: Proportion of red flags among long-term suboptimally controlled CD (n=99) and UC (n=79) patients based on QoL. 'Paired QoL red flag' refers to patients with more than one red flag, including a QoL red flag accompanied by one or more additional non-QoL-related red flags.

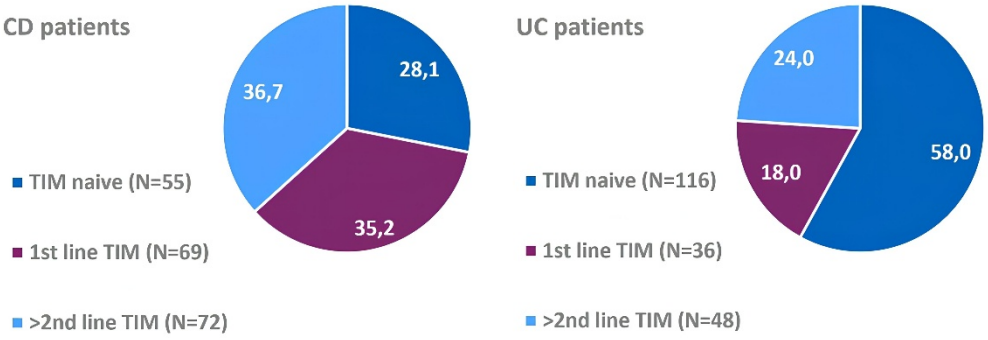

Figure 2. Proportion of CD and UC patients by TIM use. TIM use includes TIM-naive, TIM as first-line treatment, and TIM as second-line treatment or beyond.

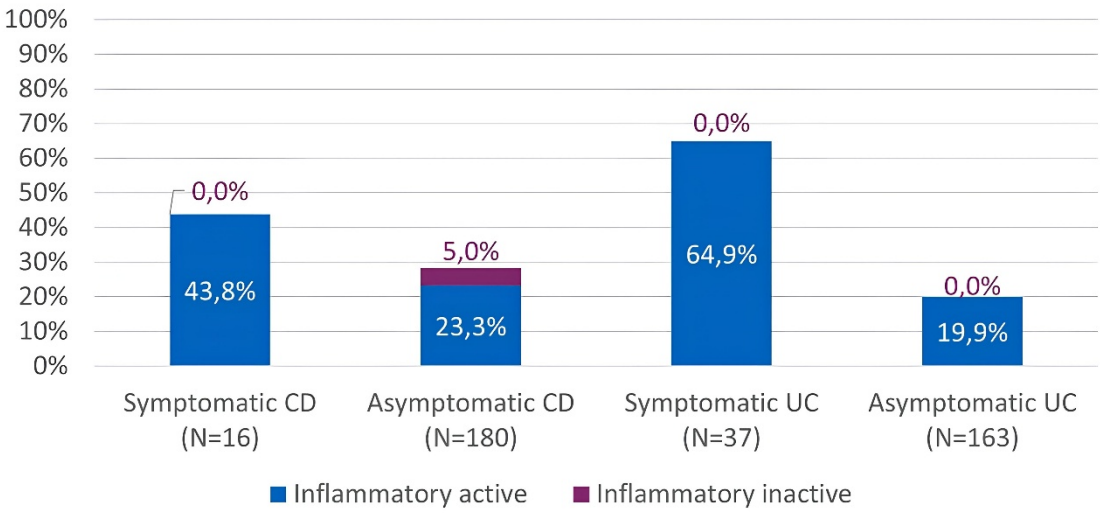

Figure 3. Inflammatory status in patients with biomarker/imaging evaluations (according to disease symptoms).

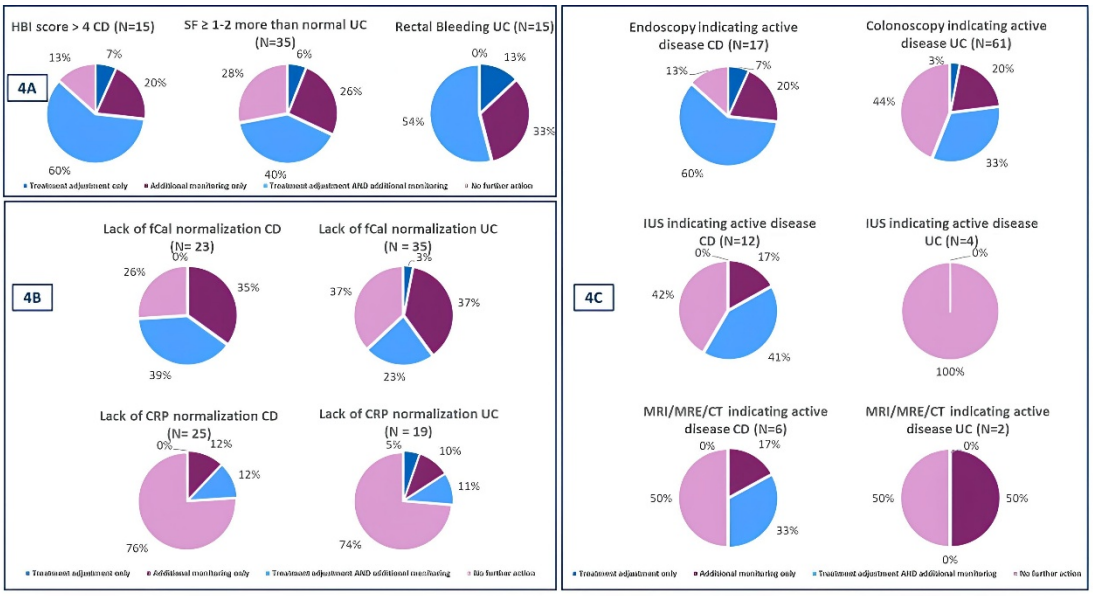

Figure 4. Actions taken in CD and UC patients according to symptoms (Figure 4A), biomarkers (Figure 4B) and imaging (Figure 4C) assessment