



## Original Article

# Quality of life of patients with inflammatory bowel disease using immunobiological therapy



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### ABSTRACT

**Objectives:** To assess the quality of life of patients diagnosed with inflammatory bowel disease (IBD) using immunobiological therapy and to relate the general and domain scores of the Inflammatory Bowel Disease Questionnaire (IBDQ) to the immunobiological drug in use and the clinical and sociodemographic variables.

**Methods:** This was a descriptive observational cross-sectional study, conducted from June to September 2018 in a tertiary hospital in Sergipe, which included 47 patients with a diagnosis of Crohn's disease. The IBDQ questionnaire was applied together with a sociodemographic questionnaire, and the clinical data and the history of the disease were analyzed.

**Results:** Female, mixed-race, married patients from the countryside of the state of Sergipe, Brazil, who had never undergone any intestinal surgery, represented most of the study participants. 24 patients were on infliximab and 23 were on adalimumab. Variables such as gender, type of immunobiological drug and duration of its use, and association of therapy with other medications were shown to statistically significantly influence the report quality of life ( $p$ -value < 0.05).

**Conclusion:** Further studies with larger samples are necessary to allow a more accurate delimitation of the impact of clinical and sociodemographic variables on the quality of life of patients with inflammatory bowel disease.

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### Qualidade de vida de pacientes com doença inflamatória intestinal em uso de terapia imunobiológica

#### RESUMEN

**Objetivos:** Avaliar a qualidade de vida de pacientes diagnosticados com doença inflamatória intestinal (DII) em uso de terapia imunobiológica e relacionar o escore geral e por domínios do "Inflammatory Bowel Disease Questionnaire" (IBDQ) com o imunobiológico em uso e as variáveis clínicas e sociodemográficas.

#### Palabras clave:

Doença inflamatória intestinal

Qualidade de vida

Imunobiológicos

Doença de Crohn

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**Métodos:** Estudo observacional descritivo analítico transversal, realizado no período de junho a setembro de 2018, em hospital terciário de Sergipe, que incluiu 47 pacientes com diagnóstico de Doença de Crohn. Foi aplicado o questionário IBDQ, associado a um questionário sociodemográfico e analisados os dados clínicos e da história da doença.

**Resultados:** Pacientes do sexo feminino, pardos, casados, procedentes do interior de Sergipe e que nunca foram submetidos a nenhuma cirurgia intestinal representaram a maioria dos participantes do estudo. 24 pacientes estavam em uso de Infiximabe e 23 em uso de Adalimumabe. Variáveis como o gênero, tipo de imunobiológico e duração de seu uso e associação da terapêutica com outras medicações mostraram influenciar a qualidade de vida relatada, com significância estatística ( $p$ -valor < 0,05).

**Conclusão:** Novos estudos com amostras maiores são necessários para que se possa permitir uma delimitação mais acurada do impacto de variáveis clínicas e sociodemográficas na qualidade de vida dos pacientes com doença inflamatória intestinal.

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## Introduction

Inflammatory bowel diseases (IBD) are a group of diseases best represented by ulcerative colitis (UC) and Crohn's disease (CD). Despite their higher incidence in more developed regions, in recent years they have become more prevalent in developing countries, which may be related to the Westernization of lifestyle, which includes changes in diet and smoking, as well as variations in sun, pollution, and chemical exposure<sup>1</sup>; this increase cannot be attributed solely to the improvement of diagnostic propaedeutics.<sup>2</sup>

The main current hypothesis for IBD etiology emphasizes the genetic predispositions in the dysregulation of the gastrointestinal immune system, also indicating an inescapable influence of the environment.<sup>2</sup> The course of IBD is of exacerbation and inflammation remission with symptoms characterized by chronic abdominal pain, diarrhea, and weight loss.<sup>3</sup>

Treatment is essentially clinical and has been evolving in the last decade with the advent of immunobiological drugs, which are the last generation therapeutic weapon in the treatment of IBD, reducing complications, hospitalizations, and need for surgery.<sup>3,4</sup>

Quality of life is determined by the extent to which ambitions and hopes correspond to personal experience; by the individual's perceptions of their position in life, taking into account the context of culture and the value systems in which the person lives, in relation to their goals, expectations, standards, and concepts, assessing the current state in relation to the ideal and what these individuals regard as important factors in their lives.<sup>5,6</sup> Inflammatory bowel diseases may hinder work activities and reduce social interaction due to factors such as profuse chronic diarrhea, asthenia, abdominal pain, hyporexia, hospitalizations, and even adverse effects of medications used in therapy, thus affecting patient-reported quality of life.<sup>7</sup>

In Brazil, there is a shortage of studies that assess the quality of life of these patients; this is further intensified when considering the reality of the state of Sergipe. Another relevant

factor is the high cost of drugs such as infliximab and adalimumab for national and global public healthcare systems,<sup>3</sup> which reinforces the need for studies that analyze their impact on patients' quality of life.

