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Alimentary Tract

IBD impact on quality of life and perception of disease activity in Italian patients and physicians: An IBD-PODCAST study sub analysis

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ABSTRACT

Background: IBD-PODCAST was a global real-world study to assess suboptimal disease control (SDC) in patients with Crohn's disease (CD) and ulcerative colitis (UC) using STRIDE-II criteria.
Aim: To evaluate quality of life (QoL), disease characteristics and control in patients with SDC, comparing perspectives of patients and healthcare providers (HCPs) in the Italian subpopulation.
Methods: IBD-PODCAST-Italy enrolled adult outpatients from 17 centers. The study used a combination of retrospective chart reviews and cross-sectional assessments to gather data on treatment, patient-reported outcomes (QoL, fatigue, work productivity) and clinical activity. Patient and HCP perceptions of disease control based on STRIDE-II criteria, which included clinical, laboratory and endoscopic findings were also assessed.
Results: SDC was identified in 53.4 % (95 % CI: 44–62.8 %) of CD and 49.0 % (95 % CI: 39.1–59.0 %) of UC patients. Those with SDC had lower short IBD questionnaire scores (45.9 ± 12.0) compared to optimal disease control (ODC) patients (57.4 ± 9.9). Extraintestinal manifestations and bowel urgency were more frequent in SDC patients. Physician-perceived SDC (14.5 %) was higher than patient-perceived SDC (8.8 %) and agreement between patient and HCP assessments was low.

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Conclusions: Patients with SDC experienced impaired QoL. The discrepancy between patient and physician perceptions of disease control, alongside objective measures, highlights the need for further research to optimize care and improve outcomes.
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1. Introduction

Inflammatory bowel diseases (IBD) are chronic inflammatory disorders affecting the gastrointestinal tract, with Crohn's disease (CD) and ulcerative colitis (UC) being the two primary forms [1,2].

The worldwide prevalence of IBD exceeds 0.3 %, with rising incidence rates [3] and by 2030 the prevalence is projected to reach 1 % in most Western countries [4]. In Italy, prevalence ranges from 187 to 442 per 100,000 inhabitants, with annual incidence of CD and UC ranging from 6.1 to 17.9 and 12.2–15.3 per 100,000 inhabitants, respectively [5–7], posing a significant public health challenge.

Suboptimal disease control (SDC) of IBD, often due to delayed treatment or limited drug effectiveness is associated with severe complications, including hospitalization, surgery, increased cancer risk, and disability [8,9]. These complications impact upon quality of life (QoL), disrupt work and daily activities and increase the risk of anxiety and depression [8,10–13].

The IBD-PODCAST study [14], revealed a high prevalence of SDC based on objective criteria of optimal disease control (ODC) defined by Selecting Therapeutic Targets in Inflammatory Bowel Disease-II criteria (STRIDE-II) [15]. A steering committee of seven international experts in IBD further refined these criteria introducing "red flag" criteria for inadequate disease control [14,16–18]. SDC affected 52.2 % of CD patients and 44.3 % of UC patients with contributing factors including impaired QoL, extraintestinal manifestations (EIMs), steroid overuse, and ongoing inflammation [14]. Consistent findings emerged from PODCAST subgroup studies in Canada Spain, and Italy [16–18].

Clear, standardized treatment goals are essential for long-term disease management. The treat-to-target (T2T) approach, developed by the International Organization for the Study of Inflammatory Bowel Disease (IOIBD), helps optimize patient outcomes through tight monitoring of disease activity, early intervention, and prevention of complications. The STRIDE recommendations [19], including the updated STRIDE-II version [15] define treatment targets for CD and UC, including clinical response, clinical remission, normalization of inflammatory markers, endoscopic remission, and improved QoL [15]. Two key studies, CALM [20] and REACT [21] have demonstrated the effectiveness of this strategy in CD management.

Effective communication between healthcare professionals (HCPs) and patients improves patient health outcomes [22] and treatment adherence in IBD [23]. Nevertheless, recent studies highlight a discrepancy between patient and healthcare provider perspectives on symptom severity, with providers often underestimating patient concerns [24–26].

While previous studies have explored differences in symptom burden perception, few have evaluated alignment between patient perspectives, physician assessments of the disease, and the criteria indicated in the STRIDE recommendations.

This study aimed to investigate the QoL of patients with SDC and explore discrepancies in disease perception between HCPs and patients under both ODC or SDC in relation to STRIDE-II objective criteria. Understanding these disparities can inform improved communication and tailored treatment strategies to effectively address patient needs.

2. Methods

2.1. Study design and population

This was a non-interventional, international, multicenter cross-sectional, retrospective study, previously described in detail elsewhere both at international [14] and at Italian level [16]. The study comprised a retrospective chart review and cross-sectional physician and patient assessments. This report presents a sub analysis of the Italian study [16].

SDC was defined as the failure to achieve optimal disease management, characterized by the presence of symptoms and/or active inflammation. This determination was made at the date of the single visit for the cross-sectional assessment (index date), using adapted Red Flags (RFs; previously reported [14,16–18] and described below and in Supplementary Table S1) indicative of symptomatic disease based on the recently published STRIDE-II recommendations [15].

The retrospective component of the study collected data on Health Care Resource Utilization (HCRU) within the last 12 months, treatment history, and the initial occurrence of RFs that at the index date led to the classification of SDC. There were no protocol-mandated tests, procedures, or clinic visits for this study.

The study population has been previously described [16]. The study included adult CD/UC outpatients from private practices, centers, and hospitals treating IBD patients. Patients were consecutively enrolled (April 30th - November 30th, 2022). Eligibility criteria included being $\geq$19 years old, having a confirmed diagnosis of UC or CD for $\geq$1 year, providing informed consent, and being able to read and complete study materials. Patients with $<$12 months of documentation, those receiving investigational treatments, and those with unclassified IBD or a history of proctocolectomy were excluded.

