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Validation of a self-reported work disability questionnaire for ulcerative colitis

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Abstract

Ulcerative colitis (UC) may severely limit patients' capacity to work. Recently, we validated a work disability questionnaire (WDQ) for Crohn disease. As UC shares clinical characteristics with Crohn disease, we hypothesized that the questionnaire might also be useful for UC. The study was aimed to validate the WDQ for use in UC.

Consecutive patients with UC (n = 142, 67 women; age 48 ± 1) completed the UC-WDQ and the inflammatory bowel disease questionnaire-9 (IBDQ-9), and EuroQoL-5D quality-of-life questionnaires. Validation of the UC-WDQ included an assessment of its construct validity, including: discriminant validity, convergent validity, and reproducibility (test–retest). We also calculated the intraclass correlation and the Cronbach alpha.

1. Discriminant validity: Mean UC-WDQ scores were 12.8 ± 4.4 (remission phase) and 17.2 ± 6.1 (with clinical activity) ($P < .05$).
2. Convergent validity: The correlations of UC-WDQ were $r = 0.74$ ($P < .001$) with IBDQ, $r = 0.44$ ($P < .01$) with disease activity, $r = 0.56$ ($P < .01$) with EuroQoL-5D, and $r = 0.60$ ($P < .01$) with the EuroQoL-5D visual scale.
3. Reproducibility:
   - Test–retest reproducibility: UC-WDQ scores obtained after a 2-week interval were similar (15.8 vs 15.1), ($r = 0.91$, $P < .01$).
   - Intraclass correlation was 0.93 (95% confidence interval 0.92–0.95).
   - Cronbach alpha was 0.94.

The UC-WDQ is a valid and reliable tool for measuring work disability in patients with UC.

Abbreviations: IBD = inflammatory bowel disease, IBDQ = inflammatory bowel disease questionnaire, QoL = quality of life, UC = ulcerative colitis, UC-WDQ = ulcerative colitis work disability questionnaire, WDQ = work disability questionnaire.

Keywords: disability, inflammatory bowel disease, quality of life, self-reported questionnaires, ulcerative colitis

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1. Introduction

Ulcerative colitis (UC) is a chronic disease characterized by remissions and relapses of varying intensity. Incidence of the disease peaks in early adulthood, a time when a worker's productivity tends to be at its highest.[1] Usually, the symptoms are controlled by medical treatment; however, a small percentage of patients present refractory evolution[2] with important physical, emotional, and social effects, reducing health-related quality of life (QoL) and leading to different degrees of disability.[2]

Disability is defined as a partial or total inability to perform social roles such as work activity, and is a potential consequence of disease.[3] Sick leave rates are higher in patients with UC than in the general population and are associated with lower quality of life (QoL).[4] Disability can be measured by specific instruments that may be of use both in clinical practice and in research. Recently, our group developed and validated a 9-item questionnaire that measured self-reported work disability in patients with Crohn disease (CD-WDQ)[5] (Annex 1).

As UC and CD share clinical characteristics, we thought that this instrument might also be useful in patients with UC, although it has not been validated in this setting. The aim of our study was to validate the WDQ for use in patients with UC.

2. Materials and methods

2.1. Subjects

All patients with UC registered in the inflammatory bowel disease (IBD) community-based database at the Hospital Universitario de Burgos were evaluated.

Inclusion criteria were: age between 18 and 65 years (working age); UC diagnosed at least 6 months before the interview; capacity (judged by the interviewer) to understand and answer the questionnaires used in the evaluation.

Patients completed the following set of questionnaires recording clinical data and assessing QoL:

1. A self-reported demographic data form.
2. The Montreal IBD classification,[6] which uses predominant phenotypic elements classifying patients according to age at diagnosis and predominant location of the lesions.
3. The Mayo score[7] to evaluate disease activity; this score assesses symptoms, their severity and complications, and classifies activity as remission, mild, moderate, or severe.
4. The inflammatory bowel disease questionnaire-9 (IBDQ-9),[8] a QoL questionnaire specifically for patients with IBD. It is an abbreviated, self-administered version of the IBDQ.[9,10]
5. The EuroQoL-5D,[11] a short self-administered generic questionnaire for QoL. It includes 5 items representing 5 dimensions of health and a visual analog scale that ranges from 0 (worst imaginable health state) to 100 (best imaginable health state).
6. The UC-WDQ,[5] including 9 items (Table 1).

Additionally, patients were given another UC-WDQ questionnaire to be completed 14 days later, along with an envelope to return the test to the research team for evaluation of the test–retest reproducibility. Patients were contacted by telephone to confirm that their clinical situation had not changed in the previous 14 days.

2.2. Ethical considerations

All eligible patients who agreed to participate provided written informed consent prior to enrolment. The study was approved by the ethical review board of the Hospital de Burgos. The study conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

To maintain subject confidentiality and to comply with applicable data protection and privacy laws and regulations only the investigator that recruited the questionnaires and transcribed to database knew the identity of patients

Table 1

Characteristics of patients with ulcerative colitis included in the study.