Therefore, the present study aimed to assess the quality of life of patients diagnosed with IBD using immunobiological therapy, to list the sociodemographic aspects of the patients studied, and to associate the general score and the domains of the Inflammatory Bowel Disease Questionnaire (IBDQ) with the immunobiological drug in use (adalimumab or infliximab) and with the clinical and sociodemographic variables under study.

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## Methods

This was an observational descriptive cross-sectional study, carried out from June to September 2018, at the University Hospital of the Universidade Federal de Sergipe.

### Patients

The study included 47 randomly chosen patients who met the inclusion criteria.

Inclusion criteria: patients diagnosed with IBD (CD or UC, diagnosed according to conventional clinical, endoscopic, radiological, and histological criteria),<sup>8</sup> aged above 18 years, who agreed to participate in the study by signing an informed consent form, and who were in use of immunobiological therapy (infliximab or adalimumab), at the University Hospital of the Universidade Federal de Sergipe.

Exclusion criteria: Pregnant patients, those who were breastfeeding, those with neuromotor physical limitations, diabetes, heart failure, chronic obstructive pulmonary disease, and/or history of alcoholism or ostomy surgery.

The study followed the ethical standards set forth by Resolution 416/12 of the National Health Council. It was approved by the Research Ethics Committee of the Universidade Federal de Sergipe under the number 90516918.4.0000.5546.

### Quality of life assessment

All interviews were conducted by a single interviewer. The IBDQ questionnaire was applied to assess the quality of life related to IBD aspects. Furthermore, a sociodemographic questionnaire was also applied, which included the main variables of importance for the study: age, race, gender, marital status, smoking history, and city of origin.

Finally, the following factors were analyzed through clinical data and the history of the disease: immunobiological drug in use, clinical diagnosis, need for prior surgery, total time of disease, total duration of immunobiological drug use, location of the disease, and other medications currently in use.

The IBDQ questionnaire was initially developed and validated in Canada in 1989.<sup>9</sup> It consists of 32 items divided into four domains: intestinal symptoms (10 items), systemic symptoms (five items), social aspects (five items), and emotional (12 items), and the responses are presented in the form of multiple choice, with seven alternatives. A score of 1 indicates the worst quality of life and 7, the best.<sup>6</sup> The score reflects the quality of life of the post two weeks, so that a simple sum of all domains results in the total score obtained by the patient, which can range between 32 and 224 points. The version used in this study was translated and validated for the Brazilian Portuguese language in 2004, being a reliable and reproducible instrument for the evaluation of the quality of life of Brazilian patients with IBD.<sup>10</sup>

### Statistical analysis

Categorical variables were described as absolute and relative frequencies and percentages. Continuous variables were described as means, standard deviations, and minimum and maximum values. Mean differences were tested using the Mann-Whitney test. Correlations between continuous variables were tested and quantified using Spearman's correlation. Linear regressions for IBDQ and its domains were adjusted using the Backward method of variable selection. The significance level adopted was 5%, and the statistical software used was the R Core Team 2018.

## Results

### Characteristics of the patients studied

The study included 47 patients, all of whom had a diagnosis of CD (24 using infliximab and 23 using adalimumab). The mean age of the patients studied was 41.3 years; the youngest patient was 19 years old, while the oldest patient was 70 years old. Regarding gender and race, 59.6% of the patients were female, and 59.6% declared themselves to be mixed-race. Of all patients, 55.3% were married and 53.2% were from the countryside of Sergipe, while 44.7% were from the capital, Aracaju, and 2.1% came from other states. A total of 48.9% of the patients had undergone some surgery due to CD and 29.8% declared current and/or previous smoking.

