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The development and validation of a new coeliac disease quality of life survey (CD-QOL)

S. D. DORN*,†, L. HERNANDEZ‡, M. T. MINAYA§, C. B. MORRIS*, Y. HU*, J. LESERMAN*, S. LEWIS¶, A. LEE¶, S. I. BANGDIWALA*, P. H. R. GREEN§,¶ & D. A. DROSSMAN*,†

*Center for Functional GI and Motility Disorders, University of North Carolina; †Division of Gastroenterology and Hepatology, Department of Medicine, University of North Carolina School of Medicine, Chapel Hill, NC, USA; ‡Section of Gastroenterology and Hepatology, Department of Medicine, Tulane University Health Sciences Center, New Orleans, LA, USA; §Celiac Disease Center at Columbia University, New York, NY, USA; ¶Division of Digestive and Liver Diseases, Department of Medicine, Columbia University, New York, NY, USA

Correspondence to:
Dr D. A. Drossman, Division of Gastroenterology and Hepatology, 4150 Bioinformatics Bldg. CB#7080, University of North Carolina at Chapel Hill, Chapel Hill, NC 27599-7080, USA.
E-mail: drossman@med.unc.edu

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SUMMARY

Background
Previous studies on coeliac disease (CD)-related quality of life (QOL) have been limited by their use of a 'generic' rather than coeliac disease-specific assessment instruments.

Aim
To develop and psychometrically validate a new coeliac disease-specific instrument, the CD-QOL.

Methods
Through a series of focus groups, we elicited items from patients that related to the specific nature of their disease and its impact on their basic needs. Through expert review, cognitive debriefing with patients and pilot testing, a scale was developed, refined and administered to 387 patients on a gluten-free diet from both community-based support groups and a tertiary care referral centre. Finally, a formal validation study was conducted to assess the psychometric properties of the CD-QOL.

Results
The final CD-QOL has 20 items across four clinically relevant subscales (Limitations, Dysphoria, Health Concerns, and Inadequate Treatment). The CD-QOL has high internal consistency, reliability, and psychometric validation indicates both convergent and discriminate validity.

Conclusions
The CD-QOL is a reliable and valid measure of coeliac disease related QOL. As a new disease-specific instrument, it is likely to be a useful tool for evaluating patients with this disorder.

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INTRODUCTION

Coeliac disease is a chronic disorder that can impact patients in many ways including their health-related quality of life (HRQOL). Several studies on HRQOL in coeliac disease (CD) have been conducted, but show variable results. In European studies, compared with the general population, patients with coeliac disease suffer a reduced HRQOL.[1–4] Conversely, a Canadian survey suggested that the HRQOL of those with coeliac disease is similar to that of the general population.[5] In the U.S., studies have not focused on HRQOL in coeliac disease, but rather on its clinical spectrum and the patient's perspective of its diagnosis and treatment.[6, 7] Nonetheless, because at the time of these studies there was no coeliac disease-specific HRQOL instruments, each of these studies used 'generic' assessment instruments. These generic functional status and symptom-based questionnaires may not adequately capture those attitudes, perceptions and needs that specifically relate to coeliac disease.[8] This may result in findings that are less sensitive or responsive to treatment. Furthermore, because of the variable clinical presentation of individuals having this disease from asymptomatic to severely impaired, differences in the results may also reflect the clinical heterogeneity of the populations studied.

Accordingly, we developed a CD-specific QOL instrument, the CD-QOL. The methodology was similar to that used by our group to create other QOL measures.[9–11] Furthermore, given the clinical heterogeneity of this population, we focused on developing and standardizing a measure that has clinical relevance, by targeting both those patients in the community who were members of local Coeliac disease support groups and patients seeking treatment for their symptoms at a major referral centre for coeliac disease. In this article, we report the results of a study to develop and assess the psychometric properties of the CD-specific QOL measure (CD-QOL) including conceptual and measurement model (subscale structure), reliability (internal consistency) and validity (content validity as well as convergent and discriminant construct validity).