2.2. Red flags defining suboptimal disease control

A steering committee of seven international IBD experts developed the adapted RFs, which included short-term symptomatic parameters, intermediate-term symptoms and biochemical parameters, and long-term QoL and imaging targets as previously described [14,16–18]. The applicability of these targets depended on the duration of treatment with specific IBD medications. RFs cutoff values used to define SDC are summarized in Supplementary Table S1.

2.3. Data collection

A description of the data collection process is present in published studies [14,16–18] and in Supplementary Figure S1. During this visit, both clinician and patient perceptions of disease control were evaluated. Clinicians reported their perception of disease control, while patients completed a dedicated questionnaire (Supplementary figure S2).

2.4. Quality of life assessment

Cross-sectional assessment included the following patient reported components: the Short Inflammatory Bowel Disease Ques-

tionnaire (SIBDQ) [27] to evaluate overall quality of life, Work Productivity and Activity Impairment (WPAI) questionnaire [28], Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) [29,30], IBD DISK [31] to assess daily life burden, and Patient Simple Clinical Colitis Activity Index (p-SCCAI) [32] a simplified version of the SCCAI filled out by the patient focused on bowel urgency (see Supplementary Table S2 for detailed scoring and interpretation criteria).

2.5. Statistical analysis

The analysis was descriptive in nature and was performed separately for CD and UC patients. Continuous variables were described by the number of observations (n), median, mean, and standard deviation (SD). Categorical variables were described as the total number and percentage of patients in the total study population, excluding any missing data. The proportion of patients identified with SDC or ODC were presented as percent and 95 % confidence intervals (CI). Missing data were not inputted with substitute values but were handled by excluding those cases from further descriptive analysis that required complete data. The number of missing data was reported for QoL measures.

Since analysis was descriptive, the sample size was not based on any formal power calculation, but on the expected width of a two-sided 95 % CI with 100–125 patients for each indication, estimated to be 9.8 %–8.7 %.

3. Results

3.1. Patient characteristics

Patients included in the present study have been described previously in detail [16]. This study included 220 patients (aged 39.5 ± 14.0 years) diagnosed with IBD (116 with CD and 104 with UC) and mean disease duration of 11.8 ± 8.0 years (Table 1). SDC was identified in 51.4 % (95 % CI: 44.6–58.1 %) of all patients and in 53.4 % (95 % CI: 44–62.8 %) of CD and 49.0 % (95 % CI: 39.1–59.0 %) of UC patients respectively. A higher proportion of SDC patients presented with extraintestinal manifestations (EIMs; 23.9 %) with respect to those in ODC (2.8 %).

Among patients in long-term treatment, 57.9 % were under SDC and 42.1 % were under ODC.

51.2 % of patients with SDC were currently on IBD-specific treatment, similar to those under ODC (48.8 %). No differences were observed in the proportion of patients who had previously experienced or currently were on targeted immunomodulatory therapy treatment (respectively 58.8 % in SDC; 49.2 % in ODC and 50 % for both). No difference was observed between UC and CD groups for any of the aforementioned parameters (Table 1).

3.2. Short IBD questionnaire (SIBDQ)

In patients with SDC the mean SIBDQ score was lower in the entire population (45.9 ± 12.0) and in CD; 46.7 ± 12.1 and UC; 44.9 ± 13.1) compared to patients with ODC (total population; 57.4 ± 9.9; CD: 58.20±9.84 and UC: 56.60±9.91) (Fig. 1a).

This result was consistent across the four domains covered by the SIBDQ (bowel, systemic, emotional, and social domains, Fig. 1b) and in long-term treated patients (Supplementary Figure S3).

3.3. Extra intestinal manifestations

EIMs (rheumatological or psoriatic) were more frequently reported of SDC patients compared to ODC patients (23.9 % vs 2.8 %). All cases reporting psoriasis (1.8 %) were under SDC, and treatment was not adjusted, nor was further monitoring planned in any of

Table 1
Patient disease characteristics of the overall study population stratified by suboptimal control and optimal control subgroups in Crohn's disease and ulcerative colitis.

	Total			Crohn's disease			Ulcerative colitis		
	Suboptimal Control *N=113 (51.4%)*	Optimal Control *N=107 (48.6%)*	Total *N=220*	Suboptimal Control *N=62 (53.4%)*	Optimal Control *N=54 (46.6%)*	Total *N=116*	Suboptimal Control *N=51 (49.0%)*	Optimal Control *N=53 (51.0%)*	Total *N=104*
HBI Score									
N*	N/A	N/A	N/A	62	54	116	N/A	N/A	N/A
Mean (SD)	N/A	N/A	N/A	2.0 (2.5)	1.1 (1.6)	1.6 (2.2)	N/A	N/A	N/A
Mayo Score									
N*	N/A	N/A	N/A	N/A	N/A	N/A	51	53	104
Mean (SD)	N/A	N/A	N/A	N/A	N/A	N/A	1.2 (1.8)	0.6 (1.2)	0.9 (1.5)
Extraintestinal manifestations, n (%),	27 (23.9)	3 (2.8)	30 (13.6)	15 (24.2)	2 (3.7)	17 (14.7)	12 (23.5)	1 (1.9)	13 (12.5)
Long Term treatment window, n (%)	106 (57.9)	83 (42.1)	189 (100.0)	59 (59.0)	41 (41.0)	100 (100.0)	47 (52.8)	42 (47.2)	89 (100.0)
Patients currently on IBD specific treatment, n (%)	107 (51.2)	102 (48.8)	209 (100.0)	56 (53.3)	49 (46.7)	105 (100.0)	51 (49.0)	53 (51.0)	104 (100.0)
TIM experienced, n (%)	98 (50.8)	95 (49.2)	193 (100.0)	58 (55.2)	47 (44.8)	105 (100.0)	40 (45.5)	48 (54.5)	88 (100.0)
Patients currently on TIM, n (%)	92 (50.0)	92 (50.0)	184 (100.0)	53 (53.0)	47 (47.0)	100 (100.0)	39 (46.4)	45 (53.6)	84 (100)