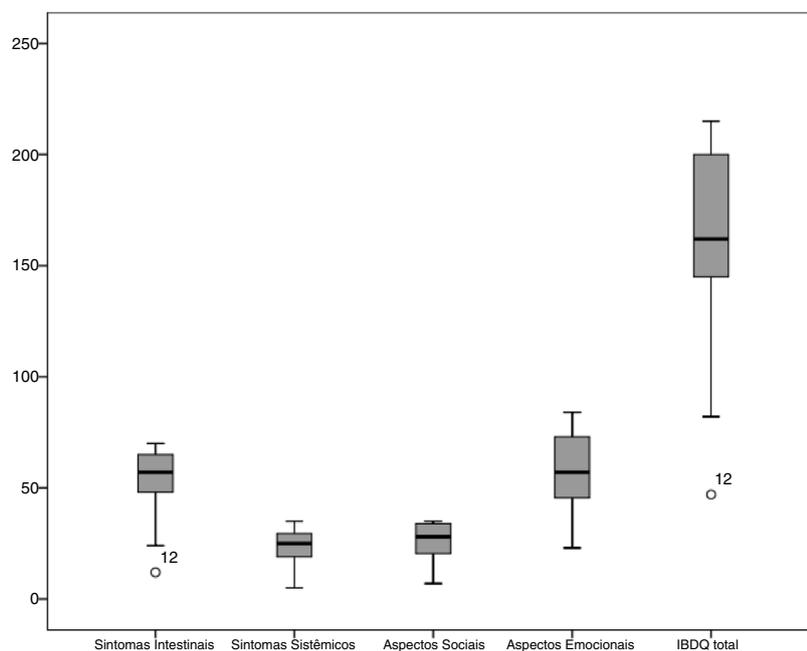
Of the patients using adalimumab, five (21.7%) had previously used infliximab. Regarding the location of the disease, 53.2% had large and small intestine involvement. The mean time since diagnosis was of 8.1 years; in turn, the mean duration of immunobiological drug use was 39.9 months. Other CD medications were used by 70.2%; 59.6% of the interviewees used azathioprine, 29.8% mesalazine, and 2.1% corticosteroid.

Table 1 summarizes the clinical and sociodemographic characteristics of the patients studied.

**Table 1 – Sociodemographic and clinical characteristics of patients with IBD using immunobiological therapy.**

	Mean	SD
Age (years) (19–70)	41.3	13.4
Time since diagnosis (years)	8.1	6.8
Duration of immunobiological drug use (months)	39.9	32.9
	N	%
<b>Gender</b>		
Female	28	59.6
Male	19	40.4
<b>Marital status</b>		
Single	16	34.0
Married	26	55.3
Separated	5	10.6
<b>Ethnicity</b>		
White	14	29.8
Black	2	4.3
Mixed-race	28	59.6
Asian	2	4.3
Native Brazilian	1	2.1
<b>Origin</b>		
Aracaju	21	44.7
Countryside Sergipe	25	53.2
Other states	1	2.1
<b>Immunobiological drug in use</b>		
Adalimumab	23	48.9
Infliximab	24	51.1
<b>Prior surgery</b>	23	48.9
<b>Smoking</b>	14	29.8
If you are using adalimumab: have you used infliximab before?	5	21.7
<b>Location of disease</b>		
Small intestine	11	23.4
Small and large intestines	25	53.2
Small and large intestines and perianal	11	23.4
<b>Medication</b>	33	70.2
Azathioprine	28	59.6
Mesalazine	14	29.8
Corticosteroid	1	2.1

N, absolute frequency; %, percentage relative frequency; SD, standard deviation; IBD, inflammatory bowel disease.



**Fig. 1 – Total and domain IBDQ scores in IBD patients in immunobiological therapy.**

### Patient-reported quality of life

The IBDQ total and domain scores are shown in Fig. 1. The mean total IBDQ observed in the patients studied was 163.5 points (SD = 39.4); the lowest value was 47 points, while the highest was 215 points.

### Factors influencing quality of life in patients with IBD

In the study of the clinical and sociodemographic factors associated with the patient's quality of life, the emotional aspects domain of the IBDQ was statistically significantly associated with gender: women presented a mean of 54 points (SD = 16.5) and men, 63.8 points (SD = 14.3;  $p = 0.05$ ). In addition, in the systemic symptom domain, patients on adalimumab (mean: 25.9; SD = 7.6) had a statistically significant higher score than those using infliximab (mean: 22.5; SD = 5.2;  $p = 0.034$ ). For such associations, the Mann-Whitney test was used. The other associations observed were summarized in Table 2.