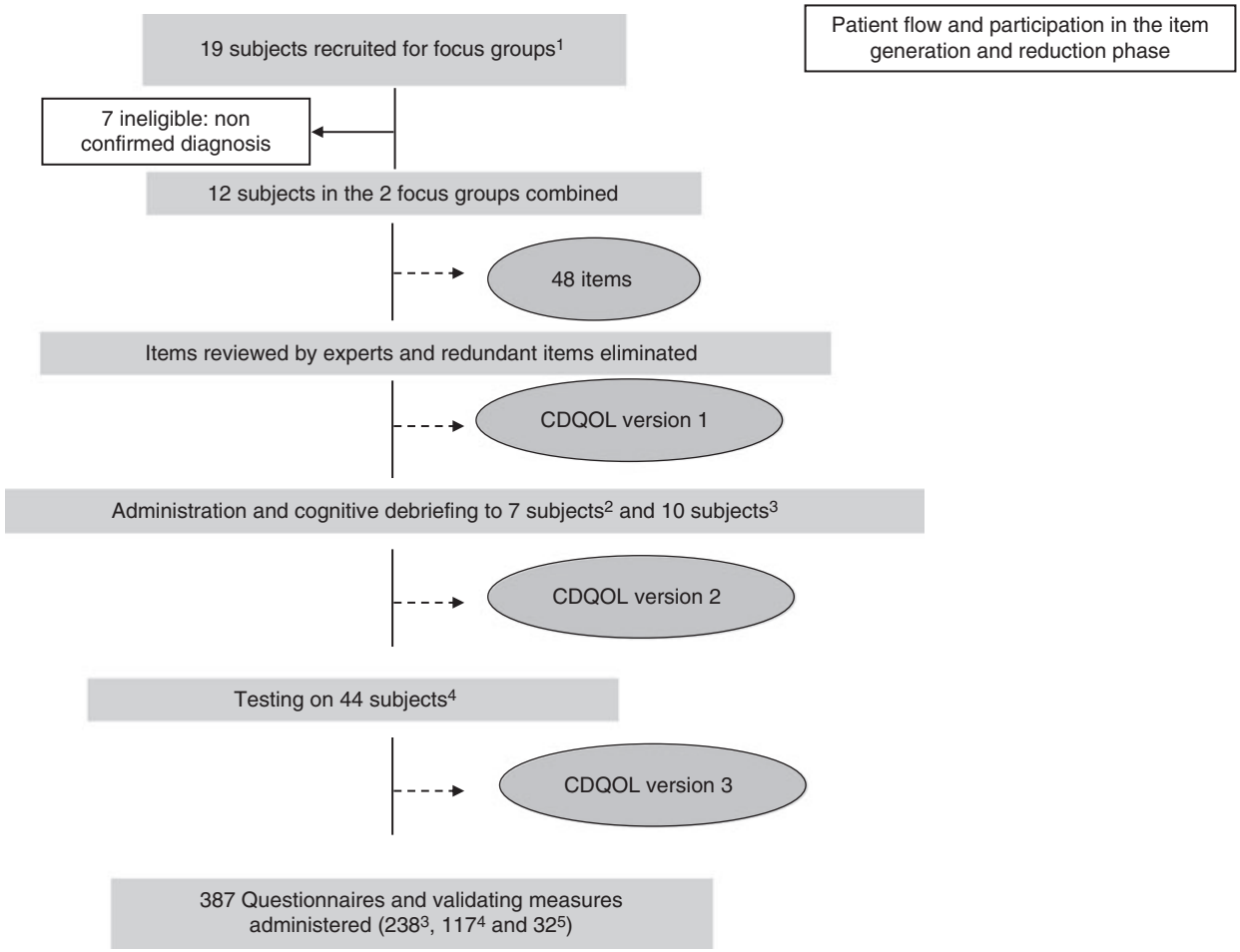
METHODS

We sequentially followed steps to develop patient-derived items for the instrument and then psychometrically validated it (See Figure 1). First, through a series of focus groups, we elicited items from patients that related to questions about the specific nature of their disease and its impact. Next, these items were reviewed by experts and other patients with CD. Then, a draft of the CD-QOL was developed, administered to additional patients, and further refined. Finally, a formal validation study was conducted to assess the psychometric properties of the CD-QOL.

Questionnaire development

Identification of CD-QOL question items. After receiving approval from the Columbia University Institutional Review Board, subjects aged 18 years and older with physician diagnosed coeliac disease (without restrictions related to disease or symptom severity or duration) were recruited from a community-based coeliac disease support group (Westchester, NY) to participate in focus groups. Nineteen subjects expressed interest and after eliminating those who did not have a confirmed diagnosis of coeliac disease, a total of 12 subjects participated. All subjects were Caucasian and most (10/12) were women. Illness characteristics varied in terms of time since diagnosis (weeks to many years), presenting symptoms (atypical symptoms such as peripheral neuropathy or infertility to classical symptoms of diarrhoea and weight loss), and duration of support group membership (first time to many years).