Data are reported as number of individuals (n), mean and standard deviation (SD) or percentage (%).
[a]Age was based on index date and year of birth; [b] year of diagnosis minus year of birth + 1, where year of birth = year of index minus – age at index; [c] year of index minus year of diagnosis + 1; TIM, Targeted Immunomodulatory Therapy.
N number of patients for whom information was available. N/A, not applicable; HBI, Harvey-Bradshaw Index
Note: A TIM experienced patient is one who is currently and/or previously on a TIM medication. Abbreviations: IBD, Intestinal Bowel disease; ,SD standard deviation

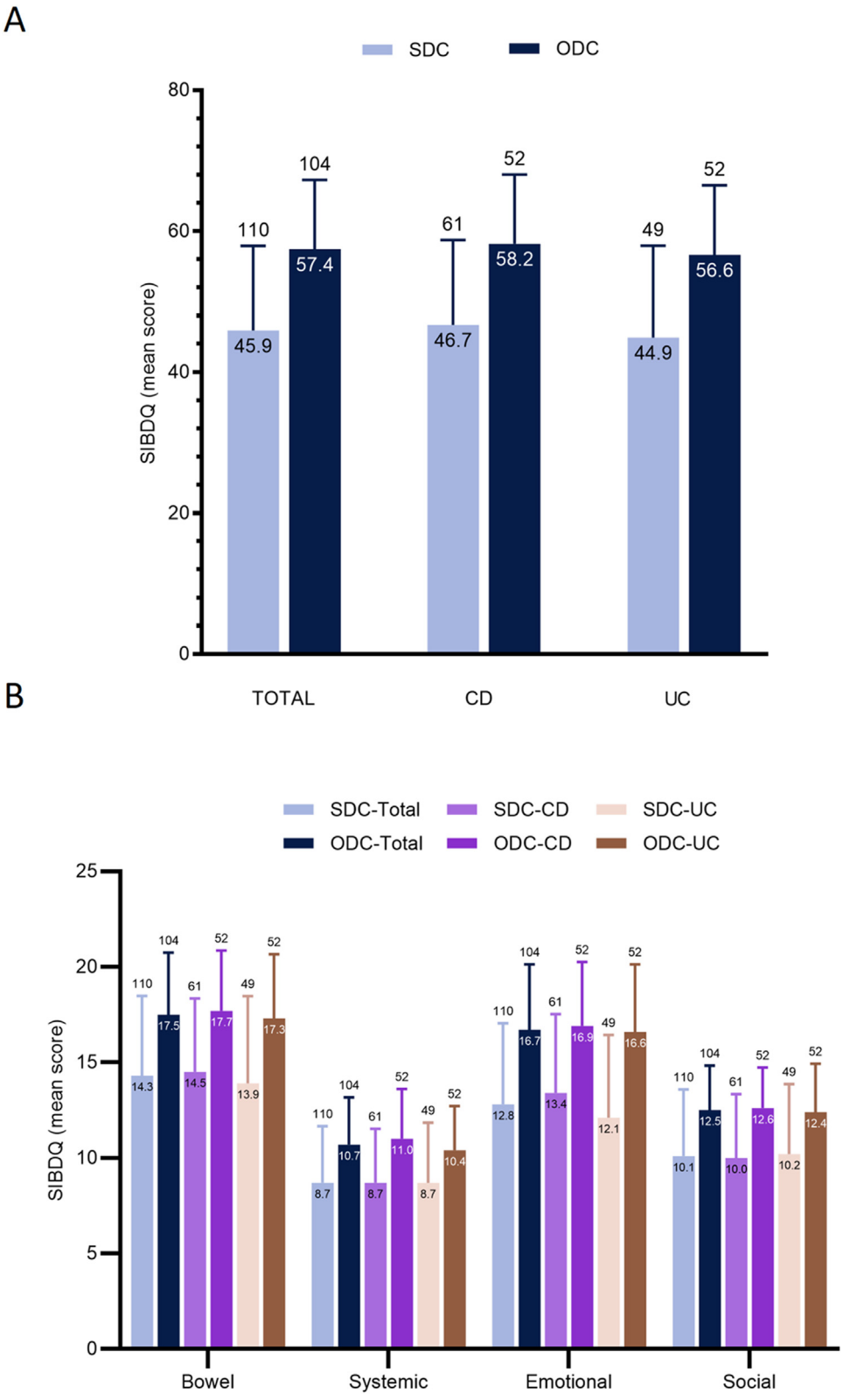

Fig. 1. Mean Short IBD Questionnaire (SIBDQ) scores in the overall population and in Crohn's disease (CD) and ulcerative colitis (UC) patients, divided into suboptimal disease control (SDC) and optimal disease control (ODC) (A). Mean SIBDQ scores for bowel, systemic, emotional, and social domains are represented (B). Above the error bars, the number of patients for whom the data were available is shown. Inside error bars, mean values are reported. Missing values ranged from 1–3 for patients reporting SIBDQ scores.

Table 2
Stool urgency assessment by disease control status at index through the Patient Simple Clinical Colitis Activity Index (P-SCCAI) questionnaire inpatients with Crohn's disease and Ulcerative Colitis.

