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The concerns of Spanish patients with inflammatory bowel disease as measured by the RFIPC questionnaire

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ABSTRACT

Background and objectives: Concerns impact the quality of life for patients with inflammatory bowel disease (IBD). We attempted to identify the concerns of IBD patients in our practice, and to assess the applicability of the Rating Form of IBD Patients Concerns (RFIPC) questionnaire to Spanish patients.

Patients and methods: One hundred and thirty-one patients seen in our practice filled out the Spanish version of RFIPC. The questionnaire's reliability, validity, and discriminating power were analyzed.

Results: The total score was 46.93, with a standard deviation (SD) of 21.475. Primary concerns included: "having an ostomy bag", "effects of medication", "developing cancer", "energy level", and "uncertain nature of disease". Female patients scored higher on total RFIPC and on most items. Cronbach's alpha was 0.924. A good correlation was seen between two consecutive answers for 37 patients; the Spearman's coefficient was 0.842 (p < 0.001), and the intraclass correlation coefficient (ICC) was 0.775 (p < 0.001). Correlation was also found between RFIPC and both the IBDQ-32 emotional domain (0.413, p < 0.001) and anxiety scale (0.543, p < 0.001).

Conclusions: The RFIPC questionnaire may be administered to Spanish patients.

Key words: Concerns. Crohn's disease. Ulcerative colitis. Quality of life.

INTRODUCTION

Health-related quality of life (HRQoL) in patients with inflammatory bowel disease (IBD) has become an end-point for recent clinical trials (1,2) given its obvious significance. A wider HRQoL concept has been suggested from various interrelated dimensions, biological or physiological data, symptoms, performance status, perceived health status, and patient concerns (3,4). Correlation among these dimensions is poor or non-existent, hence they provide more encompassing information on patient experience. The RFIPC questionnaire (5,6) has been available for nearly 30 years now, and has identified the major concerns of IBD patients in different countries (5-14), and found a North-South severity gradient within them (15). We found no Spanish papers where this questionnaire was used, and thought it might be applicable in our country as well. With the present study we set out to validate and check the applicability of the RFIPC questionnaire in Spanish patients.

MATERIAL AND METHODS

Study design

This was a cross-sectional study of 180 patients consecutively seen from November 2014 to April 2016 at the outpatient gastroenterology clinic, Hospital Clínico Universitario, Valladolid, Spain, who were invited to take part. This clinic covers most patients with IBD in the hospital's health area, but it is not a monographic unit.

To be included, patients had to be of advanced age and suffer from ulcerative colitis (UC) or Crohn's disease (CD). Exclusion criteria included: patients living in a different town or city, hence needing to travel to our hospital to participate in the study, difficulties in interpreting the questionnaire or in understanding the study's goals, and inappropriate doctor-patient relationship.

Patients who agreed to participate were scheduled for an interview. Interviews lasted for about 20 minutes. Patients were briefed on the study's objectives, and then given questionnaires once their consent was obtained. The study was approved by the Ethics Committee of the Hospital Clínico Universitario de Valladolid, with the code: PI 15-324.

Questionnaires

Patients received the IBDQ-32 quality-of-life questionnaire, HAD anxiety and depression scales, and the RFIPC questionnaire.

The RFIPC questionnaire assesses the extent of patient concern on various aspects (16). It consists of 25 items under the following heading: "because of your condition, how concerned are you with...?" Patients respond using a visual analogue scale ranging from 0 to 100 (0 meaning "not at all" and 100 meaning "a great deal") (5). A score is obtained for each item, and a mean total score is then estimated. This questionnaire has been translated into Spanish by and remains the intellectual property of the Fundación Roma (17), which granted user rights to LFS for research purposes. Validated Spanish versions of IBDQ-32 (18) and HAD scales (19) were used.

In addition to this initial interview, 50 patients were asked to fill out the RFIPC questionnaire on a second occasion. A self-addressed pre-stamped envelope with a RFIPC copy was handed to 39 patients, who were instructed to fill out the questionnaire after four weeks and then return it by mail provided their clinical status had not changed, and the questionnaire was again administered to 11 patients with improved clinical status after treatment with biologics or surgery.

Patient demographic and clinical characteristics were obtained from hospital records. The applicability of the RFIPC questionnaire in our setting was assessed as follows: a) an analysis of reliability took into account the percentage of patients who completed the questionnaire, floor and ceiling effects, internal consistency, and reproducibility; b) validity was established by assessing correlation between RFIPC responses and IBDQ-32 scores (total and for the bowel, systemic, emotional, and social domains) as well as HAD scales; and c) discriminating power to detect clinical changes was assessed by comparing the differences seen in initial and second RFIPC scores between patients with unchanged and improved clinical status.