Two focus groups containing five and seven patients respectively were held consecutively on the same day. All subjects were told that the purpose of the focus group was to get a better idea of how coeliac disease affected their 'activities, capabilities, thoughts and feelings'. Open-ended questions ('scripted probes') were asked following the 'needs-based' model,[9, 12] where questions relate to perceptions and concerns relating to the impact of the disease rather than to specific symptoms or functional limitations. Specific domains of interest were determined *a priori* based on expert opinion. Examples of these questions included the following: (1) 'As you think about your disease, in what ways does it affect you?' (2) 'How does your disease affect your day-to-day activities? Socializing? Thoughts and feelings?' (3) 'If you didn't have your disease, how would things be different?' (4) 'How does coeliac disease affect the quality of your life?' (5) 'Is there anything else that we didn't discuss that you think is important about having coeliac disease?' The responses from the focus groups were recorded and transcribed. We analysed transcripts and identified 48 items related to living with CD and broadly categorized them as related to health care, coping, social life, diet, disease or health.



1. Westchester Support Group, 2. Suffolk County Support Group, 3. Celiac Disease Center at Columbia University, 4 . Central Long Island Support Group, 5. Northern Ohio Support Group.

Figure 1. Flow chart of questionnaire development and validation process. Initially, 48 disease-specific items were generated by two focus groups. This was further refined to a 24-item final questionnaire (CD-QOL 3) which was then administered to 387 subjects. See text for further details.

Scale development and refinement. Next, the 48 items were reviewed by a group of medical professionals [four gastroenterologists (PHRG, LH, SDD, DAD) and one nutritionist (AL)] experienced in working with coeliac disease patients. Items that were redundant and/or not 'needs-based' were eliminated. These steps resulted in 24 items.

We then transformed each item into a question with a 5-point Likert Scale response to form a preliminary scale (CD-QOL Version 1), which was administered to an additional cohort of seven patients from another community-based support group (Suffolk County, New York) and 10 patients with CD seen at the Columbia University Celiac Center. After completing the scale, subjects underwent a cognitive debriefing interview where they discussed their thoughts and interpretation of each item. Items that were confusing were re-worded to form a refined preliminary scale.

Next, CDQOL version 2 was administered to 44 subjects recruited from a third community-based support group (Central Long Island, New York). For half of these items, a majority of patients (>50%) responded as moderately or significantly bothersome. These items were kept unchanged. For the remaining items, a minority of patients (<50%) responded as moderately or significantly bothersome. These items were reviewed and, if necessary, re-worded.

Finally, the 24-item CD-QOL Version 3 (See Appendix), along with several validating measures (see below) was administered to 387 subjects. These

subjects were recruited from the Columbia Celiac Disease Center (n = 238), the Central Long Island Celiac Support Group (n = 117) and the Northern Ohio Celiac Support Group (n = 32) (see Figure 1).

Factor analysis

Item reduction. Preliminary to the factor analysis, we eliminated question items that performed poorly, as their retention in the instrument would adversely affect the scale's ability to discriminate between different groups and diminish chances of detecting important changes that result from treatment. Items were eliminated using the following criteria: (1) ceiling effect of an item in which >60% of participants responded 'not at all' and thus could not improve on the item; (2) any item that had > 5% missing data; (3) any item that correlated poorly with the total scale (i.e., item-to-total correlation <0.40) and thus measured a different construct; (4) pairs of redundant items (i.e. an item-item correlation >0.70).

Identification of sub-scales. Next, exploratory factor analysis was performed to identify subscale structure. The number of factors suggested was based on eigenvalues, which reflect the amount of variance in all variables explained by a single factor. By convention, we only included factors with eigen values greater than 1. Orthogonal or oblique rotations help define clear loading patterns per item so that it can be easily determined which items group with which factor. SAS version 9.1 (SAS Institute Inc, Cary, NC, USA) was used to perform the factor analysis.

Internal consistency reliability. Cronbach's alpha was used as a measure of internal consistency reliability. A high internal consistency suggests that the scale or subscales are measuring a single construct. Alpha values should exceed 0.7 and preferably 0.9.