	Total			Crohn's disease			Ulcerative colitis		
	Total N = 220	Suboptimal Control N = 113	Optimal Control N = 107	Total N = 116	Suboptimal Control N = 62	Optimal Control N = 54	Total N = 104	Suboptimal Control N = 51	Optimal Control N = 53
Proportion of patients who were not able to hold up their stool for 15 minutes or longer or made adjustments to their activities, n (%)	80 (38.8)	59 (56.2)	21 (20.8)	38 (34.9)	31 (53.4)	7 (13.7)	42 (43.3)	28 (59.6)	14 (28.0)
Proportion of patients who were not able to hold up their stool for 15 minutes or longer and made adjustments to their activities, n (%)	29 (14.1)	23 (21.9)	6 (5.9)	12 (11.0)	10 (17.2)	2 (3.9)	17 (17.5)	13 (27.7)	4 (8.0)

SIBDQ, Short Inflammatory Bowel Disease Questionnaire.

these cases during the visit (Supplementary Table S3). Rheumatic diseases were reported in 11.8 % of the overall patients, in 20.4 % of patients with SDC, and only in 2.8 % of those with ODC. Among rheumatic diseases, peripheral arthritis was the most frequently reported (6.8 %), with a higher proportion in SDC patients (10.6 %) compared to ODC patients (2.8 %). Among patients with peripheral arthritis, 50 % of those with SDC did not have any treatment adjustments or additional monitoring planned at the time of the visit (Supplementary Table S3).

3.4. Bowel urgency

Among the IBD population, 56.2 % under SDC were unable to hold their stool for 15 min or longer or had to make adjustments to their activities, compared to 20.8 % under ODC (Table 2). Furthermore, 21.9 % of patients under SDC were not only unable to hold their stool for 15 min or longer but also had to make changes to their activities, compared to 5.9 % of ODC patients.

A concerning aspect is that even among UC patients with ODC, one-third still experienced urgency issues. Specifically, 28 % were unable to hold their stool for 15 min or longer or had to make adjustments to their activities. These percentages were lower in CD patients: 13.7 % of patients with ODC were unable to hold their stool for 15 min or longer or had to make adjustments to their activities.

3.5. Inflammatory bowel disease disk

SDC patients were observed to have consistently higher IBD-Disk scores compared to those with ODC in all domains considered (Supplementary Table S4). In CD patients, energy domains (4.5 ± 2.8 versus 2.7 ± 2.4 in SDC and ODC, respectively) and sexual function (2.3 ± 2.9 in SDC compared to 0.9 ± 1.9 in ODC) revealed marked differences in SDC and ODC groups. In UC, the domains of emotions (4.4 ± 3.2 versus 2.5 ± 2.3 in SDC compared to ODC) and regulation of evacuation (3.3 ± 3.3 in SDC compared to 1.9 ± 2.1 in ODC) also exhibited notable differences (Supplementary Table S4).

3.6. Work/Activity impairment

The average rate of absenteeism was notably higher in patients with SDC compared to those with ODC across the entire study population (8.5 ± 18.0 % for SDC and 2.1 ± 6.8 % for ODC) (Fig. 2). Likewise, presenteeism and work productivity loss were both significantly higher in the SDC group compared to the ODC group. The average presenteeism rate for SDC patients was 27.3 ± 25.0 % compared to 15.8 ± 21.9 % for ODC patients. Similarly, the mean work productivity loss score for SDC patients exceeded 30 % (30.5 ± 27.9 %), while the ODC group averaged 18.0 ± 23.2 %.

The average activity impairment score was also significantly higher in the SDC group (34.1 ± 30.0 %) compared to the ODC group (20.0 ± 29.5 %). The association between SDC and a substantial burden on work productivity and daily activities for patients with IBD held true for both CD and UC subgroups (Fig. 2).

3.7. Perception of fatigue

The FACIT-F questionnaire indicated less fatigue in patients with ODC, reflected by a higher mean FACIT-F score of 127.6 ± 18.8 in ODC patients compared to 111.0 ± 24.6 in those with SDC (Fig. 3). This trend was consistent in both CD and UC patients, with average scores of 130.4 ± 19.8 in ODC vs. 111.4 ± 26.0 in SDC for CD, and 124.8 ± 17.4 in ODC vs. 110.6 ± 22.9 in SDC for UC. This pattern was also observed across all subcategories covered by the questionnaire (Fig. 3). In particular, the fatigue assessment scores were 43.4 ± 7.2 in ODC patients, compared to 37.4 ± 10.5 in the SDC group (37.1 and 37.7 for SDC CD and UC patients, respectively, and 44 and 42.8 for optimally controlled CD and UC patients) (Fig. 3).

3.8. Disease perception

Only 8.8 % of patients believed their disease to be uncontrolled, whereas physicians perceived 14.5 % of patients as having uncontrolled disease. Among patients with SDC, 36.8 % believed their disease was sub optimally controlled for >12 months. When asked about the reasons for SDC, 52.6 % cited limited QoL/daily functions (Supplementary Table S5). Clinicians attributed SDC mainly to poorly controlled symptoms in 62.5 % of cases, while only 37.5 % believed patients had significant impairment in QoL and/or daily activity (Supplementary Table S5). This trend was consistent in both CD and UC patient groups.

When evaluating the QoL of patients considered to have ODC by clinicians, 24.2 % had a severely compromised QoL. The same trend was observed from the patient's perspective, with more than one-quarter of ODC patients in the overall population (23.6 %), while SDC was perceived to be higher for patients compared to physicians (78.9 % vs. 57.1 %).

Considering patients with SDC according to RFs, as reported by clinicians and patients (Fig. 4), what was evident was a very low percentage of overlap for these three parameters (6.5 % in the overall population, 4.5 % in CD, and 8.8 % in UC).

