

Impact of fatigue and bowel urgency on the health-related quality of life of Crohn's disease patients: results from the NAVETA project

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INTRODUCTION

- Symptoms such as fatigue and bowel urgency significantly impact patients' daily functioning and well-being¹. Despite their relevance, they are often underreported or not adequately assessed in clinical practice. The NAVETA telemedicine project monitors patients with chronic diseases, including Crohn's disease (CD), systematically collecting electronic Patient-Reported Outcome Measures (PROMs) to evaluate the health-related quality of life (HRQoL) of patients treated with biologics or JAK inhibitors (JAKi)².
- This study aims to describe the patient-reported outcomes (PROs) of patients with CD in Spain included in the NAVETA project and to analyse the correlation between symptoms such as fatigue and bowel urgency and different PROMs.

CONCLUSIONS

- Despite advances in treatment and disease monitoring, patients with CD continue to experience unmet needs, as reflected in their perceptions of HRQoL.
- Symptoms such as fatigue and bowel urgency are significantly associated with HRQoL in CD patients, underscoring the importance of routine, systematic evaluation and management of these symptoms to improve clinical outcomes and patient well-being.

REFERENCES. 1. Burisch J, Jess T, Martinato M, et al. The burden of inflammatory bowel disease in Europe. *J Crohns Colitis* 2013; 7: 322-337. 2013/02/12. DOI: 10.1016/j.crohns.2013.01.0103. Mercadal-Orfila G, Herrera-Pérez S, Piqué N, et al. Implementing Systematic Patient-Reported Measures for Chronic Conditions Through the Naveta Value-Based Telemedicine Initiative: Observational Retrospective Multicenter Study. *JMIR Mhealth Uhealth* 2024; 12: e56196. 2024/03/28. DOI: 10.2196/56196.

CONFLICTS OF INTEREST. Marisa Iborra declares consulting fees and/or payments or honoraria for lectures, presentations, writings or educational events and/or support attending meetings from: Abbvie, Johnson and Johnson, Eli Lilly, Pfizer and Takeda. Silvia Díaz-Cerezo, Sebastián Moyano, Hugo Gabilondo and Itxaso Aguirregabiria are employees and minor shareholders of Eli Lilly and Company. Joan Gelabert, Gabriel Mercadal-Orfila and Salvador Herrera-Pérez have no conflicts of interest to declare.

METHODS

- A retrospective observational study was carried out in three Spanish hospitals. Patients aged ≥18 years diagnosed with CD who were receiving treatment with a biologic or JAKi and who agreed to participate in the NAVETA telehealth project were included in the study.
- Participation involved completing electronic PROMs: I. Manitoba Inflammatory Bowel Disease Index (MIBDI); II. Inflammatory Bowel Disease Questionnaire (IBDQ-32); III. IBD-Control; IV. Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-Fatigue); V. Work Role functioning Questionnaire (WRFQ). Fatigue was evaluated with the FACIT-Fatigue and bowel urgency with the IBDQ-32 urgency item “How often have you been worried about not finding a restroom nearby over the past two weeks?”, taken as a reference of the patient's concern related to the urgency of having an accessible restroom.
- Individuals were classified based on the duration of their current treatment at the time of enrolment in the NAVETA project. The follow-up period analysed for the study was 12 months since the start of the current treatment. Descriptive analyses were performed, using mean and standard deviation (SD) for continuous variables, and frequencies and percentages for categorical variables. Spearman correlations were used to assess the relationships between PROMs.

RESULTS

Table 1. Sociodemographic, clinical and treatment-related characteristics (n=118)

Variable	Value
Gender, n (%) male	62 (53.0)
Age, mean (SD)	43.5 (13.0)
BMI, n (%)	
Underweight	4 (3.4)
Normal	67 (56.8)
Overweight	25 (21.2)
Obesity	18 (15.3)
Unknown	4 (3.4)
Smoking status, n (%)	
Never	38 (38.4)
Yes	32 (32.3)
Former smoker	29 (29.3)
Employment status, n (%)	
Student	8 (6.8)
Working	86 (72.9)
Unemployed	11 (9.3)
Retired	7 (5.9)
Temporary sick leave	3 (2.5)
Permanent sick leave	3 (2.5)
Current treatment line, n (%)	
First line	63 (53.4)
Second line	42 (35.6)
Third line	7 (5.9)
Fourth line or more	6 (5.1)
Current treatment, n (%)	
TNFi	58 (49.2)
IL-12/23i	48 (40.7)
IL-23i	4 (3.4)
Integrin a4b7i	1 (0.8)
Unknown	7 (5.9)
Previous treatment, n (%)	
TNFi	62 (52.5)
IL-12/23i	4 (3.4)
Integrin a4b7i	1 (0.8)
Unknown	51 (43.2)

BMI: body mass index; IL: interleukin; SD: standard deviation; TNF: tumor necrosis factor.

- A total of 118 patients were included, mostly men (53.0%) and with a mean (SD) age of 43.5 (13.0) years. 53.4% were on their first treatment line, mostly receiving tumor necrosis factor inhibitors (TNFi). Mean (SD) C-reactive protein and fecal calprotectin levels were 2.4 (14.3) mg/L and 435.5 (460.2) µg/g, respectively, and 35.3% had moderate-severe disease according to Harvey-Bradshaw Index (Table 1).
- After 24 months on current treatment, improvements in PROMs were seen. Nevertheless, 47.4% of patients still exhibited active disease according to MIBDI and 12.8% reported insufficient disease control based on the IBD-Control questionnaire. In line, 15.8% of patients presented moderate/low quality of life in the IBDQ-32, with 13.1% showing moderate-severe fatigue using the FACIT-Fatigue questionnaire. However, all patients showed high work performance according to the WRFQ (Figure 1).
- Fatigue correlated with quality of life, meaning greater fatigue linked to worse perception of overall well-being. It also showed correlation with disease activity, perceived disease control and work functioning, suggesting that higher inflammation and lower sense of control worsen fatigue, ultimately affecting daily life. On the other hand, BU had correlation with quality of life, highlighting its impact on well-being.
- There was also a correlation with disease activity, indicating that greater inflammation is associated with greater concern about finding a bathroom (Table 2).