Psychometric validation

Psychometric validation measures. To achieve construct validation, several psychosocial questionnaires were given:

(i) Single-item HRQOL question: This question item was given to all subjects. Each subject was asked 'How would you rate your quality of life related to your illness?' and this was scored as 1 = poor, 2 = fair, 3 = good, 4 = very good and 5 = excellent. Additionally, a proportion (n = 82) of the subjects completed several other standardized measures in order to obtain psychometric validation.

(ii) Brief Symptom Inventory (BSI-18): This 18-item questionnaire commonly used in research on patients with gastrointestinal disorders was used to quantify overall psychological distress. For each question, responses ranged from 0 (not at all) to 18 (extremely). The scores were summed to derive a general severity index (GSI), the most sensitive indicator of the respondent's overall distress level. Subjects with GSI scores greater than 59 are considered to have significant psychological distress.[13]

(iii) Sickness Impact Profile (SIP): a 136-item generic measure of health-related functional status. Items are grouped into twelve categories; each category relates to an aspect of daily living. An overall score (with all 12 categories) is calculated.[14]

(iv) IBS quality of life (IBS-QOL): This is a 34-item validated, condition-specific measure of health-related quality of life for IBS.[15] The IBS-QOL was used to assess gastrointestinal symptom-related health status for subjects with coeliac disease.

(v) Pain: subjects were asked to rate their daily level of abdominal pain using a Visual Analogue Scale (VAS) (100 mm; 0 = 'none', 100 = 'very severe'). The daily scores averaged over 2 weeks were used to calculate an overall (two-week) average daily pain score.

Psychometric validation process. The final step involved psychometric testing of the CD-QOL following standardized procedures for construct validity.[16] The self-rated health, BSI, SIP, abdominal pain (VAS) and IBS-QOL scores were used to assess convergent validity. Strengths of association were tested by calculating correlation coefficients between the CD-QOL and these measures at baseline. Correlations >0.4 were considered to be strong. However, correlations of >0.7 would be too high and redundant with the validating instrument.

Known groups validity was used to test the ability of the CD-QOL to discriminate between groups varying on known characteristics independent of the QOL measure. For each measure, subjects were categorized based on the distribution of the scores on each measure into high, medium and low tertiles. Then, the average CD-QOL for each group was compared. We predicted that those with lower self-rated health, poorer daily function (SIP), higher psychological

distress (BSI) and increased abdominal pain (VAS scale) would have a poorer CD-QOL.

RESULTS

Population

A total of 387 patients completed the refined CD-QOL scale as well as a single-question self-report of QOL. In general, these subjects were middle-aged, Caucasian, highly educated, women with a mean CD duration of almost 9 years. All subjects were diagnosed by a physician with coeliac disease. Most patients (72.4%) had a confirmatory biopsy, whereas a minority of patients were diagnosed by serology alone (21.6%) or by another or unknown method (6.0%). Nearly all patients were on a gluten-free diet (Table 1).

Factor analysis results

Five items of the initial 24-item questionnaire met criteria for elimination. Three of these items demonstrated ceiling effects and were eliminated because they contributed little variance to the factor analysis (see below). One item correlated poorly with the total scale (i.e. item-to-total correlation <0.4) and one item was considered redundant (item-item correlation >0.7). These two items were sequentially included and then excluded from the subsequent factor analysis (see below). The factor solution that gave the highest internal consistency included one of these two questionable items. Thus, that item was retained with the other eliminated. In total, four items were eliminated yielding a final scale with 20 items (See Appendix).

The factor analysis was performed using a varimax rotation, which provided a solution with clear loading patterns for the items. The higher the factor loading, the higher the degree of association or correlation of that particular item with the factor grouping. We set 0.5 as meaningful and therefore all loadings over 0.5 are boldfaced (Table 2) to demonstrate the clustering of relevant items in each factor. A four-factor solution best fit the data, based on eigenvalues ≥1, indicating the amount of total variance explained by each item. Cronbach's alphas were then calculated for each factor, and for the items within each factor, to examine each item's contribution to the factor and to ensure that all items within each factor measured the same construct. In one case, we omitted an item because of its low correlation with the other items in that factor. This omission increased the cronbach alpha, a measure of reliability, for that factor from 0.60 to 0.73. The factors identified were reviewed by the investigators and by consensus were labelled based on their clinical features: (1) Limitations, (2) Dysphoria, (3) Health Concerns, (4) Inadequate treatment (Table 2).