4. Discussion

The IBD-PODCAST study provides an overview of IBD management in real-world clinical practice across several countries [14,16–18], based on STRIDE-II recommendations. This sub analysis of the Italian IBD-PODCAST [16] focused on evaluating the QoL in patients with SDC, characterizing the disease, and comparing perceptions of disease control between patients and HCPs. We found

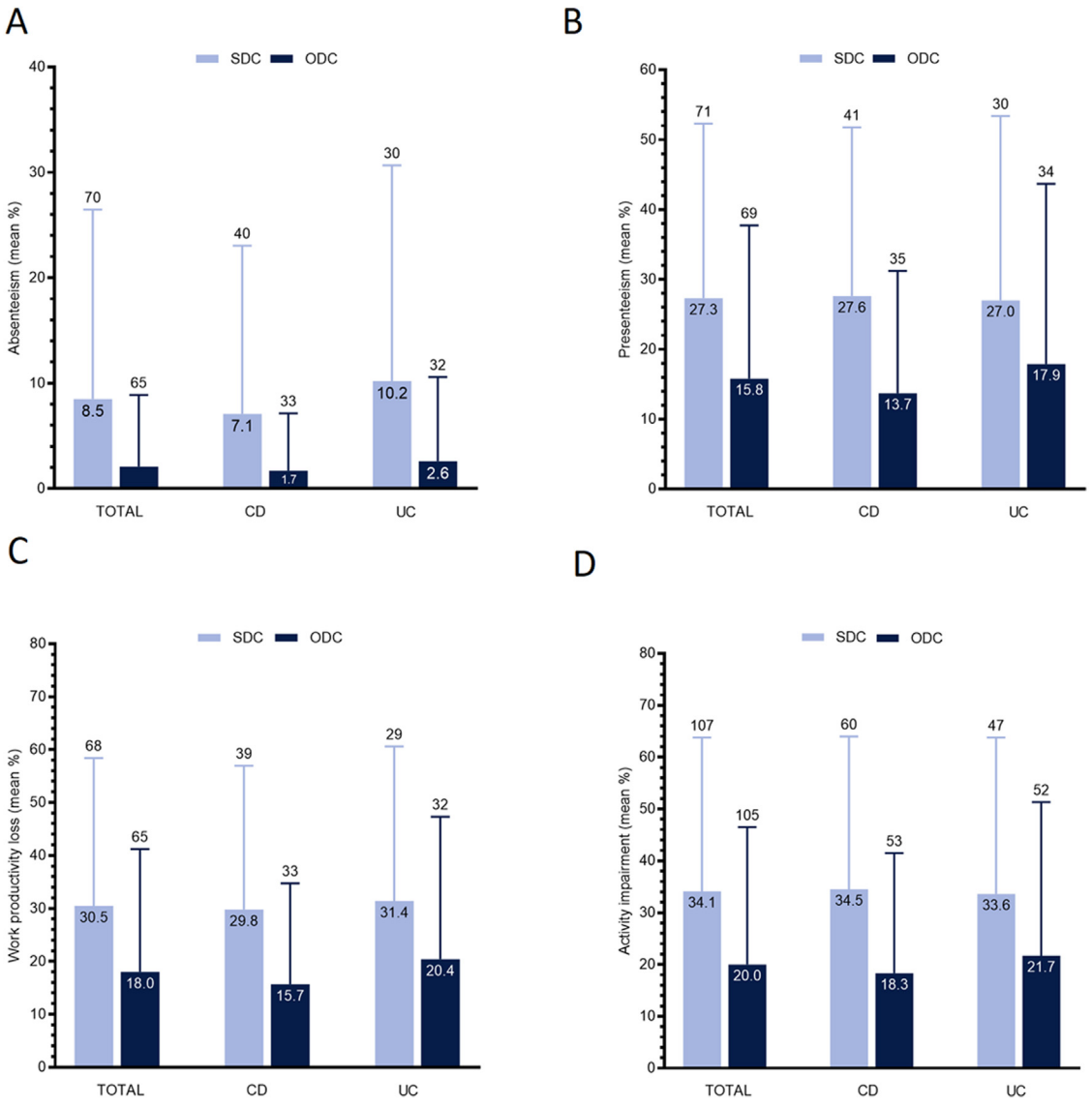

Fig. 2. Work Productivity and Activity Impairment Questionnaire (WPAI) scores at index in the overall study population and in Crohn's disease (CD) and ulcerative colitis (UC) patients, divided into suboptimal disease control (SDC) and optimal disease control (ODC). Above the error bars, the number of patients for whom the data were available is shown. Inside the error bars, the mean value is reported. Missing values ranged from 1–4 for patients reporting WPAI scores.

that patients with SDC had compromised QoL, with lower SIBDQ, higher frequency of EIMs, IBD Disk and FACIT-F scores, greater work absenteeism, and reduced work capacity compared to patients with ODC. Bowel urgency emerged as a major factor affecting QoL. Notably, there was a substantial disconnect between clinician- and patient-perceived disease control, as well as misalignment with STRIDE-II criteria. Approximately 9 % of patients deemed optimally controlled still reported severely impaired QoL (SIBDQ <45), compared to 14.5 % for physicians, highlighting a critical gap in current assessment approaches. These findings align with those from the CONFIDE [24,25] and ICONIC studies [33] and reinforce the need to integrate patient-reported outcomes into routine IBD management to inform more meaningful, personalized therapeutic strategies.

We did not observe differences in outcomes between UC and CD patients, but only between the SDC and ODC subpopulations. Previous PODCAST studies [14,17,18] also revealed no significant differences between UC and CD, as also observed in a recent Italian study [34]. In this regard, only outcomes assessed in the IBD population will form the focus of the present discussion.

QoL is known to be compromised in patients with IBD [35], with SIBDQ score correlating with QoL. A SIBDQ score of <50 indicates impaired QoL and a score of <45 indicates severely impaired QoL [27,36]. In our study, mean SIBDQ score was lower in SDC patients (45.9 ± 12.0) compared to ODC patients (57.4 ± 9.9). Almost half (47.3 %) of SDC patients had SIBDQ scores from 10–44, compared to only 8.7 % of ODC patients. The international IBD-PODCAST study [14] demonstrated similar trends, with lower mean SIBDQ scores for SDC patients in countries such as Canada [17] and Spain [18], as well as in our previous study from Italy [37].