In the correlation between age, time of diagnosis, and duration of immunobiological drug use with IBDQ total and domain scores, using the Spearman correlation, the score in the intestinal symptoms domain showed a weak positive correlation ( $R = 0.312$ ;  $p = 0.033$ ) with duration of immunobiological drug use (Table 3).

Using Spearman's correlation and the Mann-Whitney test, no statistically significant correlation was observed between IBDQ total and domain scores and the variables age, smoking history, race, origin, diagnosis time, marital status, previous surgery, location of the disease, and use of other medications, as shown in Tables 2 and 3. However, with regards to gender, origin, immunobiological drug in use, history of previous surgery, history of smoking, and current use of other medications, IBDQ total and domain scores were higher in male patients, from Aracaju, using adalimumab, with a history of

previous intestinal surgery, without current or past history of smoking, and who were not using other medications.

After the introduction of the independent clinical and sociodemographic variables in the linear regression models within the Backward process of variable selection, a statistically significant association was observed between gender and score in the emotional aspects domain (linear regression coefficient -  $B = -9.9$ ;  $p = 0.011$ ; Table 4), with women reporting poor quality of life in that domain. Statistically significant relationships between total IBDQ scores ( $B = 28.7$ ;  $p\text{-value} = 0.002$ ) and in all domains, summarized in Table 4, were also observed with the immunobiological drug in use, so that the scores presented by patients using adalimumab were superior to those observed in patients using infliximab. Patients who were in use of mesalazine also presented a statistically significant worse quality of life in the systemic symptoms ( $B = -3.4$ ,  $p = 0.048$ ) and social aspects domains ( $B = -4.5$ ,  $p = 0.036$ ). Regarding the significant association found between IBDQ total and domain scores and race, although statistically significant given the fact that the sample included only one Native Brazilian patient, the results should be relativized.

### Discussion

Many studies worldwide have assessed the quality of life of patients with IBD, but Brazilian data are still limited, particularly when considering the reality of the state of Sergipe. The study of the reported quality of life allows assessing the quality of care, conducting economic analyzes of the therapy, and developing guidelines for clinical practice and public policies.<sup>9,11</sup>

Regarding sociodemographic aspects, the gender distribution of the study was in accordance with the literature, as CD