Patient's variables	Patients characteristics (n = 142)
Age (mean ± SD), y	48.01 ± 10.28
Sex (male/female)	75/67
Age at diagnosis, n (%)	
<16 y	1 (0.7)
Between 16 and 40 y	87 (61.3)
More than 40 y	54 (38.0)
Mayo score, n (%)	
<2 inactive disease	33 (23.2)
2–9 mild to moderate activity	104 (73.2)
>9 severe activity	4 (2.8)
Localization, n (%)	
Proctocolitis	40 (28.2)
Left colitis	52 (36.6)
Extensive colitis	10 (7.0)
Pancolitis	40 (28.2)
Treatment, n (%)	
5-ASA topic	42 (29.6)
5-ASA oral	99 (69.7)
Oral corticosteroid	11 (7.7)
Topical corticosteroid	3 (2.1)
Azathioprine	45 (31.7)
Infliximab	6 (4.2)
Adalimumab	5 (3.5)
Methotrexate	1 (0.7)
Time since diagnosis, y (mean ± SD)	9.6 ± 7.9
Surgery, n (%)	8 patients (n = 8)
Psychological treatment, n (%)	13 (9.2)
Laboral status, n (%)	
Actively working	98 (69)
Temporary sick leave	8 (5.6)
Housewife	15 (10.6)
Student	4 (2.8)
Unemployed	7 (4.9)
Others	10 (7.1)
Educational level, n (%)	
Primary	38 (26.8)
Secondary	55 (38.7)
University	49 (34.5)

ASA = aminosalicylic acid, SD = standard deviation.

2.3. Analysis of psychometric properties

All data obtained from the patients were included in a database. The psychometric properties of the UC-WDQ were evaluated.[12] The UC-WDQ's convergent validity was established by correlating its scores with disease activity (measured by the Mayo index and days of hospitalization) and QoL (measured by the IBDQ-9 and the EuroQol-5D). Discriminant validity was measured by comparing the UC-WDQ scores in patients with active vs inactive UC, hospitalized vs not hospitalized in the previous year, and patients who had needed sick leave vs those who had not, also in the previous year.

Cronbach coefficient was calculated as an indicator of the internal consistency of the questionnaire.[13] The UC-WDQ was administered twice (with an interval of at least 2 weeks) to measure test–retest reproducibility. Test–retest reliability was also measured using the intraclass correlation coefficient.

2.4. Statistical analysis

When the distribution of variables was non-normal, variables were described using the median and 25th and 75th percentiles. Differences between medians were established using the Mann–Whitney or the Kruskal–Wallis test when appropriate. Correlations were calculated with Spearman rank correlation test. Statistical analysis was performed with the SPSS statistical package v21.0 (SPSS Inc, Chicago, IL).

3. Results

3.1. Patient characteristics

One hundred forty-two consecutive patients with UC were included. Seventy-five were men and 67 women; mean age was 48.01 ± 10.28 and mean time since disease diagnosis was 9.2 ± 7.2 years. Characteristics of the patients are displayed in Table 1.

3.2. Psychometric properties

3.2.1. Discriminant validity. The UC was considered inactive when the Mayo score was below 2, mild to moderate when it was between 2 and 9, and severe above 9.

Thirty-three patients were inactive and their mean UC-WDQ was 12.6 ± 4.5. The 104 patients with mild to moderate disease had a UC-WDQ of 15.6 ± 5.4 and the 4 patients with severe active disease had a UC-WDQ of 26.3 ± 8.6 ($P < .005$).

Mean UC-WDQ was 14.7 ± 5.4 in 124 patients who had not been hospitalized in the last year vs 18.5 ± 7.1 ($P < .05$) in the 17 patients who had been hospitalized. Finally, mean UC-WDQ scores were 19.9 ± 6.5 in the 30 patients who had been on sick leave and 13.9 ± 4.9 ($P < .05$) in the 111 who had not needed sick leave.

3.2.2. Convergent validity. Spearman correlations were $r = 0.74$ ($P < .001$) between UC-WDQ and IBDQ, $r = 0.56$ ($P < .01$) between UC-WDQ and EuroQoL-5D, and $r = 0.60$ ($P < .01$) between UC-WDQ and the EuroQol-5D visual scale. Finally, there was an inverse correlation between the UC-WDQ and the Mayo score with a $r = 0.33$ ($P < .01$).

3.2.3. Reproducibility. No patients presented changes in their clinical status 14 days after the first interview. Mean disability scores were similar (15.8 vs 15.1), with a correlation of $r = 0.91$ ($P < .01$).

Intraclass correlation was 0.93 (95% confidence interval 0.92–0.95) and Cronbach alpha was 0.94.

