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Validation of the Portuguese Version of IBD-Control Questionnaire and Comparison with IBD-Disk

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Keywords
IBD-Control · IBD-Disk · Inflammatory bowel disease · Patient-reported outcome measures

Abstract

Introduction: The IBD-Control questionnaire and IBD-Disk are two patient-reported outcome measures designed to evaluate the impact of inflammatory bowel disease (IBD) on different health domains. Unlike IBD-Disk, there is no fully published validated Portuguese version of IBD-Control. Furthermore, the two instruments have not yet been compared. We aimed to translate and validate IBD-Control in Portugal and compare it with IBD-Disk. ***Methods:*** After translation into Portuguese, the IBD-Control was administered to IBD patients, at baseline (T0), after 1–4 weeks (T1), and >3 months (T2). Patients also completed the Portuguese versions of the PRO2, EQ-5D, SIBDQ, and IBD-Disk. We assessed the reliability, validity, responsiveness, and interpretability of IBD-Control. We compared the usability (3 questions) and the ability to identify good disease control (area under the curve [AUC]) of IBD-Control and IBD-Disk. ***Results:*** At T0, the IBD-Control was completed by 142 patients (108 Crohn's disease, 34 ulcerative colitis). At T1 and T2, 68 and 101 patients completed the questionnaire, respectively. Factor analysis confirmed the one-dimensionality of the scale with 8 items (IBD-Control-8). Internal consistency (Cronbach's alpha) was 0.80. Test-retest reproducibility for stable patients ($n = 54$) was high (intraclass correlation coefficient-0.86). IBD-Control-8 significantly correlated (r between 0.55 and 0.82; $p \leq 0.001$) with PRO2, EQ-5D, SIBDQ and IBD-Disk. The variation in IBD-Control-8 between T0 and T2 correlated significantly (r between 0.48 and 0.53; $p \leq 0.01$) with the variation in PRO2 (only for Crohn's disease), SIBDQ and IBD-Disk. The IBD-Control-8 significantly discriminated between well and poorly controlled disease (15 ± 2 vs. 11 ± 4; $p < 0.001$). No significant differences were observed between IBD-Control-8 and IBD-Disk regarding usability and the ability to identify good disease control (AUC: −0.79 vs. 0.76, respectively). ***Conclusions:*** The IBD-Control is reliable and valid for measuring disease control from the perspective of patients with IBD in Portugal, presenting no significant differences regarding usability and assessment of disease control when compared to IBD-Disk.

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Validação da versão portuguesa do questionário IBD-Control e comparação com o IBD-Disk

Palavras Chave
IBD-Control · IBD-Disk · Doença inflamatória intestinal · Medidas de resultado reportados pelos doentes

Resumo

Introdução: Os questionários IBD-Control e o IBD-Disk são duas medidas de saúde reportada pelos doentes, destinados a medir o impacto da Doença Inflamatória Intestinal (DII) nos diferentes domínios da saúde. Contrariamente ao IBD-Disk, não existe uma versão Portuguesa do IBD-Control validada e totalmente publicada. Além disso, os dois instrumentos não foram comparados. Pretendemos traduzir e validar o IBD-Control em Portugal e compará-lo com o IBD-Disk. ***Métodos:*** Após tradução para Português, o IBD-Control foi administrado a doentes com DII, numa avaliação inicial (T0), após 1–4 semanas (T1) e >3 meses (T2). Os doentes preencheram também as versões portuguesas do PRO2, EQ-5D, SIBDQ e IBD-Disk. Avaliámos a fiabilidade, validade, responsividade e interpretabilidade do IBD-Control. Comparámos a usabilidade (3 perguntas) e a capacidade para identificar um bom controlo da doença (análise AUC) do IBD-Control e do IBD-Disk. ***Resultados:*** Em T0, o IBD-Control foi preenchido por 142 doentes com DII (108 doença de Crohn, 34 colite ulcerosa). Em T1 e T2, 68 e 101 doentes preencheram o questionário, respetivamente. A análise fatorial confirmou a unidimensionalidade da escala com 8 itens (IBD-Control-8). A consistência interna (alfa de Cronbach) foi de 0,80. A reprodutibilidade teste-reteste para doentes estáveis (n = 54) foi elevada (coeficiente de correlação intraclasse-0,86). O IBD-Control-8 correlacionou-se significativamente (r entre 0,55 e 0,82; $p \leq 0{,}001$) com o PRO2, EQ-5D, SIBDQ e IBD-Disk. A variação do IBD-Control-8 entre T0 e T2 correlacionou-se significativamente (r entre 0,48 e 0,53; $p \leq 0{,}01$) com a variação no PRO2 (apenas para a doença de Crohn), short-IBQ e IBD-Disk. O IBD-Control-8 discriminou significativamente a doença bem e mal controlada (15 ± 2 vs. 11 ± 4; $p < 0{,}001$). Não foram observadas diferenças significativas entre o IBD-Control e o IBD-Disk relativamente à usabilidade e à capacidade para identificação de doença bem controlada (AUC: –0,79 vs. 0,76, respetivamente). ***Conclusões:*** O IBD-Control é fiável e válido para medir o controlo da doença na perspetiva do doente com DII em Portugal, não apresentando diferenças significativas relativamente à usabilidade e avaliação do controlo da doença quando comparado com o IBD-Disk.