Statistics

Normality of quantitative variables was assessed based on descriptive statistics (minimum and maximum values according to standard deviation, asymmetry and kurtosis), Kolmogorov-Smirnov and Saphiro-Wilks tests, and histogram representations. In the case of normality, continuous variables were expressed as mean and standard deviation (SD), and compared using the Student's t-test. For non-normal distributions, variables were expressed as median and interquartile range (IQR), and compared using non-parametric Mann-Whitney U tests. IBDQ-32 total and domain scores, and HAD scale scores were presented as median and IQR values, and compared using non-parametric tests. Repeated measures were compared using paired-variables t-tests for normally distributed differences, or using Wilcoxon's test for non-normally distributed variables. Qualitative variables were compared using the Chi-squared test. Correlation was assessed with the Spearman's rho test. Questionnaire response consistency was estimated using the intraclass correlation coefficient (ICC) for absolute agreement. RFIPC internal consistency was measured with Cronbach's alpha coefficient.

Statistical significance was considered as $p < 0.05$. The statistical analysis was performed using the IBM SPSS Statistics 20 package.

RESULTS

Patient characteristics

Of all the 131 patients who consented to take part in the research, 127 completed the questionnaire. The IBDQ-32 instrument was appropriately completed by 120 patients. HAD scales were handed out to 57 patients. All 57 responded appropriately. Among the 39 patients with no clinical changes who were instructed to complete and return a second RFIPC questionnaire, two only filled it out partially; hence we only have 37 second questionnaires completed by patients with no clinical changes. All 11 patients with significant clinical improvement completed the questionnaire appropriately.

Patients were around 52 years of age, and had suffered from IBD for around ten years. Overall, their clinical status was good at the time of being interviewed. Over one third were receiving immunosuppressants (IMs), and 15% were on biologics. The demographic and clinical characteristics of all 131 patients are listed in table I.

Total RFIPC score was 46.93 (CI 43.29-50.57), and the SD was 21.47. Concerns with higher scores included: "having an ostomy bag" 80 (50), "effects of medication" 80 (60), "developing cancer" 70 (60), "energy level" 70 (60), and "uncertain nature of disease" 70 (60). Women scored higher than men in total RFIPC, with a mean difference of 13.5 (CI 6.3-20.7, $p < 0.001$), and in 18 out of 25 items. Table II summarizes the results obtained for total RFIPC and for each item both in all patients and by gender.

No statistically significant differences in total score or item scores were seen between UC and CD patients. Patients with CD scored higher on "pain or suffering", 60 (50) *vs* 50 (50), and "effects of medication", 80 (58) *vs* 70 (60), with p values of 0.089 and 0.097, respectively.

The study of RFIPC applicability to Spanish patients

RFIPC *reliability* was confirmed in the study patients. The questionnaire was viable and was thoroughly completed by 100% of study subjects. The questionnaire's internal validity was assessed giving consideration to the "floor" and "ceiling" effects. No patient provided a maximum 100-point score or a minimum 0-point score. The item where fewer patients scored highest was "attractiveness", and the item where more patients scored highest was "having an ostomy bag". The frequencies were 1.5% and 31.2%, respectively. "Being a burden or depending on others" was the item least scored as zero, and "ability to have children" was the item most commonly scored as zero. The frequencies were 5.3% and 63.3%, respectively. Internal consistency was assessed using Cronbach's alpha for all patients who completed the initial questionnaire, which was 0.924.

Correlation and consistency between two consecutive measurements were also analyzed for each item and total

Table I. Characteristics of all 131 patients

UC/CD	61 (46.5%)/70 (53.4%)
Men/Women	73 (55.7%)/58 (44.2%
Age*	52.3 (12.1)
Age at diagnosis*	40.7 (14.5)
UC extension E1/E2/E3	17(27.8%)/21 (34.4%)/23 (37.7%)
CD localization L1/L2/L3	36 (51.4%)/9 (12.8%)/25 (35.7%)
CD behavior B1/B2/B3	43 (61.4%)/13 (18.5%)/14 (20%)
Perianal CD	18 (25.7%)
Partial Mayo index, UC < 3	52 (85.2%)
Harvey-Bradshaw index < 3	51 (72.8%)
Corticoids	22 (16.7%)
IM (AZA, MP, MTX)	49 (37.4%)
Biologics	20 (15.2%)
Prior abdominal surgery (CD)	19 (27.1%)
Prior admission	61 (46.5%)
IBDQ-32 (1-7)	6.0 (1.6)
HAD (0-21)	6.5 (6)
HAD (0-21)	2 (6)