Table 1. Validation study population characteristics

	N = 387
Age (mean, s.d.)	48.3 years (15.8)
Race	
Caucasian	94.0%
African American	0.8%
Hispanic	3.1%
Asian	0.8%
Other	1.3%
Gender	
Female	79.5%
Male	20.5%
Self-reported gluten-free diet adherence	
No	0.8%
Yes, intermittent	7.4%
Yes, persistent	91.8%
Self-reported mode of Coeliac disease diagnosis	
Blood test only	21.6%
Biopsy	72.4%
Other/unknown	6.0%
Years since diagnosis (mean, s.d.)	6.1 (10.1)
Recruitment sites	
Central Long Island Support Group	30.2%
Northern Ohio Support Group	8.3%
Columbia University Celiac Disease Center	61.5%

Psychometric validation

In addition to the 387 patients who completed both the CD-QOL scale and self-report of QOL, a sub-set also completed the SIP (n = 79), IBS-QOL (n = 82), BSI (n = 68) and an abdominal pain diary (n = 69).

Convergent validity. Correlations were performed between the CD-QOL, the single HRQOL item and the psychometric measures. For each, there was a mild-moderate correlation that was in the expected direction and within the ideal correlation range (r^2 range = 0.35–0.65): those with higher psychological distress and abdominal pain had lower CD-QOL, whereas those with higher self-rated QOL and IBS-QOL had higher CD-QOL (Table 3).

Table 2. Factor analysis of CD-QOL*

Rotated factor pattern

		Limitations Factor 1	Dysphoria Factor 2	Health concerns Factor 3	Inadequate treatment Factor 4
QOL1†	QOL1: feel the disease is incurable	0.14461	−0.13143	0.09494	**0.62469**
QOL2	Feel limited by this disease	**0.51078**	0.28431	0.18372	0.48808
QOL3	Feel worried I will suffer from the disease	0.23420	0.38026	**0.51674**	0.46523
QOL4	Concerned disease will cause other health problems	0.14525	0.24921	**0.80266**	0.20790
QOL5	Worried about increased risk of cancer	0.13119	0.22806	**0.77878**	0.11916
QOL6	Feel socially stigmatized for having the disease	**0.58396**	0.41834	0.10586	0.20084
QOL7	Feel limited in eating meals w coworkers	**0.65449**	0.16012	0.08968	0.37092
QOL8	Feel unable to have special foods e.g. birthday cake/pizza	**0.51265**	0.15004	0.17260	0.40267
QOL9	Feel diet insufficient treatment for my disease	0.05385	0.28950	0.15562	**0.71990**
QOL10	Feel not enough treatment for my disease	0.14296	0.34002	0.20718	**0.66860**
QOL11	Feel depressed because of my disease	0.36546	**0.69978**	0.12345	0.20576
QOL12	Feel frightened by having this disease	0.23087	**0.70703**	0.37660	0.15862
QOL13	Feel like don't know enough about the disease	0.12597	**0.60761**	0.24723	0.07253
QOL14	Feel overwhelmed about having this disease	0.43722	**0.72547**	0.17000	0.12628
QOL16	Have trouble socializing b/c of my disease	**0.72563**	0.31001	0.02910	−0.02419
QOL17	Difficult travel/take long trips b/c disease	**0.62780**	0.25470	0.16947	0.20562
QOL19	Feel cannot live normal life b/o my disease	**0.50817**	0.44434	0.14486	0.42543
QOL21	Afraid to eat out because food may be contaminated	**0.58394**	0.14567	0.33606	0.26212
QOL22	Worried about increased risk of family member having coeliac	0.45292	−0.03665	**0.54993**	0.06509
QOL23	Feel like I think about food all the time	**0.53800**	0.10527	0.31698	−0.08528
QOL24	Concerned that my long-term health will be affected	0.15515	0.27484	**0.79027**	0.24447

* Numerical values represent r or factor loadings, or the degree of association between a given question item and the factors within which it is listed. A value of 0.5 or greater is considered a meaningful association and is boldfaced to demonstrate the relevant items associated with each factor that was selected for the subscale.
† QOL1 is not in the final scale.