Introduction

Inflammatory bowel disease (IBD) is a group of diseases characterized by idiopathic and chronic inflammation of the gastrointestinal tract, which includes Crohn's disease (CD), ulcerative colitis (UC), and unclassified colitis [1–3]. An essential goal of IBD treatment is to achieve and maintain disease control to improve and thereby optimize quality of life (QoL). The optimal strategy to identify good disease control in clinical practice is still under debate [4, 5]. Nowadays, patient-reported outcomes measures (PROMs) are gaining increasing political and professional support as a means of informing day-to-day decisions and driving service quality. Although there are several validated PROMs to measure the impact of IBD from the patients' perspective, most of them are time-consuming and complex, making them difficult to apply in routine clinical practice [5].

In 2017, the IBD-Disk, a simplified adaptation of the Inflammatory Bowel Disease Disability Index, was developed to give an immediate visual representation of disability in IBD. This questionnaire has already been validated in several countries, including Portugal [6].

To quickly capture IBD-Control from the patient's perspective, in 2014, Bodger et al. [7] developed and validated a new PROM in the UK, named IBD-Control questionnaire, that measures overall disease control during the past 2 weeks. The IBD-Control questionnaire has been validated in other countries, such as the Netherlands and Spain [4, 8]. A recent study conducted in the UK has shown that IBD-Control has strong psychometric properties and can be applied to various populations [9]. As a screening tool completed by the patient, IBD-Control provides a quick and reliable means of identifying those in a quiescent state, and the individual items and summary scores have the potential to support efficient models of disease monitoring. The use of this questionnaire is recommended by the International Consortium for Health Outcomes Measurement [8].

As this questionnaire was developed and validated in an English-speaking culture, it is necessary to re-establish validity, reproducibility, and acceptability in the new national context because patients' responses to such instruments depend on underlying cultural trends [8]. To

date, there is no fully published validated Portuguese version of the IBD-Control questionnaire. Therefore, the aim of our study was to translate and adapt the IBD-control for use in Portuguese patients and to assess its reliability, validity, responsiveness, and interpretability. We also aimed to compare the usability and association with good disease control of IBD-Control and IBD-disk.

Materials and Methods

Scores

IBD-Control

The IBD-Control consists of five sections, including 4 sections with a total of 13 categorical items and a fifth section with a visual analog scale (VAS) ranging from 0 (worst possible disease control) to 100 (best possible disease control). Sections 1 and 3 are related to disease control during the past 2 weeks and consist of 8 categorical questions: the IBD-Control-8 score. These 8 questions derived from IBD-Control were selected for IBD-Control 8 because they correlated with other IBD PROMs and were designed to measure current health status. Section 2 addresses changes of bowel symptoms and section 4 evaluates additional treatment-related questions, such as side effects or difficulties using medication. As section 2 does not directly measure current health status and section 4 had only a weak correlation with other PROMs, in the original development paper, it was decided not to include them in the IBD-Control-8. A three-point scale is provided for each item ("yes," "no," and "not sure" or regarding changes in bowel symptoms: "better," "no change," or "worse"). The items of the IBD-Control-8 are scored as follows: least advantageous answer: 0 points, intermediate answer: 1 point, and most advantageous answer: 2 points, adding up to a total IBD-Control-8 subscore ranging from 0 points (worst control) to 16 points (best control) [7].

PRO2

Disease activity assessment utilized the PRO2 for CD and UC. PRO2-CD combines daily stool frequency (SF) and abdominal pain (AP) from the CDAI. According to STRIDE-II, most studies use SF ≤3 and AP ≤1 for clinical remission in CD [10]. PRO2-UC includes SF and rectal bleeding (RB) from the Mayo score, with SF = 0 and RB = 0 indicating UC clinical remission as per STRIDE-II [10].

SIBDQ

The Short Inflammatory Bowel Disease Questionnaire (SIBDQ), a concise version of the IBDQ, measures disease-specific QoL with 10 items on a seven-point scale. Scores range from 7 (poorest QoL) to 70 (most optimal QoL), with a 9-point increase typically considered a positive response [10–12].

EQ-5D

EQ-5D measures generic health-related QoL and consists of a descriptive system (5Q-5D index value) and a visual analog scale (EQ-5D-VAS). To calculate index values we used the Portuguese EQ-5D value set [13]. A higher index value reflects a higher level of health-related QoL. The EQ-5D-VAS records the patient's self-rated health on a vertical VAS where the endpoints are anchored on 100 = the best health you can imagine and 0 = the worst health you can imagine.

IBD-Disk

IBD-Disk consists of 10 questions that explore abdominal pain, regulating defecation, interpersonal interactions, education and work, sleep, energy, emotions, body image, sexual function, and joint pain. Each answer is marked on an 11-point visual scale, from 0 to 10, corresponding 0 to "absolutely disagree" and 10 to "absolutely agree." A higher score reflects a higher level of disease disability [6, 14].