EIMs are associated with increased morbidity, impaired QoL, and higher risk of surgery [38]. Patients with SDC had a higher probability of EIMs, particularly rheumatic diseases, which aligns with findings from other IBD-PODCAST studies [14,17,18,37], particularly the international PODCAST study [14] reporting that impaired QoL in SDC patients was mostly associated with clinically relevant EIMs [12,39].

In our study, IBD Disk scores were higher in SDC than in ODC, indicating greater disability, consistent with findings from Spanish

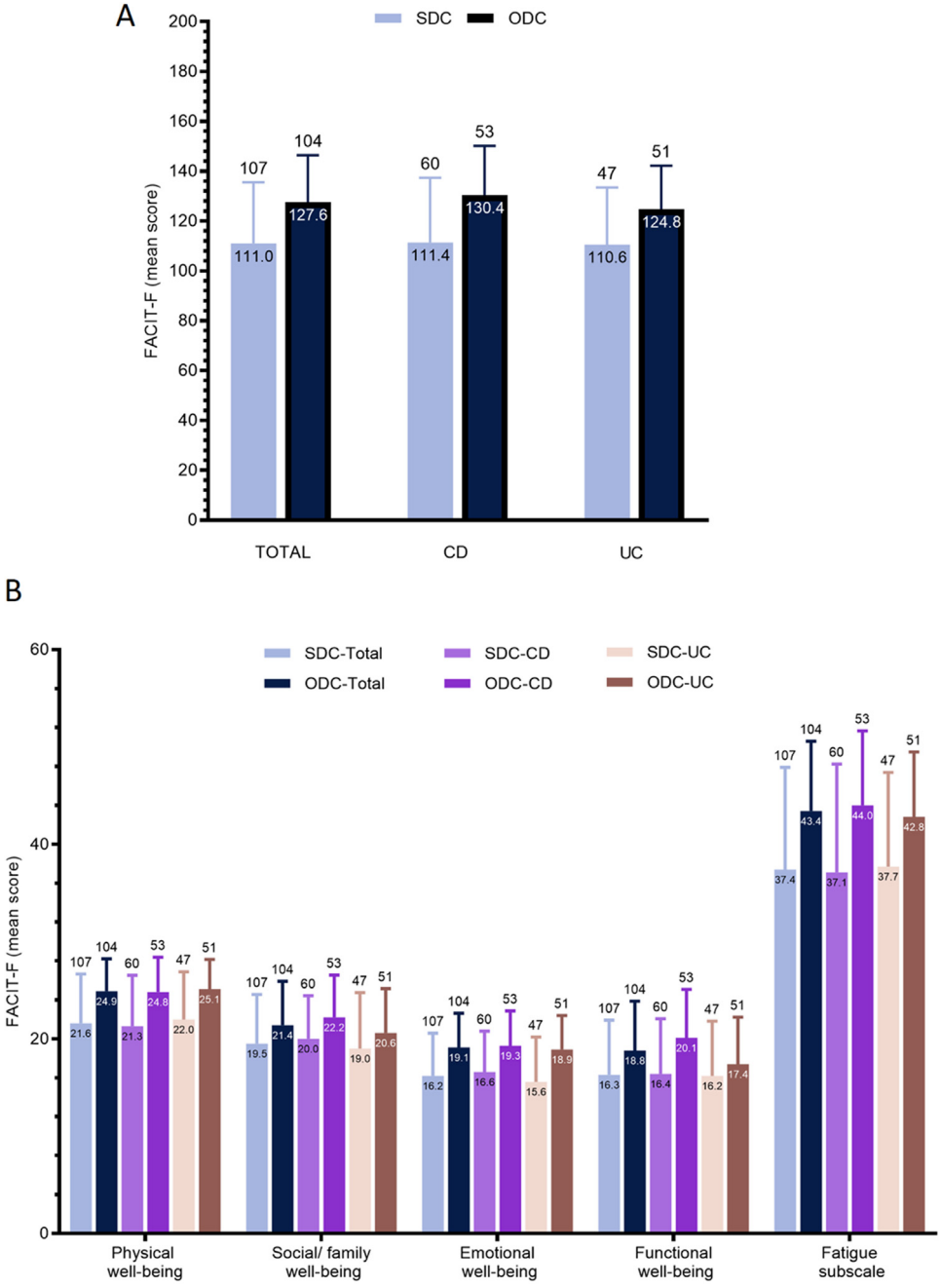

Fig. 3. Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scores at index in the overall study population and in Crohn's disease (CD) and ulcerative colitis (UC) patients, divided into suboptimal disease control (SDC) and optimal disease control (ODC) (A) and further divided into FACIT-F subcategories (physical, social-emotional, and functional well-being) (B). Above the error bars, the number of patients for whom the data were available is shown. Missing values ranged from 1–4 for patients reporting FACIT-F scores.

and Canadian PODCAST studies [17,18]. Recent studies have associated the IBD-Disk with disease-related disability in a Saudi Arabian population [40] and French populations [41,42]. We also reported lower FACIT-F scores in SDC than in ODC, reflecting greater fatigue, which aligns with the findings from the Spanish IBD-PODCAST Study [18].

Impaired QoL and higher levels of fatigue in SDC are consistent with previous reports, indicating that severe fatigue and poor QoL are strongly associated with disease activity. This may be related to the significant psychosocial burden and reduced social functioning seen in these patients [35,43].

Regarding the impact of SDC on work productivity, we observed higher rates of absenteeism, presenteeism (reduced productivity at work), and overall work productivity loss in SDC compared to ODC patients. This corroborates with a previous report, where IBD patients were observed to have greater work productivity impairment compared to the general population, with significantly higher absenteeism and presenteeism [44]. Other studies have also reported a significant negative impact of IBD on labor force participation, particularly among CD patients [45,46].