Known groups discriminant validity. For each of the comparison measures, the sample distribution was examined and used to stratify subjects into three different groups. For the self report of QOL, this included low (poor or fair self rating of QOL), medium (good) and high (very good and excellent) self-rated QOL. For the SIP, this included low (<1), medium (1 to <5), and high (>5) daily function. For the BSI, this included low (<48), medium (48–60) or high (>60) psychological distress. For daily abdominal pain, this included low (<10), medium (10–25) or high (>25) abdominal pain. For each of these measures, the mean CD-QOL of subjects in each group (low, medium, and high) was compared. In all cases, the mean CD-QOL scores were in the expected direction. Those with higher self-rating of health had higher CD-QOL total scores as well as higher CD-QOL sub-scale scores. Likewise, those with less daily impairment (SIP), lower psychological distress

Table 3. Pearson's Correlations between CD-QOL and convergent measures

CDQOLSUM	*N*	R	*P*-value
IBS-QOL	82	0.62	<0.0001
SIP	79	−0.49	<0.0001
BSI	68	−0.47	0.0002
Abdominal Pain	69	−0.36	0.003
Self-rated QOL	385	0.58	<0.0001

Table 4. CD-QOL scores stratified by scores on psychometric measures

Self-rated health									*P*-values for comparisons			
Poor			Medium			Good						
N	Mean	s.d.	*N*	Mean	s.d.	*N*	Mean	s.d.	All 3	*P* vs. M	*P* vs. G	M vs. G
56	37.6	15.58	146	47.31	12.49	184	59.07	11.55	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**

Daily function (Sickness impact profile)									*P*-values for comparisons			
Low (<1)			Mid (1–<5)			High (≥5)						
N	Mean	s.d.	*N*	Mean	s.d.	*N*	Mean	s.d.	All 3	1 vs. 2	1 vs. 3	2 vs. 3
28	57.77	13.89	29	53.99	12.75	22	43.9	19.72	**0.0074**	0.3566	**0.0022**	**0.0228**

Psychological distress (Brief symptom inventory) category									*P*-values for comparisons			
Low (<48)			Mid (48–59)			High ≥60						
N	Mean	s.d.	*N*	Mean	s.d.	*N*	Mean	s.d.	All 3	1 vs. 2	1 vs. 3	2 vs. 3
18	61.39	10.34	34	51.62	15.14	16	39.84	18.44	**0.0004**	**0.0281**	**<0.0001**	**0.0115**

Average daily abdominal pain (VAS)									*P*-values for comparisons			
Low (<10)			Mid (10–<25)			High (≥25)						
N	Mean	s.d.	*N*	Mean	s.d.	*N*	Mean	s.d.	All 3	1 vs. 2	1 vs. 3	2 vs. 3
32	57.4	13.51	17	49.22	11.96	20	46.5	22.04	**0.0472**	0.0959	**0.0208**	0.6116

Values in bold have a significance level of $P < 0.05$.

(BSI) and less abdominal pain had higher CD-QOL scores (Table 4).

These findings are displayed graphically, first comparing the CD-QOL overall score with the three psychometric measures (Figure 2) and then comparing the overall score and the four subscale scores (Dysphoria, Limitations, Health Concerns, Inadequate Treatments) with the single-item self-report of health measure (Figure 3).

DISCUSSION

Over the past two decades, there has been growing interest in assessing the HRQOL of patients with digestive diseases,[17, 18] especially for measuring outcomes in health services research and clinical trials. For coeliac disease, the assessments have relied on generic instruments (e.g. the Short Form-36), designed to measure HRQOL across a wide variety of medical conditions. As generic instruments do not assess the special states and concerns of patients living with coeliac disease (e.g. treatment with a highly restrictive gluten-free diet), they may be insensitive and unresponsive to changes over time, particularly those that may result from a therapeutic intervention.[19]

Accordingly, we used standard scale development methods to develop a coeliac disease-specific QOL instrument, the CD-QOL. Factor analysis revealed a strong, clinically relevant four factor solution (coeliac disease related limitations, dysphoria, health concerns,