Global Perceived Effect

The Global Perceived Effect (GPE) scale was coded as shown: 1 = "much better"; 2 = "better"; 3 = "somewhat better"; 4 = "no change"; 5 = "somewhat worse"; 6 = "worse"; and 7 = "much worse" [15].

Translation and Cross-Cultural Adaptation

The Portuguese version of IBD-Control was developed through a cultural adaptation process involving forward translation into Portuguese and backward translation into English. Two bilingual physicians proficient in both languages independently conducted this process, with the backward translator blinded to the original version. To ensure accuracy, an English-fluent IBD expert compared these two translated versions and the original version and conciliated them to have one final translated version. A pre-test was also performed on a sample of ten IBD patients, to check the ease of comprehension and cultural relevance of the items [16].

Study Design

Patients' Selection

The study population included patients diagnosed with CD or UC for at least 3 months, who were followed in the IBD outpatient clinic at Unidade Local de Saúde de Braga (ULS-Braga). Patients were excluded according to the

following criteria: unclassified IBD, age younger than 18 years, illiteracy, cognitive impairment or none or low fluency in Portuguese. From June to November 2023, patients who met the above criteria were consecutively invited to participate in the study during routine outpatient visits or daycare visits. Subsequent contacts were made by email and/or letter, according to patients' preferences.

Study Design

This was a prospective observational study, performed at the Gastroenterology Department of ULS-Braga. It was conducted in three sequential phases: at baseline (T0), 1–4 weeks (T1), and at least 3 months (T2) after baseline.

Form for Data Collection

Eligible patients received a brief presentation outlining the project's objectives. Upon obtaining oral and written consent, they completed the initial questionnaire set (T0). Subsequently, participants were contacted via letter or email at T1 and T2 to complete subsequent sets of questionnaires. All documents were pseudonymized using numerical codes assigned by the researchers. The baseline questionnaire set (T0) included PRO2 for CD and UC, Portuguese version of SIBDQ, EQ-5D, IBD-Disk, and IBD-Control, along with three questions comparing the usability of IBD-Disk and IBD-Control. The second set (T1) included PRO2 for CD and UC, the Portuguese version of SIBDQ and IBD-Control. The third set (T2) included PRO2 for CD and UC, Portuguese SIBDQ, IBD-Disk, and IBD-Control, and a question related to patient clinical status evolution using the GPE. The socio-demographic and clinical characteristics of the participants were collected from the electronic medical record.

Statistical Analysis

There is no consensus on the number of subjects required to assess the psychometric properties of health measurement instruments, but a sample with 7 times the number of items and ≥100 patients has been recommended. A sample of at least 50 patients has been recommended to assess reliability [16]. Considering that the IBD-Control questionnaire has 13 categorical items and one VAS, the minimum number of patients requested for our study would be 100 patients.

The personal and clinical data collected were recorded in an anonymous database using the software Microsoft Excel. Statistical analysis was performed using IBM® SPSS® Statistics, version 27, with a type I error of 0.05 for inferential statistics. All quantitative variables were evaluated for normality using the Kolmogorov-Smirnov test, combined with a visual assessment of histograms and skewness and kurtosis measures. For descriptive statistics, all normally distributed variables were described using mean ± standard deviation; for non-normally distributed variables' location measures were used, namely median and interquartile range (IQR). For qualitative variables, absolute and relative frequencies were used for descriptive analysis.

Acceptability and Missing Data

Acceptability of IBD-Control was assessed by reporting the proportion of questionnaires with complete filling (completion rate), as well as the number of answers per item. Patients with incomplete questionnaires were contacted upon receipt of the questionnaire and invited to complete the data on the same day. In our study, we included only patients with complete questionnaires for the analysis. The average response time was also assessed Methodological testing and evaluation of measurement properties of IBD-Control was performed following the COSMIN checklist [16].

Item Reduction and Data Structure

A principal component analysis (PCA) was performed to confirm the one-dimensionality of the IBD-Control 8. The scree plot of eigenvalues was used to determine the number of components. Items with factor loading <0.4 were considered for deletion.

Internal Consistency

The internal consistency of the IBD-Control-8 was assessed using Cronbach's alpha. A score between 0.70 and 0.90 was considered desirable [8]. The item-total correlation was also calculated to test whether the individual items correlated with the total. A score >0.3 is considered desirable [8]. In addition, we also evaluated the correlation between individual items and the total score of IBD-Control-8 and IBD-Control-VAS.

Test-Retest Reliability

In patients with a stable disease status between T0 and T1, we analyzed test-retest reliability with the intraclass correlation coefficient (ICC). In order to identify patients with no change in disease status, we followed the criteria of the original study of Bodger et al. [7]: transition question (question 2) of the IBD-Control answered as "no change" and ≤10 points change on the SIBDQ total score. An ICC between 0.60 and 0.75 was classified as "good" and an ICC >0.75 as "excellent" [6].