**Table 2 – Factors influencing the quality of life reported by patients with IBD in the IBDQ (Mann–Whitney test).**

	Intestinal symptoms Mean (SD)	Systemic symptoms Mean (SD)	Social aspects Mean (SD)	Emotional aspects Mean (SD)	IBDQ total Mean (SD)
<b>Gender</b>					
Female	52.7 (13.2)	22.9 (6.7)	25.8 (7.6)	54 (16.5)	155.4 (38.6)
Male	57.4 (12.1)	25.9 (6.3)	28.3 (8.3)	63.8 (14.3)	175.5 (38.5)
p-Value	0.175	0.127	0.165	0.050	0.071
<b>Marital status</b>					
Single	55.1 (8.6)	25.2 (6.2)	28.6 (6.9)	57.6 (14.9)	166.4 (33.4)
Married	52.8 (15.3)	23.3 (7)	25.7 (8.1)	58.3 (17.8)	160 (44.2)
Separated	62.6 (7.3)	25.2 (6.7)	26.8 (10.3)	57.6 (14.8)	172.2 (35.6)
p-Value	0.251	0.726	0.575	0.929	0.883
<b>Ethnicity</b>					
White	56.5 (9.7)	24.3 (5.8)	28.6 (7.4)	56.9 (14.4)	166.3 (33.4)
Black	29.5 (24.7)	15 (14.1)	17.5 (14.8)	34 (15.6)	96 (69.3)
Mixed-race	57.4 (10.4)	24.9 (5.9)	27.3 (7.5)	61.3 (14.5)	170.9 (33.7)
Asian	42.5 (9.2)	27 (11.3)	21.5 (3.5)	57.5 (36.1)	148.5 (60.1)
Native Brazilian	24 (0)	13 (0)	15 (0)	30 (0)	82 (0)
p-Value	0.116	0.439	0.339	0.085	0.144
<b>Origin</b>					
Aracaju	55.1 (10.3)	24.5 (6.3)	27.8 (8)	58.3 (14.2)	165.8 (34.8)
Countryside Sergipe	54.4 (15)	24 (7.1)	26.3 (7.9)	57.6 (18.4)	162.3 (44.1)
Other states	48 (0)	21 (0)	18 (0)	60 (0)	147 (0)
p-Value	0.615	0.865	0.345	0.983	0.789
<b>Immunobiological drug in use</b>					
Adalimumab	55.6 (14.4)	25.9 (7.6)	28.3 (7.7)	61.9 (18.4)	171.7 (44.2)
Infliximab	53.7 (11.5)	22.5 (5.2)	25.3 (8)	54.2 (13.2)	155.7 (33.3)
p-Value	0.322	0.034	0.105	0.076	0.057
<b>Prior surgery</b>					
Yes	55 (10.2)	24.6 (5.8)	27.2 (7.3)	59.4 (15.1)	166.1 (32.3)
No	54.3 (15.2)	23.8 (7.5)	26.4 (8.6)	56.6 (17.5)	161 (45.7)
p-Value	0.623	0.945	0.811	0.544	0.945
<b>Smoking</b>					
Yes	52.4 (15.4)	23.4 (8.5)	26.6 (9.8)	57.1 (18.7)	159.4 (49.4)
No	55.5 (11.8)	24.5 (5.8)	26.9 (7.1)	58.3 (15.4)	165.2 (35.1)
p-Value	0.666	0.867	0.631	0.778	0.986
<b>If you are using adalimumab: have you used infliximab before?</b>					
Yes	51.8 (23.5)	21 (10.8)	24.8 (11.3)	59.2 (22.5)	156.8 (67.7)
No	56.6 (11.5)	27.2 (6.2)	29.3 (6.5)	62.7 (17.7)	175.8 (36.9)
p-Value	0.870	0.190	0.400	0.843	0.986
<b>Location of disease</b>					
Small intestine	49.5 (12.6)	21.6 (7.1)	26.5 (9.2)	51.7 (16.4)	149.4 (41)
Small and large intestines	56.9 (13.4)	24.9 (6.7)	27.4 (8.1)	58.6 (17.2)	167.7 (41.6)
Small and large intestines and perianal	54.5 (11.4)	25 (5.9)	25.7 (6.8)	62.8 (12.9)	168.1 (31.9)
p-Value	0.198	0.344	0.643	0.222	0.389
<b>Medication</b>					
Yes	54 (13.3)	23.5 (6.8)	25.6 (8.4)	57.1 (16.8)	160.2 (40.6)
No	55.9 (12.2)	25.8 (6.3)	29.5 (6)	60.1 (15.3)	171.3 (36.7)
p-Value	0.674	0.284	0.174	0.523	0.341
<b>Azathioprine</b>					
Yes	53 (13.8)	23.4 (6.6)	25.9 (8.4)	57.3 (16.4)	159.5 (41)
No	57 (11.3)	25.3 (6.7)	28.1 (7.2)	59.1 (16.3)	169.4 (37.2)
p-Value	0.260	0.334	0.445	0.719	0.375
<b>Mesalazine</b>					
Yes	52.6 (17.2)	22.3 (7.7)	23.9 (9.8)	54.7 (18)	153.5 (49.3)
No	55.5 (10.7)	24.9 (6.1)	28 (6.8)	59.4 (15.5)	167.8 (34.4)
p-Value	0.995	0.295	0.219	0.403	0.378

– Table 2 (Continued)

	Intestinal symptoms Mean (SD)	Systemic symptoms Mean (SD)	Social aspects Mean (SD)	Emotional aspects Mean (SD)	IBDQ total Mean (SD)
Corticosteroid					
Yes	58 (0)	28 (0)	33 (0)	49 (0)	168 (0)
No	54.5 (13)	24.1 (6.7)	26.7 (8)	58.2 (16.4)	163.4 (39.8)
p-Value	0.957	0.638	0.681	0.681	0.979

SD, standard deviation; IBDQ, Inflammatory Bowel Disease Questionnaire; IBD, inflammatory bowel disease.

was marginally more frequent in women.<sup>1,6,7</sup> The age range presented in the study reinforces the bimodal age distribution described for CD, which presents a first peak between 15 and 30 years and a second between 50 and 70 years.<sup>1</sup> The higher prevalence of mixed-race and white individuals was also observed in other studies conducted in Brazil<sup>6</sup>; nonetheless, there is a wide debate that ethnic and racial differences may be more related to lifestyle and environmental influences than to genetic differences,<sup>2</sup> so that the distribution of IBDs between ethnic groups remains dynamic.<sup>1</sup> Furthermore, most patients came from the countryside, since this University Hospital is a state reference in the management of IBD, especially with regard to the use of immunobiological drugs.