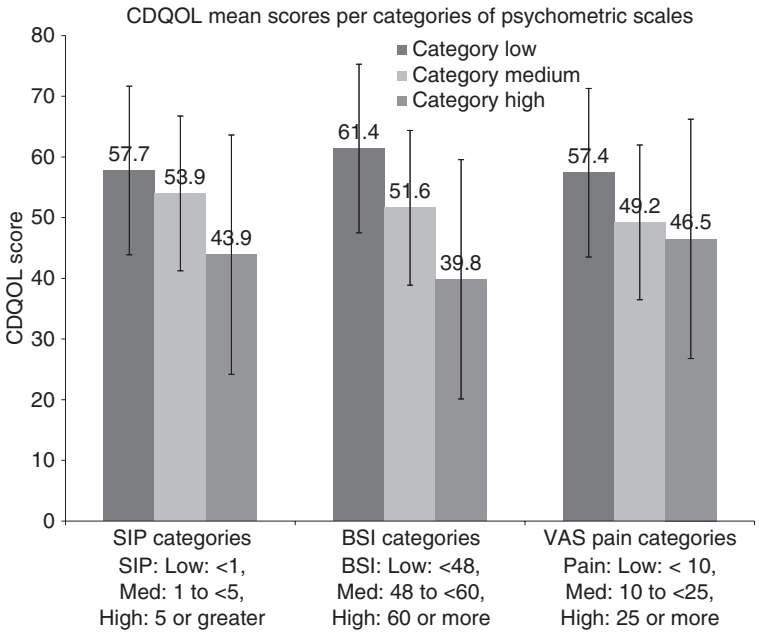


Figure 2. CD-QOL Scores by Daily Function, Psychological Distress and VAS Abdominal Pain. Subjects who reported less daily impairment (SIP), lower psychological distress (BSI) and less abdominal pain had higher CD-QOL scores.

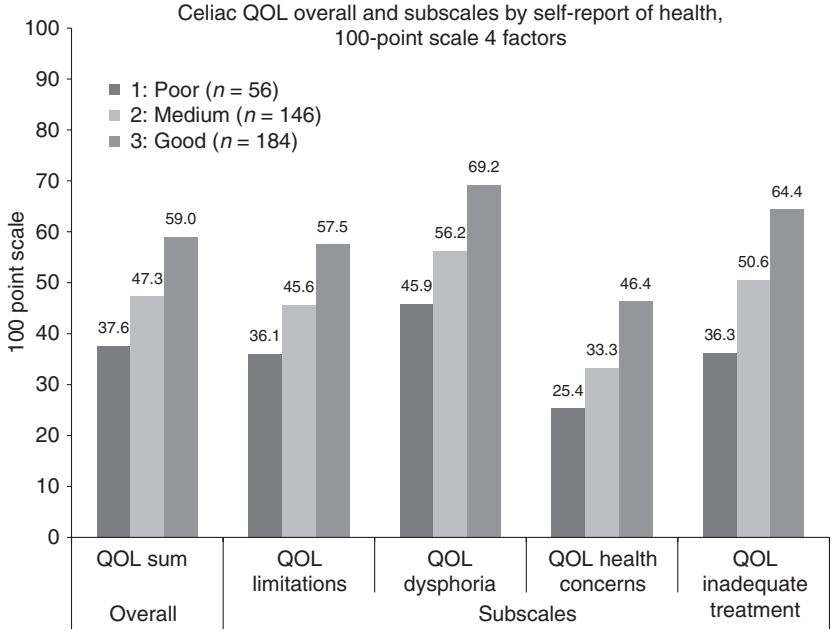


Figure 3. CD-QOL Scores by Self Report of Health. Subjects with a higher self report of health had higher overall CD-QOL scores as well as individual sub-scale scores.

and inadequate treatment) that shows face validity and high internal consistency reliability (Cronbach's alpha exceeded the recommended cutoff of 0.7). Notably, psychometric testing revealed a high degree of construct validity: the correlations between the CD-QOL, self report of HRQOL and the psychometric measures were all in the expected direction and within the ideal range of 0.35–0.65, showing convergent validity. Furthermore, the CD-QOL easily discriminated between known groups: those with lower self rated health, poorer daily function (SIP), higher psychological distress (BSI) and increased abdominal pain (VAS scale) all had lower CD-QOL overall scores and these findings were retained for the four subscales.