The standard error of measurement (SEM) of the test-retest reliability was calculated as SD × $\sqrt{1}$-ICC, where SD is the standard deviation of all scores from the participants. SEM was converted into the smallest detectable change (SDC), which reflects the smallest within-individual change in score that can be interpreted as a "real" change, above the measurement error, in one individual (SDCind = SEM × 1.96 × $\sqrt{2}$) and a group of individuals [SDCgroup = (SEM × 1.96 × $\sqrt{2}$)/$\sqrt{n}$].

Construct Validity

The construct validity of the IBD-Control was assessed by determining Spearman's correlation coefficients of IBD-Control-8 and IBD-Control-VAS with QoL (EQ-5D and SIBDQ), disability (IBD-Disk), and clinical disease activity (PRO2) measures. We anticipated positive correlations with QoL measures and negative correlations with disability and clinical disease activity measures. Furthermore, we expected correlations with disease-specific QoL (SIBDQ) to be stronger than with generic QoL (EQ-5D).

Responsiveness

The responsiveness was tested by measuring change scores between T0 and T2 in IBD-Control-8 and IBD-Control-VAS compared with change scores of PRO2, IBD-Disk and SIBDQ. Next, we calculated the effect size (size of change scores/SD of baseline score) and the standardized response mean (size of change scores/SD of change scores). An effect size <0.2 was considered small, 0.5 as medium and ≥0.8 as large [8]. In order to calculate effect size, as there is no true external gold standard to define a change in disease control, we used a GPE scale to define a change in health state between T0 and T2. Only patients reporting scores as "no change" were considered stable. Patients reporting scores as "much better," "better" or "somewhat better" were considered improved in their condition. Patients reporting scores as "much worse," "worse" or "somewhat worse" were considered worse in their condition.

Interpretability

For interpretability, ceiling and floor effects were assessed. A ceiling effect was present when more than 15% of answers had the highest possible score; a floor effect was present when more than 15% of answers had the lowest possible score [6].

We also tested whether the IBD-Control differentiates between patients with well-controlled disease and patients with poor disease control. We defined well-controlled disease using a combination of the following parameters: PRO2 of remission, SIBDQ score >53 and no bowel symptoms worsening in the past 2 weeks (IBD-Control Q2). Differences between the IBD-Control-8 and IBD-Control-VAS of the two disease states were tested with an independent-sample *t* test.

Accuracy to Identify Good Disease Control

To assess the accuracy of the IBD-Control to identify good disease control, receiver operating characteristic (ROC) analysis was used. We used the above-mentioned criteria to define good disease control. The cut-off value with the highest specificity × sensitivity was selected. To analyze discriminative accuracy, the area under the curve (AUC) was calculated. An AUC of 0.7–0.9 indicates moderate accuracy, and an AUC >0.9 indicates high accuracy [8].

Comparison of IBD-Control and IBD-Disk

We compared usability and ability to identify good disease control of IBD-Control and IBD-Disk. Usability was compared through three questions extracted from the System Usability Scale (SUS) [17]:

1. Which of the following questionnaires is easier to complete (i.e., easier to understand and faster to complete)?
2. Which of the following questionnaires best reflects the impact of your bowel disease on your life?
3. Which of the following questionnaires would you be willing to fill out regularly to monitor your bowel disease?

To each question, patients were asked to choose between IBD-Control and IBD-Disk. Ability to identify good disease control was compared through comparison of AUC of IBD-Control and IBD-Disk.

Ethical Considerations

The research protocol was approved by the Ethics Subcommittee for Health of the ULS-Braga. Informed consent was obtained from all patients.

Results

Translation and Cross-Cultural Adaptation of IBD-Control Questionnaire

An English-fluent IBD expert compared the translated and original versions of the IBD-Control to identify and correct potential errors in terms of content, interpretation and language. Thereafter, the sample of ten patients reported ease of comprehension and relevance of all items. No alterations were required in either steps. The

Table 1. Baseline characteristics of the patients

Socio-demographic and clinical characteristics of included patients	
Age, median (IQR), years	35.9 (13.6)
Sex, *n* (%)	
Female	55 (38.7)
Male	87 (61.3)
Level of education, *n* (%)	
Elementary school	5 (3.5)
Middle school	22 (15.5)
High school	62 (43.7)
Bachelor's degree	35 (24.6)
Master's degree	18 (12.7)
Professional status, *n* (%)	
Student	23 (16.2)
Employed	101 (71.1)
Unemployed	7 (4.9)
Retired	5 (3.5)
On sick leave	6 (4.2)
IBD type, *n* (%)	
UC	34 (23.9)
CD	108 (76.1)
Previous surgery, *n* (%)	
No surgery	108 (76.1)
Bowel surgery	18 (12.7)
Perianal surgery	12 (8.5)
Bowel surgery and perianal surgery	4 (2.8)
Active perianal fistula	23 (16.2)
Stoma	11 (7.7)
Current treatment, *n* (%)	
Oral mesalazine	23 (16.2)
Rectal mesalazine	7 (4.9)
Oral corticosteroid	3 (2.1)
Topical corticosteroid	0 (0.0)
Azathioprine	40 (28.2)
Methotrexate	3 (2.1)
Infliximab	126 (88.7)
Adalimumab	1 (0.7)
Vedolizumab	8 (5.6)
Ustekinumab	2 (1.4)
Tofacitinib	0 (0.0)
Others	1 (0.7)

IQR, interquartile range; IBD, inflammatory bowel disease.

final version of the Portuguese version of the IBD-control is included in online supplementary File A (for all online suppl. material, see https://doi.org/10.1159/000541219).