Patient description. Values include mean and standard deviation (*), median and interquartile range, absolute and relative frequencies. UC: Ulcerative colitis; CD: Crohn's disease; E: Extension; B: Behavior; IM: Immunosuppressants; AZA: Azathioprine; MP: Mercaptopurine; MTX: Methotrexate; HAD: Anxiety and depression scale.

score in 37 patients with no clinical changes, a repeat questionnaire being completed at least four weeks after the initial interview. Spearman's correlation coefficient analysis was 0.842 (p < 0.001), and the intraclass correlation coefficient was 0.775 (p < 0.001). The mean difference between both scores was 0.200 (95% CI -4.290-4.690), with a SD of 14.770. A comparison of both scores using a t-test for related samples reflects a p value of 0.929. For the various items, the Spearman's correlation coefficient ranged from 0.507 for energy level to 0.808 for financial difficulties, and the intraclass agreement coefficient ranged from 0.500 for ability to have children to 0.825 for financial difficulties. For all 25 items correlation and intraclass agreement had a p value < 0.001.

Validity was confirmed by measuring the correlation between the RFIPC and IBDQ-32 scores (-0.328, p = 0.001), and between RFIPC and IBDQ-32 bowel (-0.228, p = 0.018), systemic (-0.277, p = 0.003), emotional (-0.413, p < 0.001), and social (-0.285, p = 0.002) domains, and between the RFIPC and HAD anxiety (0.543, p < 0.001) and depression (0.293, p = 0.033) scales.

Discriminating power to detect changes as related to clinical changes was confirmed by comparing differences in two consecutive measurements between two patient groups. In the first group, including 37 patients with no clinically significant changes, the scores hardly varied,

with a difference (RFIPC pre-RFIPC post) of 0.4 (14.6). In the second group, including 11 patients with improved clinical status because of treatment with biologics or surgery, the scores were slightly reduced (-6.0, 13.2). A comparison of these differences almost reached statistical significance (Mann Whitney U test, p = 0.054).

DISCUSSION

The concerns of IBD patients cared for in our institution are similar to those of patients in other countries. In the pioneering studies by Drossmann, and in the subsequent studies carried out in countries such as Germany, Austria, Canada, France, Norway, and Sweden with the RFIPC, primary patient concerns also include having surgery (mainly because of ostomy bags), uncertain nature of disease, energy level, and effects of medication. Their order varies in the different studies, and surgery is not always present among those receiving higher scores. Other highly scored items in other studies include developing cancer, loss of bowel control, passing the disease onto others (which is a barely present concern according to our results and, on the contrary, among those most highly scored in a Norwegian study [9]) and being a burden (or depending) on others (5-14).

As in other studies (6,7,10,11,14,20), items of least concern for patients seen in our clinic include the ability to have children (likely related to patient age), passing the disease onto others, being treated as different and attractiveness.

Aspects missed in the RFIPC questionnaire, at least given the present situation in our country, include unemployment and absenteeism (21), which in our setting are likely not equivalent to financial difficulties.

We found a clear relationship between female gender and higher scores in the RFIPC tool, both total and in many items. Our results are consistent with those obtained by other authors (6,11,14,22). As early as in 2002, a Spanish paper showed that women with IBD had a poorer quality of life (23). Other authors have also confirmed that women have a poorer quality of life as well as higher anxiety and depression rates (24). Also women with rheumatic conditions or psoriasis score higher than men in subjective indices in spite of similar therapies (25). However, a study in nearly one thousand patients was recently reported, which demonstrates poorer IBD control and IBD management in female patients (26).

According to our results, only pain or suffering and effects of medication receive higher scores among CD patients as compared to UC patients, albeit without statistical significance. Abdominal pain is more common in CD, which may explain this difference that others have identified as well (8).