Regarding history of previous intestinal surgery, there was a slight superiority for patients who were never underwent such procedures, a finding also observed by Souza et al. (2011),<sup>6</sup> Casellas et al. (2001),<sup>7</sup> Zhou et al. (2010),<sup>9</sup> and Pontes et al. (2004).<sup>10</sup> Approximately one-third of the patients had a current or past history of smoking, which is considered the strongest environmental factor for IBD, particularly for cigarette users. Smokers with CD have a worse disease course than nonsmokers, with higher recurrence rates, frequent

surgical interventions, and a greater need for immunosuppressive agents.<sup>1</sup>

Most patients presented disease in the large and small intestines (53.2%), a distribution distinct from that described in a review by Baumgart and Sandborn (2007),<sup>12</sup> which showed the disease located in the colon in 28% of patients. Nonetheless, in the study by Casellas et al. (2001),<sup>7</sup> the largest group of patients presented colon and small bowel involvement, similarly to the present study.

In the present study, all patients had a diagnosis of CD, which is due to the fact that the Brazilian Unified Health System (SUS) does not list infliximab in the treatment of severe UC refractory to corticosteroids and cyclosporine.<sup>13</sup> The use of adalimumab for the treatment of UC is also not standard in the SUS.<sup>14</sup> Slightly over one-fifth of the patients using adalimumab had previously used infliximab; this drug change was made due of inadequate/insufficient therapeutic response to the use of the latter. The CHOICE study<sup>15</sup> corroborates this change in immunobiological drug, having demonstrating the effectiveness of adalimumab in patients who responded to it, but developed intolerance, those who stopped responding to it, and those who never responded clinically to infliximab. It is noteworthy that, of the 47 patients studied, 28 used azathioprine, of whom 20 used infliximab as an immunobiological drug. This is justified by the superiority of the combination infliximab and azathioprine when compared with the use of infliximab monotherapy, as shown by Colombel et al. (2010).<sup>16</sup>

Comparing the present IBDQ total and domain scores with other Brazilian and international studies evaluating the quality of life of IBD patients through this instrument, the scores in all domains and in total IBDQ were similar to those observed by Zhou et al. (2010).<sup>9</sup> Xu et al. (2014)<sup>17</sup> also presented similar results, with the exception of the emotional aspects domain, in which the score was over 10% higher than that of the present study. In turn, Souza et al. (2011)<sup>6</sup> presented results over 10% lower than those of the present study in the systemic symptoms and social aspects domains; the other domains and the total IBDQ score were similar to the present findings. Pontes et al. (2004)<sup>10</sup> demonstrated scores over 10% higher than those of the present study in the social aspects and emotional aspects domains and in the total IBDQ; the systemic symptoms and intestinal symptoms scores were similar to the present findings.

Among the sociodemographic and clinical factors that influenced the domains of the IBDQ and its total score, it was observed that women presented lower scores in the emotional aspects domain, which is possibly justified by the fact that they report with more intensity negative emotions such as sadness, fear, guilt, and shame.<sup>18</sup> The association between

Table 3 – Factors influencing the quality of life reported by patients with IBD in the IBDQ (Spearman's correlation).

Correlations	Age	Time since diagnosis (years)	Duration of immunobiological drug use (months)
<i>Intestinal symptoms</i>			
R	–0.088	0.014	0.312
p-Value	0.556	0.924	0.033
<i>Systemic symptoms</i>			
R	–0.093	0.005	0.192
p-Value	0.535	0.976	0.197
<i>Social aspects</i>			
R	–0.018	–0.048	0.227
p-Value	0.904	0.749	0.126
<i>Emotional aspects</i>			
R	0.108	0.053	0.170
p-Value	0.469	0.726	0.253
<i>IBDQ total</i>			
R	0.004	0.015	0.268
p-Value	0.981	0.918	0.069

R, Spearman's correlation; IBDQ, Inflammatory Bowel Disease Questionnaire; IBD, inflammatory bowel disease.