Sample Characterization

A total of 142 patients were included at T0, 108 with CD and 34 with UC. The socio-demographic and clinical characteristics of included patients are presented in Table 1.

Acceptability and Missing Data

At T0, all 142 questionnaires were completely fulfilled. At T1, 68 patients completed the IBD-Control questionnaire, with missing values in five questionnaires (completion rate 92.6%). At T2, 101 patients completed the IBD-Control questionnaire, with eleven questionnaires with missing data (completion rate 89.1%). Overall completion rate was 295/311 (94.9%). The most unfilled questions were Q2 ($n = 5$), the VAS ($n = 4$), and Q3e ($n = 3$). All questionnaires were reviewed for missing values and patients were asked to fulfill the unanswered questions on the same day. After this process, all patients completed the missing data and were included. Completion time of IBD-Control was measured in a sample of 15 patients (aged between 21 years and 67 years) with a mean ± SD completion time of 2.8 ± 1.6 min (range: 1–6 min).

Item Reduction and Data Structure

All 8 items of the IBD-Control-8 were included in the PCA analysis. We identified a single component, that explained 42.5% of the total variance. Scree plot eigenvalue analysis by number of components confirmed that one component is adequate for the underlying construct. All items showed factor loadings on the main component over 0.4, meaning that all items should be included in the overall score for IBD-Control-8.

Internal Consistency

With the inclusion of all 8 items in the IBD-Control, a value of 0.80 was observed for Cronbach's alpha. Performing the one-at-a-time removal procedure, Cronbach's alpha varied between 0.76 and 0.80 confirming that all items contribute to the construct.

The correlation coefficients between the individual IBD-Control-8 questions and IBD-Control-8 total score and IBD-Control-VAS at T0 are all statistically significant (r: 0.370–0.679, with the exception of Q1b) (Table 2). The correlation coefficient between the IBD-Control-8 total score and IBD-Control-VAS at T0 was also statistically significant (Table 2).

Test-Retest Reliability

Sixty-eight patients repeated the questionnaire at T1 to assess reliability. Of these 68 patients, 54 fulfilled both criteria for stable disease described above. In this subset of patients, we obtained an ICC of 0.86 (95% CI: 0.76–0.91) for IBD-Control-8 and 0.72 (95% CI: 0.51–0.84) for IBD-Control-VAS, demonstrating an excellent and good test-retest reliability, respectively.

Table 2. Correlation between individual items and total score of IBD-Control-8 and IBD-Control-VAS at T0

Question	IBD-Control-VAS	Item-total correlation
Q1a Do you believe that your IBD has been well controlled in the past 2 weeks?	0.545	0.566
Q1b Do you believe that your current treatment is useful in controlling your IBD?	0.225	0.286
In the past 2 weeks, did you		
Q3a ... miss any planned activities because of IBD?	0.407	0.549
Q3b ... wake up at night because of symptoms of IBD?	0.425	0.493
Q3c ... suffer from significant pain or discomfort?	0.632	0.599
Q3d ... often feel lacking in energy (fatigued)?	0.370	0.504
Q3e ... feel anxious or depressed because of your IBD?	0.432	0.587
Q3f ... think you need a change to your treatment?	0.395	0.528
IBD-Control-8	0.679	

All value with $p \leq 0.01$. IBD, inflammatory bowel disease; VAS, visual analog scale.

Measurement Error

Considering the value of ICC for IBD-Control-8, we obtained an SEM of 0.45 (95% CI: 0.32–0.52), an SDCind of 1.25 (95% CI: 0.89–1.44), and an SDCgroup of 0.17 (95% CI: 0.12–0.20). Considering the value of ICC for IBD-Control-VAS, we obtained an SEM of 4.05 (95% CI: 3.09–5.30), an SDCind of 11.23 (95% CI: 8.57–14.69), and an SDCgroup of 1.53 (95% CI: 1.17–2.08).

Construct Validity

We found a significant correlation between IBD-Control-8 and SIBDQ, EQ-5D index value, EQ-5D-VAS, IBD-Disk and PRO2 (r range = 0.554–0.817; $p < 0.001$) (Table 3). The IBD-Control-VAS also showed a significant correlation with SIBDQ, EQ-5D index value, EQ-VAS, IBD-Disk and PRO2-CD (r range = 0.517–615; $p < 0.001$) (Table 3). The correlation between IBD-Control-VAS and PRO2-UC was not significant.

As anticipated, we obtained positive correlations with EQ-5D and SIBDQ and negative correlations with IBD-Disk and PRO2. As expected, we found stronger correlations of IBD-Control with SIBDQ than with EQ-5D.