LIMITATIONS

- This study presents the PROs of real-world patients who remain on treatment, and who are therefore likely to be experiencing clinical benefit. Moreover, its generalizability is limited by regional scope, treatment-stage variability, potential selection bias, and subjective or inconsistent patient-reported outcomes.

Figure 1. PROMs by category over time on treatment: A) MIBDI, B) IBDQ-32, C) IBD-Control, D) FACIT-Fatigue, E) WRFQ

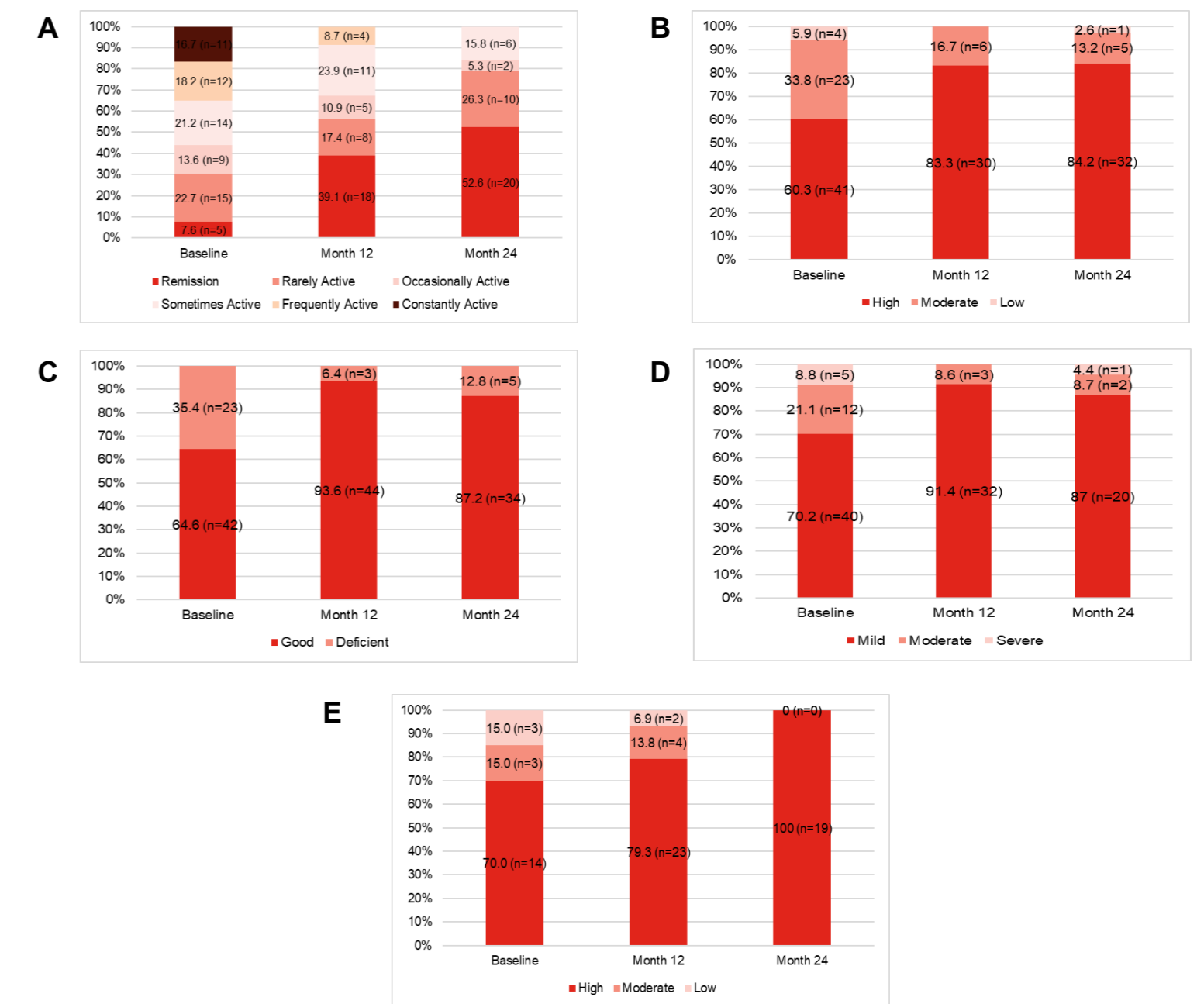


Table 2. Pearson correlations between scores from different PROMs

	FACIT-Fatigue	IBD Control	IBDQ32	IBDQ32 item*	MIBDI	WRFQ
FACIT-Fatigue		0,46	0,29	0,48	0,57	0,44
IBD Control	0,46		0,22	0,39	0,43	0,39
IBDQ32	0,29	0,22		0,32	0,27	0,24
IBDQ32 item*	0,48	0,39	0,32		0,45	0,43
MIBDI	0,57	0,43	0,27	0,45		0,46
WRFQ	0,44	0,39	0,24	0,43	0,46	

All correlations are significant (p<0.05). Coral, moderate (0.4-0.69); Light pink, mild (0.1-0.39). *Approximation of BU: How often have you been worried for fear of not finding a restroom nearby for the last two weeks?