Bowel urgency is recognized as a highly burdensome symptom, with major impact on QoL compared to other symptoms [47–49]. In our study, over half of SDC patients (56.2 %) reported being unable to hold their stool for at least 15 min or had to adjust their activities, compared to 20.8 % of ODC patients. These findings are consistent with the Canadian PODCAST Study [17]. Although bowel

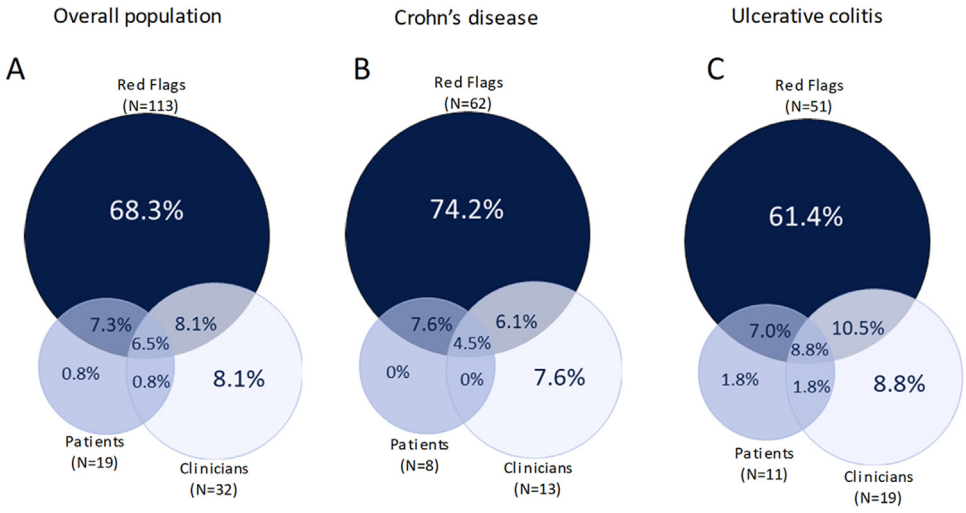

Fig. 4. Three-way Venn diagram of the number patients with SDC at index according to patient, clinician, and red flag assessments with a Short IBD Questionnaire red flag score of <50 in A) the overall population ($N = 126$); B) Crohn's Disease patients ($N = 67$); and C) Ulcerative Colitis patients ($N = 59$). Percentages were calculated using only non-missing patient, clinician, and red flag data. The dimensions of the circles are proportional to the number of patients in the group represented by each circle. Missing patient or clinician or red flags ranged from 1–2.

urgency is clinically significant, there is limited literature research on its impact in CD and UC patients. A study by Wolf et al. emphasized its substantial impact on UC patients, suggesting suboptimal treatment in real-world settings [50]. Further studies have highlighted the importance of bowel urgency as a critical patient-reported outcome, with strong associations between urgency, social impairment, depression, anxiety, and fatigue in UC patients [51].

Effective communication between clinicians and patients is crucial for optimizing health outcomes and treatment adherence in IBD [23,52,22]. However, a lack of agreement exists between patient and HCP views on symptom burden, with HCPs underestimating issues important to patients [24,25,33,47,53,54]. In our study, only 9 % of patients perceived their disease as uncontrolled, compared to 15 % of physicians who believed their patients had uncontrolled disease. This aligns with findings from the ICONIC study [33] performed on UC patients. Moreover, the IBD GAPPS study [47], showed that physicians often underestimated the severity of rectal urgency in CD patients or the need for immediate toileting after eating in both CD and UC patients. The CONFIDE [24,25] study also reported differences in perceptions of bowel urgency between patients and HCPs across the US, Europe, and Japan. This disconnect in perception of disease control is not unique to IBD; in psoriasis, for instance, the SHAPE survey [55] showed that about 40 % of psoriatic patients felt that their dermatologist did not fully consider their wellbeing, highlighting a broader issue of communication gaps between patients and physicians in autoimmune diseases.

Another key finding from our study was the discrepancy among RFs, which reported around 50 % of SDC, and the patient and clinician assessments of SDC in the current study, with 24.2 % of patients considered optimally controlled still having compromised QoL. Implementing STRIDE-II recommendations for disease monitoring may be challenging due to the need for a systematic approach to patient evaluations and access to healthcare professionals to meet targets. These findings highlight the necessity for a strong therapeutic partnership between clinicians and patients. This partnership should encompass thorough evaluations of daily life and symptom burden, to bridge the perception gap between patients and clinicians. Future studies should explore whether achieving objective targets (as outlined in STRIDE II) leads to better disease control compared to targets selected by patients.

While our study is indeed a sub-analysis, it provides critical real-world data on the discordance between patient and physician perceptions of disease control in IBD, based on STRIDE-II criteria. These findings highlight the substantial burden experienced by patients deemed to have "optimal control," thus highlighting gaps in current assessment approaches. Given the increasing emphasis on T2T strategies, we believe our results contribute meaningful insights that can enhance both clinical decision-making and the development of future interventions focused on aligning therapeutic targets with patient-centered outcomes.

Despite insights gained, several limitations should be noted. Given the exploratory nature of this study, the sample size was smaller than desired for subgroup analysis for some outcomes. A larger sample size in a future study will be important to confirm these findings. In addition, we did not have data on the presence of EIMs in the 12 months preceding the index date. Data derived from patient's and physician's perceptions were not always from the same questionnaire with potential variations to these questions therefore precluding the possibility to accurately make direct comparison or assess differences in a more formal manner. As the study was descriptive, no formal statistical analysis was planned.

Another limitation of the study is that some PROs assessing QoL and fatigue may be influenced by comorbidities and nutritional/vitamin deficiencies, which were not investigated.