**Table 4 – Factors influencing the quality of life reported by patients with IBD in the IBDQ (Linear Regression Model).**

	Intestinal symptoms B (95% CI) p-Value	Systemic symptoms B (95% CI) p-Value	Social aspects B (95% CI) p-Value	Emotional aspects B (95% CI) p-Value	IBDQ total B (95% CI) p-Value
<b>Gender</b>					
Female				–9.9 (–17.5 to 2.3)0.011	
Male				1	
<b>Ethnicity</b>					
White	35.6 (15.8–55.5) <0.001	15 (4.1–25.9) 0.007	17.5 (4–31.1) 0.011	28.9 (3.3–54.5) 0.027	98.6 (35.4–161.8)0.002
Black	5.5 (–17.8 to 28.8)0.643	3.7 (–9.1 to 16.5)0.571	4.7 (–11.1 to 20.6)0.559	4 (–25.7 to 33.7) 0.792	14 (–60 to 88) 0.711
Mixed-race	37 (17.4–56.6) <0.001	16 (5.3–26.8) 0.003	16.6 (3.2–29.9) 0.015	35 (9.8–60.2) 0.006	105.3 (43–167.7)0.001
Asian	21.6 (–1.8 to 45.1)0.071	18.4 (5.5–31.4) 0.005	11.4 (–4.7 to 27.4)0.165	34.5 (4.5–64.4) 0.024	80.8 (6.3–155.4) 0.034
Native Brazilian	1	1	1	1	1
<b>Immunobiological drug in use</b>					
Adalimumab	6.3 (0.5–12.1) 0.033	5.5 (2.3–8.6) 0.001	5.2 (1.3–9.2) 0.009	13.9 (6.5–21.4) <0.001	28.7 (10.3–47) 0.002
Infliximab	1	1	1	1	1
<b>Mesalazine</b>					
Yes		–3.4 (–6.8 to 0) 0.048	–4.5 (–8.6 to 0.3)0.036		
No		1	1		

B, linear regression coefficient; 95% CI, 95% confidence intervals; IBDQ, Inflammatory Bowel Disease Questionnaire; IBD, inflammatory bowel disease.

ethnicity and the scores presented in the IBDQ should be relativized, since there was only one Native Brazilian patient, which distorts the interpretation of the data. Regarding the lower score in the systemic symptom domain in patients using mesalazine associated with an immunobiological drug, it is important to note that the evidence shows only a marginal benefit of mesalazine in CD, and some studies have demonstrated its ineffectiveness against placebo.<sup>19</sup>

Furthermore, patients using adalimumab presented higher scores in the IBDQ and its domains than those using infliximab. The literature does not present a direct comparison between infliximab and adalimumab; therefore, a superiority of one over the other cannot be suggested.<sup>19</sup> In patients who responded to induction therapy with the index biological agent, the efficacy of all agents appears to be comparable.<sup>20</sup> The large samples size required to demonstrate differences between anti-TNF agents make such attempts at comparisons impractical and unlikely to occur.<sup>21</sup>

A positive correlation was observed between the duration of immunobiological drug use and the score in the intestinal symptoms domain, which is in agreement with Casellas et al. (2012),<sup>22</sup> who demonstrated that a long-term effective treatment with anti-TNF immunobiological agents optimizes clinical status, reduces clinical disease activity rates and, in parallel, increases patient-reported quality of life.

One of the main limitations of the present study is that the size of the sample used limits generalizations. Further studies would thus be required to increase the number of patients assessed. Moreover, the disease activity was not determined in this study, which did not allow establishing differences in reported quality of life according to the phases of activity and remission of the disease. As a generic questionnaire to evaluate quality of life was not applied, comparisons with the general population and in relation to other diseases are difficult. Finally, due to its cross-sectional design, cause-consequence relationships cannot be determined in the face

of the findings. Nonetheless, the present study was of great value in understanding the quality of life in patients with IBD in both Sergipe state and Brazil, stimulating new studies to be conducted in the future.

## Conclusion

The evaluation of patients' quality of life, in addition to being an excellent clinical assessment instrument, is also a valid method to determine the therapeutic impact not only for the ability to significantly improve the symptoms of the disease, but also to optimize the social and emotional aspects of IBD patients. Factors such as gender, type of immunobiological drug, and duration of use, as well as other associated medications, showed an influence on the quality of life scores observed in the IBDQ, reinforcing the need for new studies with larger samples that could allow a more accurate delimitation of the impact of such variables.

## Conflicts of interest

The authors declare no conflicts of interest.

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