4. Discussion

Our results show that the UC-WDQ is a valid and reproducible tool for measuring disability in patients with UC. Evaluating and preventing disability is important in these patients because most of them are in working age. In fact, productivity loss is an important contributor to the notably high costs associated with UC.[14] Recent studies suggest that between 9% and 19% of patients with IBD suffer from short-term absences from work and that 19% to 22% have long-term disability,[15] although disability seems less prevalent in UC than in CD patients.[16] Determining the prevalence and the degree of disability in the UC population would help to evaluate the economic burden of the sequelae of the disease and to assess the potential usefulness of early aggressive therapy to prevent disability and reduce long-term costs.

An interesting finding in our study was the higher correlation between QoL and disability than between clinical activity and disability. This may be because the concept of QoL covers many other aspects, not just the patient's symptoms; it suggests that extradigestive findings such as anemia or fatigue may make a major contribution to work disability in UC.

The medical criteria applied by the authorities for assessing disability have not been systematized in UC, and access to a reliable measure of work disability may be an important step forward. Probably as a consequence, previous studies have shown that the criteria applied for awarding disability benefits vary very widely.[17] Having tools to measure disability might help to reduce this heterogeneity.

For all these reasons, measuring disability has become a hot spot in IBD. Feagan et al[18] recommended disability as an endpoint in therapeutic trials and in fact a general disability index has been recently published.[19–21] The IBD disability index (IBD-DI) and disability score (IBD-DS) have also been developed using the WHO's International Classification of Functioning, Disability and Health (ICF).[22] The IBD-DI attempts to measure general disability in patients with IBD, and has been partially validated in patients with UC with restorative proctocolectomy.[23] This validation suggests that IBD-DI may be useful in this subgroup of patients with UC, although measures of divergent validation or reliability were not determined.

A limitation of our study is that the questionnaire was produced in Spanish. Although the validation of translations of the QoL or work impairment questionnaires has always shown identical performance when English questionnaires were translated into Spanish, validation of the English version of the questionnaire is mandatory.[11,24,25] Another limitation is that we did not use the work productivity and impairment questionnaire (WPAI) to test convergent validity.[3] Although it would be interesting to correlate acute work impairment with disability, the WPAI has not been validated for use in patients with UC, even though some studies have in fact administered it in this setting.[26,27]

In conclusion, our study demonstrates that UC-WDQ is a valid and reliable self-reported questionnaire for measuring disability in patients with UC.

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Author contributions

Mercedes Vergara: Study conception and design, analysis and interpretation of data, drafting of manuscript, critical revision.
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Luigi Melcarne: Study conception and design of the study and critical revision.
Fernando Gomollón: Study conception and design of the study and critical revision.
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Annex 1: CU-WDQ English Translation (Translation and back-translation into Spanish have been performed to ensure the stability of the meaning of the questionnaire items)

Ulcerative colitis work disability questionnaire (UC-WDQ)
Instructions for completion:

1. Read the questions carefully and circle the answer that best fits your personal situation.
2. Answer *all* the questions, if you leave one out, the questionnaire will *not* be valid for analysis.
3. Your answers are totally confidential and will on no account be disclosed.
4. Answer as sincerely as possible.
5. Your answers will contribute to advances in ongoing research on IBD.
6. All the questions refer to the *past year*.

Thank you very much.

1. In the past year, has *weight loss* related to ulcerative colitis affected your working capacity?
   1. I never lose weight or it does not affect my working capacity
   2. On few occasions
   3. Quite often
   4. All of the time
2. In the past year, has ulcerative colitis affected your working capacity in any way?
   1. Never
   2. On few occasions
   3. Quite often
   4. All of the time
3. In the past year, has your working capacity been affected by not having *toilet facilities at hand*?
   1. I have never been in this situation or it does not affect my working capacity
   2. On few occasions
   3. Quite often
   4. All of the time
4. In the past year, has the medication you take for ulcerative colitis or its secondary effects affected your working capacity in any way?
   1. I do not take medication or it does not affect my work capacity
   2. On few occasions
   3. Quite often
   4. All of the time
5. In the past year, have you had personal or work-related problems at your work place due to ulcerative colitis?
   1. I have never had any problems or only minor ones that do not affect my working capacity
   2. On few occasions
   3. Quite often
   4. All of the time
6. In the past year, has your working capacity been affected by you feeling more *depressed*, *anxious*, or *irritable* due to ulcerative colitis?
   1. I have never felt this way or it does not affect my working capacity
   2. On few occasions
   3. Quite often
   4. All of the time
7. In the past year, has *tiredness* caused by ulcerative colitis affected your working capacity?
   1. I've never felt tired or it doesn't affect my work capacity
   2. On few occasions
   3. Quite often
   4. All of the time
8. In the past year, has *diarrhea* caused by ulcerative colitis affected your working capacity?
   1. I have never had diarrhea or it does not affect my working capacity
   2. On few occasions
   3. Quite often
   4. All of the time
9. In the past year, has your working capacity been affected by anal incontinence caused by ulcerative colitis?
   1. I've never had anal incontinence or it does not affect my working capacity
   2. On few occasions
   3. Quite often
   4. All of the time

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