However, this study has several strengths. It is the first international multicenter study to explore differences in patient and physician perception in SDC and ODC patients with IBD, providing valuable insights across diverse healthcare settings. The collaborative nature of this research enhances its applicability and relevance. Additionally, the use of both patient and clinician perspectives enriches the findings, allowing for a more comprehensive understanding of the disease burden.

5. Conclusion

This study highlighted significant differences in QoL between patients with SDC and ODC. SDC patients exhibited lower QoL, higher rates of EIMs, and greater work productivity impairment with bowel urgency being a critical factor. Even optimally controlled patients experienced substantial QoL issues, indicating the need for better therapeutic understanding and communication between clinicians and patients.

A major finding was the lack of agreement in perception of disease control between patients and clinicians and STRIDE-II criteria, with many patients deemed optimally controlled still experiencing compromised QoL. Effective communication and comprehensive QoL assessments are crucial to addressing the real-world challenges faced by IBD patients.

Our findings highlight the need for revised IBD management strategies to enhance disease control and QoL.

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Author contribution

All authors contributed to the writing, revision and approval of the manuscript. EVS, FAC, DGR, SO, AV, GM, AV, SS, FC, SM, AO, MP, MED, MG, LC, GM, and FD collected data for study purposes. EVS, FAC, SO, FD contributed substantially to the critical analysis and improvement of the manuscript. DB, MCC, LG, GG and FM contributed to the study design and critical appraisal of data- FD served on the international steering committee that designed and contributed to the development of the study protocol and provided important suggestions and comments during the development of the manuscript.

Data availability

Data are available upon request.

Ethics approval

The study was approved by all the Ethical Committees in accordance with local regulations. All participants signed an informed consent for study participation and consent to transfer data.

Conflict of interest

EVS, has served as speaker for Abbvie, Abivax, Agave, AG-Pharma, Alfasigma, Apoteca, Biosline, CaDiGroup, Celltrion, Dr Falk, EG Stada Group, Fenix Pharma, Galapagos, Johnson&Johnson, JB Pharmaceuticals, Innovamedica/Adacyte, Eli Lilly, Malesci, Mayoly Biohealth, Montefarco, Novartis, Omega Pharma, Pfizer, Rafa, Reckitt Benckiser, Sandoz, Sanofi/Regeneron, SILA, Sofar, Takeda, Tillots, Unifarco; has served as consultant for Abbvie, Agave, Alfasigma, Biogen, Bristol-Myers Squibb, Celltrion, Dr. Falk, Eli Lilly, Fenix Pharma, Ferring, Giuliani, Grunenthal, Johnson&Johnson, JB Pharmaceuticals, Merck & Co, Nestlè, Pfizer, Reckitt Benckiser, Sanofi/Regeneron, SILA, Sofar, Takeda, Unifarco; he received research support from Bonollo, Difass, Pfizer, Reckitt Benckiser, anofi/Regeneron, SILA, Sofar, Unifarco, and Zeta Farmaceutici.

FAC served as consultant to: Abbvie, MSD, Takeda, Janssen, Roche, Celgene, Bristol-Meyers Squibb, Galapagos, Gllead, Pfizer, Mundipharma, Biogen, Ferring, Eli-Lilly, Nestlè, Lionhealth, AlfaSigma, Dr Falk. He received lecture fees from Abbvie, Ferring, Takeda, Allergy Therapeutics, Janssen, Pfizer, Biogen, Sandoz, Tillotts Pharma, Vifor Pharma, AlfaSigma, and unrestricted research grants from Giuliani, Sofar, MSD, Takeda, Abbvie, Celltrion, Pfizer, and Actial.

DGR has no conflict of interest to declare

SO has received consultancy and lecture fees, and has participated to advisory board for AbbVie, Alfasigma, Galapagos, Janssen, and Takeda,

AVariola has served as consultant for Abbvie, Galapagos. Celltrion, Johnson and Johnson, Pfizer, Takeda, Alfasigma, Ferring; she received lecture fees from Abbvie, Eli-Lilly, Johnson and Johnson, Pfizer, Takeda, Alfasigma, Zambon and Ferring

GM has no conflict of interest to declare

AViola has served as consultant for, Pfizer, Janssen, and Eli-Lilly

SS has received consultancy, lecture fees, and advisory board for AbbVie, Arena, Ferring, Galapagos, Gilead, Janssen, MSD, Pfizer, and Takeda.

FC served as speaker and consultant for Abbvie, Alfasigma, CaDiGroup, Celltrion, Galapagos, Johnson&Johnson, Eli Lilly, Pfizer, Sandoz, Sofar, Takeda, Biogen, Ferring, Giuliani.

SM has no conflict of interest to declare

AO has received consultancy fees, Educational grants, Lectures: Abbvie, Biogen, Celltrion, Chiesi, Eli Lilly, Ferring, Fresenius-Kabi, Galapagos, Janssen, MSD, Pfizer, Sandoz, Sofar, Takeda, Zambon. Funding: Pfizer, Takeda

MP has participated to advisory boards and has received lecture feed for Abbvie, Johnson-Johnson, Pfizer, Takeda, Lilly

MED has no conflict of interest to declare

MG has no conflict of interest to declare

LC has served as consultant for Abbvie, Galapagos, Janssen,

GMonteleone has served as a consultant for First Wave BioPharma, as a speaker for Takeda, Abbvie, Galapagos, and Pfizer, and filed a patent related to the treatment of inflammatory bowel diseases with Smad7 antisense oligonucleotide-based therapy.

DB, MCC, LG, GG and FM are AbbVie employees and may own AbbVie stocks/options.

FD has served as a speaker for Abbvie, Janssen, Galapagos, Omega Pharma, Sandoz, Takeda, and Tillotts; he has also served as an advisory board member for Abbvie, Ferring, Galapagos, Janssen, and Nestlè.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.dld.2025.05.006.

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