Responsiveness

A total of 101 patients (71.1%) completed the IBD-Control-8 and IBD-Control-VAS at T2. Change scores of IBD-Control-8 and IBD-Control-VAS between T0 and T2 correlated significantly (r values ranging from 0.33 to 0.55) with change scores of PRO2-CD, SIBDQ and IBD-Disk (Table 4). The correlation between change scores of IBD-Control-8 and IBD-Control-VAS and PRO2-UC was not significant.

Responsiveness analyses showed effect sizes for IBD-Control-8 ranging from 0.28 to 0.88 and for IBD-Control-VAS ranging from 0.02 to 1.58 (Table 5). The effect size of the IBD-Control-8 and IBD-Control-VAS was larger for patients who worsened versus patients who improved.

Interpretability

No floor effect was found for any score or assessment moment (T0, T1, or T2), but a ceiling effect was found for IBD-Control-8 at T0 (32%), T1 (44%) and T2 (36%) and for IBD-Control-VAS at T0 (17%) e T1 (16%). As expected, mean IBD-Control-8 and IBD-Control-VAS at T0 were significantly higher in patients with good disease control when compared to patients with poor disease

Table 3. Construct validity

PROM	IBD-Control-8	IBD-Control-VAS
SIBDQ	0.817*	0.615*
EQ-5D index value	0.750*	0.550*
EQ-VAS	0.609*	0.517*
IBD-Disk	−0.760*	−0.572*
PRO2 (Crohn disease)	−0.577*	−0.553*
PRO2 (UC)	−0.554*	−0.223

IBD, inflammatory bowel disease; PRO, patient-reported outcome; PROM, patient-reported outcome measures; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; VAS, visual analog scale. *$p \leq 0.01$.

Table 4. Pearson's correlation between change scores (T0–T2) in IBD-Control-8 and IBD-Control-VAS and PRO2, SIBDQ, and IBD-Disk

	PRO2-DC	PRO2-UC	SIBDQ	IBD-Disk
IBD-Control-8	−0.52*	−0.23	0.55*	−0.53*
IBD-Control-VAS	−0.53*	−0.02	0.35*	−0.33*

IBD, inflammatory bowel disease; PRO, patient-reported outcome; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; VAS, visual analog scale. *$p < 0.01$.

control (mean IBD-Control-8: 14.7 ± 1.69 vs. 10.86 ± 4.13, $p < 0.001$; IBD-Control-VAS: 90.0 ± 11.21 vs. 75.25 ± 18.13, $p < 0.001$).

Accuracy to Identify Good Disease Control

At baseline, 63 of 142 (44.4%) patients could be categorized as having good disease control. The ROC showed an optimal cut-off point for IBD-Control-8 of ≥14 points to identify good disease control with 85.7% sensitivity and 62% specificity, whereas for IBD-Control-VAS a cut-off of ≥87 points achieved 76.2% sensitivity and 67.1% specificity. The AUC for IBD-Control-8 was 0.79 (95% CI: 0.71–0.86), whereas for IBD-Control-VAS was 0.74 (95% CI: 0.66–0.82), both statistically significant with no difference between the two scores (shown in Fig. 1).

Comparison of IBD-Control and IBD-Disk

The IBD-Control questionnaire was chosen as the easiest to understand and quickest to fill in by 61.9% of the participants. However, 55.9% of participants believe that the IBD-Disk questionnaire best reflects the impact of their bowel disease on their lives. Regarding the questionnaire that patients would be willing to fill in regularly to monitor their bowel disease, 52.8% preferred IBD-Control over IBD-Disk.

The AUC for IBD-Disk to identify good disease control was 0.76 (95% CI: 0.68–0.84), being statistically significant (shown in Fig. 1). When comparing the ROC curves, the AUC of IBD-Disk was not significantly different from the AUC of IBD-Control-8 ($p = 0.448$) and IBD-Control-VAS ($p = 0.686$).

Discussion

This study provides evidence for the internal consistency, reliability, construct validity, responsiveness, and discriminant ability of the IBD-Control in the Portuguese population, supporting its implementation and use in daily IBD practice. In this study, we observed good acceptability demonstrated by the short completion time and high completion rates.

PCA confirmed the one-dimensionality of IBD-Control-8 showing that all 8 items should be included in the total score of the questionnaire. Reliability was confirmed by high internal consistency (Cronbach's α-0.80), item-total correlation of all items (except Q1b) over 0.3 and good to excellent test-retest reliability. The correlation between the IBD-Control-8 and IBD-Control-VAS was significant and moderate. These findings are consistent with previous studies [7, 8]. The SDCind was 1.25 and 11.23 for IBD-Control-8 and IBD-Control-VAS, respectively, indicating that only changes above that value can be considered significant clinical changes at the individual level. The SDCgroup was 0.17 and 1.53 for IBD-Control-8 and IBD-Control-VAS, respectively, meaning that changes in the mean score of IBD-Control above this value can be detected with 95% confidence.