The RFIPC questionnaire has been used and validated in a number of countries. While already translated into our language, no Spanish studies have reported on its use. To

Table II. RFIPC scoring

	Total	Male	Female	
	M (IQR)	M (IQR)	M (IQR)	p
Financial difficulties	30 (60)	30 (50)	40 (70)	0.237
Pain or suffering	50 (40)	50 (50)	60 (50)	0.016
Your ability to achieve your full potential	50 (60)	50 (68)	70 (70)	0.032
Loss of bowel control	50 (60)	50 (61)	70 (70)	0.043
Developing cancer	70 (60)	60 (48)	80 (80)	0.111
Dying early	40 (60)	30 (50)	60 (70)	0.062
Being a burden (or depending) on others	60 (60)	50 (50)	80 (50)	0.003
Your attractiveness	20 (40)	20 (30)	40 (60)	0.001
Feeling alone	30 (50)	30 (58)	50 (50)	0.024
Feeling out of control	40 (60)	30 (50)	50 (60)	0.001
Feeling "dirty" or "smelly"	30 (70)	20 (50)	50 (80)	0.019
Ability to perform sexually	30 (50)	20 (50)	30 (60)	0.038
Ability to have children	0 (20)	0 (10)	0 (20)	0.528
Passing disease onto others	10 (60)	20 (68)	0 (50)	0.395
Being treated as different	20 (50)	20 (38)	30 (70)	0.024
Having surgery	60 (40)	50 (58)	80 (50)	0.003
Having an ostomy bag	80 (50)	80 (58)	90 (40)	0.007
Producing unpleasant odors	50 (80)	30 (70)	80 (80)	0.001
Your energy level	70 (60)	55 (60)	80 (50)	0.001
Your feelings about your body	40 (60)	20 (50)	50 (60)	0.001
Intimacy	30 (40)	20 (50)	40 (60)	< 0.001
Loss of sexual drive	40 (60)	30 (50)	50 (60)	0.002
Having access to quality medical care	60 (60)	50 (50)	80 (70)	0.119
The uncertain nature of your disease	70 (60)	60 (50)	80 (50)	0.072
Effects of medication	80 (60)	60 (60)	90 (50)	0.001
Total	46.07 (21.2)	40.2 (19.0)	53.7 (21.8)	< 0.001

RFIPC scores for all patients, patients with ulcerative colitis, and patients with Crohn's disease, both male and female. Student's t-test was used for total score, and Mann-Whitney U test was used for each item. UC: Ulcerative colitis; CD: Crohn's disease; M: Median; IQR: Interquartile range.

ascertain its applicability we followed the guidelines of other questionnaire-validating studies (9,13,27,28). The vast majority of patients who agreed to participate responded to all questions, and the internal consistency of their answers was found to be excellent, similar or superior to other studies (9,13), with acceptable "ceiling" and "floor" effects. Questionnaire reproducibility was confirmed with a good correlation and intraclass agreement values, with a mean difference in total score between administrations of 0.2.

There is no "gold standard" available for comparison with the RFIPC questionnaire in order to demonstrate its validity. Different studies have confirmed a correlation between overall RFIPC score and the scores of functional, psychological, or mental domains of quality-of-life ques-

tionnaires such as SF36 or IBDQ (9,13), with perceived overall health status (5), psychological wellbeing (13,29) and with physical, mental, or social activities (3,5,6,30). RFIPC scores have also been correlated with indices to measure the need for psychological care or to classify coping styles (11,16). A good correlation has also been found between total RFIPC and the question "how concerned are you with your bowel disease?" (4,13,31). This simplification may be more practical in daily clinical practice.

The correlation ascertained, particularly with the IBDQ-32 emotional domain and the HAD scale, provides validity to the RFIPC questionnaire. In fact, the IBDQ-32 instrument includes questions that also address concerns related to having surgery, loss of bowel control, developing cancer, or the uncertain nature of the disease.

As other authors (13), we found RFIPC poorly sensitive to clinical change. The difference in score seen in clinically improved patients *versus* patients with no clinical change is small, only 6 points. This renders the RFIPC score complementary to clinical manifestations.

RFIPC scores are higher for Northern European *versus* Southern European patients, and a gradient in this respect has been reported (15). Differences in educational level, financial status, and culture have been suggested to account for this gradient. However, some of these papers were published over ten years ago (9,11,15), and since then additional factors may have played a role, including the use of biologics, occupational changes in the setting of the current financial crisis, social changes, etc. However, a French study comparing patient concerns between 2001 and 2011 barely managed to identify any changes in RFIPC scores (10,32).

We acknowledge the limitations of our study. While the clinical characteristics of our patients are those to be expected from a series followed at an outpatient clinic especially devoted to IBD, their mean age of around 50 years may render concerns relevant to younger patients less salient, particularly concerns involving emotional issues, intimacy, wish to have children, etc. Furthermore, only 57 patients completed the anxiety and depression scale. We introduced this scale late during the study after becoming aware of the significance that psychological aspects have among patient concerns. We believe that correlation between RFIPC and the HAD instrument would have been even more obvious were the latter used from the start.

To conclude, we may apply the Spanish RFIPC questionnaire for the identification and assessment of Spanish patient concerns.

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