The CD-QOL is not the first condition-specific quality of life measure for CD. Recently, Hauser and colleagues using similar methods developed The Celiac Disease Questionnaire, CDQ.[20] However, the key difference between the two instruments relates to their underlying conceptual framework. The CDQ is more of a health status instrument that focuses on both physical (e.g. loose stools, urge, abdominal cramping) and

psychological (depressed, happy) symptoms, as well as impairments in daily function (sexual activities, work, recreation, etc.). These constructs can be readily obtained by using questionnaires that are primarily designed to obtain them. In addition, we have recently shown that the physical symptoms of bowel dysfunction and pain are more related to the degree of emotional distress than to the disease-based measures of disease.[21] Therefore, we employed a needs-based model that is more proximate to the attitudes and perceptions of individuals with CD that relate to meeting the basic needs of the condition (e.g. I have trouble socializing because of my disease).[22] Needs-based measures are more sensitive to changes over time and therefore preferred for clinical trials.[23, 24] While physical symptoms could impact patient needs, the scale did not include measures related to the physical impact of CD patients because individuals in our population did not report these as salient concerns. This probably reflects the changing nature of coeliac disease: whereas in the past, patients were more likely to present with malabsorptive symptoms such as severe diarrhoea and weight loss, today, patients tend to present with milder symptoms of diarrhoea and also pain.[21, 25]

There are some limitations to the study. First, although we included a broad sub-set of patients from both support groups and a tertiary care referral centre, these findings may not be generalizable to undiagnosed patients or patients outside the United States. In addition, as these data were assessed at one point in time, we were not able to assess longitudinal construct validitity (i.e. responsiveness), although we plan to do this in future. Finally, although all subjects had physician-diagnosed coeliac disease, not all of them underwent duodenal biopsy and their response to gluten-free diet was not ascertained. Thus, a proportion of the population may not meet strict criteria for coeliac disease. Nonetheless, the population is representative of patients diagnosed with coeliac disease who are referred to a tertiary care centre for this disease.

In summary, using standardized scale development methods, we developed the CD-QOL, a coeliac disease-specific quality of life instrument. This instrument showed high reliability and construct validity. Unlike generic quality of life surveys and health status measures, the condition-specific and needs-based CD-QOL considers the difficulties imposed by a stringent gluten-free diet, which, in the United States, can be quite expensive and difficult to follow. This approach has not been taken by any other coeliac questionnaire. The CD-QOL is a valid measure of health-related QOL for this condition and is likely to be a useful tool for evaluating patients on a gluten-free diet with this disorder.

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APPENDIX

CD-QOL Scale (final version) CD-QOL Survey

Please think about your life over the past month (30 days), and look at the statements below. Each statement has five possible responses. For each statement, please fill in one box in each row that best describes your feelings.

		Not at all	Slightly	Moderately	Quite a bit	A great deal
		1	2	3	4	5
1	I feel limited by this disease	☐	☐	☐	☐	☐
2	I feel worried that I will suffer from this disease	☐	☐	☐	☐	☐
3	I feel concerned that this disease will cause other health problems	☐	☐	☐	☐	☐
4	I feel worried about my increased risk of cancer from this disease	☐	☐	☐	☐	☐
5	I feel socially stigmatized for having this disease.	☐	☐	☐	☐	☐
6	I feel like I'm limited in eating meals with coworkers	☐	☐	☐	☐	☐
7	I feel like I am not able to have special foods like birthday cake and pizza	☐	☐	☐	☐	☐
8	I feel that the diet is sufficient treatment for my disease	☐	☐	☐	☐	☐
9	I feel that there are not enough choices for treatment	☐	☐	☐	☐	☐
10	I feel depressed because of my disease	☐	☐	☐	☐	☐
11	I feel frightened by having this disease	☐	☐	☐	☐	☐
12	I feel like I don't know enough about the disease	☐	☐	☐	☐	☐
13	I feel overwhelmed about having this disease	☐	☐	☐	☐	☐
14	I have trouble socializing because of my disease	☐	☐	☐	☐	☐
15	I find it difficult to travel or take long trips because of my disease	☐	☐	☐	☐	☐
16	I feel like I cannot live a normal life because of my disease	☐	☐	☐	☐	☐
17	I feel afraid to eat out because my food may be contaminated	☐	☐	☐	☐	☐
18	I feel worried about the increased risk of one of my family members having coeliac disease	☐	☐	☐	☐	☐
19	I feel like I think about food all the time	☐	☐	☐	☐	☐
20	I feel concerned that my long-term health will be affected	☐	☐	☐	☐	☐