Regarding construct validity, as anticipated, significant strong correlations were found between IBD-Control-8 and SIBDQ, EQ-5D index value, EQ-VAS, IBD-Disk, and PRO2 for both CD and UC. Similarly, IBD-Control-VAS exhibited strong correlations with these measures in CD, while the correlation with PRO2 in UC was not significant. This may be due to the small sample size of UC patients. Previous studies with a larger sample of patients demonstrated a correlation of IBD-Control-VAS with clinical activity in UC, evaluated through the Short Clinical Colitis Activity Index [7, 8].

Table 5. Responsiveness analyses for the IBD-Control-8 and IBD-Control-VAS in patients who improved or worsened according to the GPE criteria

Criteria for change in state	*N*	Mean difference (SD)	Effect size	Standardized response mean
IBD-Control-8				
GPE				
Improved (GPE 1–3)	39	1.154 (2.969)	0.28	0.39
No change (GPE 4)	54	−0.037 (2.273)	0.01	0.02
Worsened (GPE 5–7)	8	−3.625 (3.662)	0.88	0.99
IBD-Control-VAS				
GPE				
Improved (GPE 1–3)	39	0.256 (11.468)	0.02	0.02
No change (GPE 4)	54	−5.463 (12.599)	0.34	0.43
Worsened (GPE 5–7)	8	−24.375 (29.452)	1.58	0.83

GPE, Global Perceived Effect Scale; IBD, inflammatory bowel disease; *N*, number; SD, standard deviation; VAS, visual analog scale.

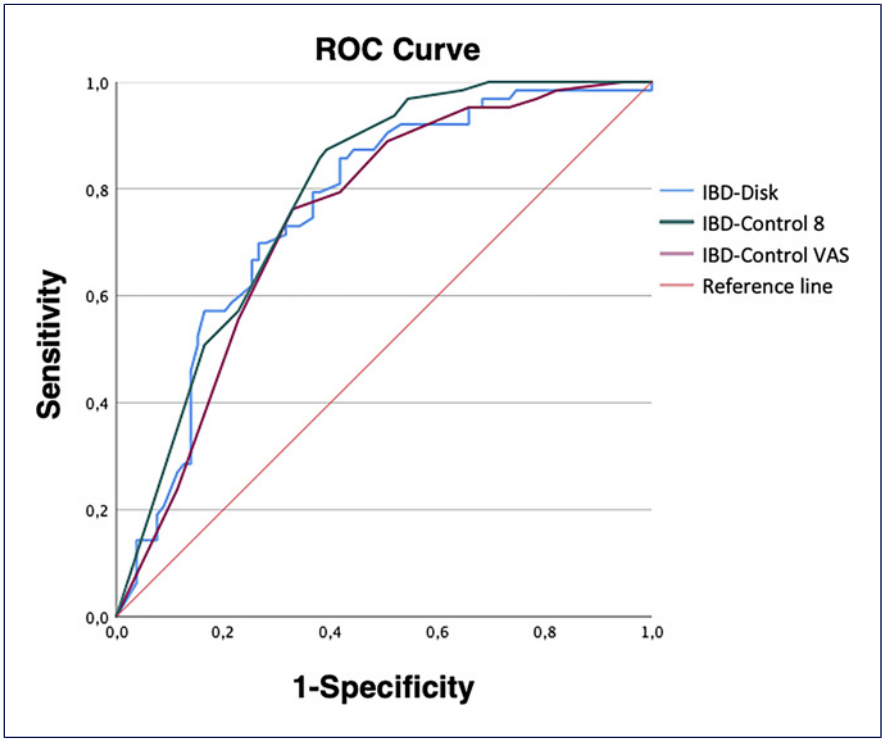

Fig. 1. IBD-Control-8, IBD-Control-VAS, and IBD-Disk as a screening tool for good disease control. Receiver operating characteristic (ROC) curves for the IBD-Control-8, IBD-Control-VAS, and IBD-Disk using strict pre-specified criteria for good disease control AUC for IBD-Control-8 was 0.79, for IBD-Control-VAS was 0.74, and for IBD-Disk was 0.76.

The responsiveness of the IBD-Control was demonstrated by significant correlations between changes in IBD-Control-8 and IBD-Control-VAS and key external outcome measures (PRO2-CD, SIBDQ, and IBD-Disk) and larger effect sizes of IBD-Control-8 and IBD-Control-VAS for patients experiencing deterioration. The smaller effect size of IBD-Control-8 and IBD-Control-VAS in patients showing improvement suggests potential limitations in detecting improvement of disease control. These findings suggest that IBD-Control may be particularly useful for detecting deterioration of disease control. This difference in responsiveness of IBD-Control may be due to various

factors. The questionnaire's design may inherently emphasize aspects related to disease exacerbation, potentially introducing a bias toward detecting negative changes. Patient perception on deterioration and improvement of disease may also contribute as improvement might be less noticeable or consistently reported than deterioration. Interestingly, in the study by Bodger et al. [7], responsiveness analyses showed larger effect size of IBD-Control for improvement versus deterioration. By contrast, the study by de Jong et al. [8] showed larger effects size of IBD-Control for deterioration versus improvement. Further studies should clarify this discrepancy.

Both IBD-Control-8 and IBD-Control-VAS significantly discriminated patients with good and poor disease control, with the former consistently obtaining higher values. This suggests that IBD-Control may provide healthcare professionals with a valuable tool to accurately assess and monitor the effectiveness of treatment interventions for IBD. The use of IBD-Control may also have other clinical implications as individuals demonstrating good disease control may reduce face-to-face appointments, increasing patients' QoL and reducing the IBD burden. Our study identified an optimal cut-off of 14 points in the IBD-Control-8 to identify good disease control, which is similar to data of previous studies (13 and 14 points). Regarding the IBD-Control-VAS, we have identified an optimal cut-off of 87 points. This value only slightly deviates from previous studies, which had values between 82 and 85 points [4, 7, 8].

The comparative analysis between IBD-Control and IBD-Disk provided valuable insights regarding the choice of PROMs in the context of IBD. Almost two-thirds of patients found IBD-Control to be the easiest to understand and the quickest to complete. However, a little over half the patients expressed the belief that IBD-Disk more accurately captures the impact of their disease on their lives. This highlights a nuanced balance between ease of use and perceived depth of information of the two PROMs. Patient preferences for regular monitoring further underscore this nuanced decision-making process, with only a slight majority of participants preferring IBD-Control. This indicates that patient engagement with the monitoring process may be influenced by factors beyond ease of use, such as the perceived relevance in reflecting the holistic impact of IBD.

IBD-Disk is a PROM that assesses disability associated with IBD, while IBD-Control questionnaire can capture the impact of intestinal and some extra-intestinal symptoms, as well as the patient's perspective about disease control. Despite recognizing that these two tools measure different constructs, they both try to provide a holistic evaluation of IBD patient, and thus, they should correlate with disease activity. We compared the association between these PROMs and good disease control (a proxy of disease activity). The analysis of the AUC values showed no statistical difference between IBD-Control and IBD-Disk, further emphasizing that both can be used to identify quiescent state and that the choice can be individualized based on assessment goal and patient's preference. Different PROMs should be proposed to patients, to decide the most appropriate for a certain patient. Probably, for younger patients and patients with extra-intestinal manifestations, such as fatigue or articular pain, IBD-Disk may be more suitable because it can capture more accurately how these domains impact the patient's life.

Our study has certain limitations: single-center study; high proportion of patients in remission and under biologics; low number of UC patients. It is important to interpret the results in the context of these limitations as these factors may limit the generalizability of our findings to the broader Portuguese IBD population and UC. Furthermore, the evaluation of the impact of IBD on patients' lives using IBD-Control is restricted by unexplored confounding factors in this study. In particular, certain items such as question 3c (experiencing pain or discomfort), d (feeling tired), or e (experiencing anxiety or depression) may be influenced by external factors unrelated to IBD. Excluding critical data on psychiatric disorders, somatic comorbidities, smoking, regular physical activity, and anxiolytic and antidepressant medication limits the evaluation of their impact on IBD-Control. This further emphasizes the need for future research to include these unexamined factors in order to explore their impact on the robustness of IBD-Control questionnaire on the monitoring of disease control. Future research should also adopt a multicenter approach and use a larger sample of patients with UC, in order to allow comparison with the CD group and use objective markers of disease activity, such as fecal calprotectin and endoscopy.

Despite the mentioned limitations, a recent study conducted by Gebeyehu et al. [9] with a sample of more than 7,000 IBD patients validated the IBD-Control-8 questionnaire in various contexts, particularly regarding the type of intestinal disease, gender, age and comorbidities of the participants.

In conclusion, the IBD-Control showed to be reliable and valid for measuring disease control from the perspective of patients with IBD in Portugal, allowing it to be a potential and rapid tool for identifying patients with good disease control. Additionally, the comparable usability and accuracy of IBD-Control and IBD-Disk highlights the importance of considering diverse perspectives when selecting PROMs.

IBD-Control questionnaire is one more tool that can be use in daily practice to take a holistic approach to IBD.

This PROM can approach social, physical, psychological, and treatment domains helping physician evaluation to be more patient-centered than disease-centered. According to our data, it seems to be easier to interpret and fill in than IBD-Disk. Thus, it can be more appropriate to assess the global impact of IBD in patients with more difficulties in completing questionnaires, such as older patients.

Statement of Ethics

The study protocol was reviewed authorized by the ULS-Braga Ethics Committee, Approval No. 170/2023. A written informed consent was obtained from all participants. The authors declare that the procedures followed were in accordance with the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

T.C. and J.F. were responsible for the data analysis, data collection, and drafting of the manuscript. A.G. and J.D. were responsible for the collection and analysis of the data and helped drafting the manuscript. J.S. and R.G. were responsible for the design of the study and interpretation and critical revision of the work for important intellectual content. All authors approved the final version to be published and agreed to be accountable for all aspects of the work.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author, Tânia Carvalho. The data are not publicly available since it can contain information that could compromise the privacy of research participants.

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