Validation of a specific quality of life questionnaire for functional digestive disorders

O Chassany, P Marquis, B Scherrer, N W Read, T Finger, J F Bergmann, B Fraitag, J Geneve, C Caulin

Abstract

Background—Dyspepsia and irritable bowel syndrome are suitable conditions for assessment of quality of life. Their similarities justify the elaboration of a single specific questionnaire for the two conditions.

Aims—To examine the process leading to the validation of the psychometric properties of the functional digestive disorders quality of life questionnaire (FDDQL).

Methods—Initially, the questionnaire was given to 154 patients, to assess its acceptability and reproducibility, analyse its content, and reduce the number of items. Its responsiveness was tested during two therapeutic trials which included 428 patients. The questionnaire has been translated into French, English, and German. The psychometric validation study was conducted in France, United Kingdom, and Germany by 187 practitioners. A total of 401 patients with dyspepsia or irritable bowel syndrome, defined by the Rome criteria, filled in the FDDQL and generic SF-36 questionnaires.

Results—The structure of the FDDQL scales was checked by factorial analysis. Its reliability was expressed by a Cronbach's α coefficient of 0.94. Assessment of its discriminant validity showed that the more severe the functional digestive disorders, the more impaired the quality of life ($p < 0.05$). Concurrent validity was supported by the correlation found between the FDDQL and SF-36 questionnaire scales. The final version of the questionnaire contains 43 items belonging to eight domains.

Conclusions—The properties of the FDDQL questionnaire, available in French, English, and German, make it appropriate for use in clinical trials designed to evaluate its responsiveness to treatment among patients with dyspepsia and irritable bowel syndrome.

(Gut 1999;44:527-533)

Keywords: digestive disorders; irritable bowel syndrome; dyspepsia; quality of life; clinical trial; validation

The need to assess subjective aspects of health related quality of life (QoL) under chronic conditions is now increasingly recognised. The prevalent functional digestive disorders (FDD), including functional dyspepsia (FD) and irritable bowel syndrome (IBS), constitute

suitable conditions for the use of a quality of life questionnaire. For FDD, there is no specific function impairment and therefore no yardstick for therapeutic evaluation.^{1,2} Current criteria such as pain score correlate poorly with the patient's own evaluation of health status.³⁻⁵ FDD are chronic non-life threatening conditions, but have been reported to have a strong impact on daily activities, wellbeing, social performance, and psychological status,^{6,7} even during symptom-free periods, because of the fear of the next bout of abdominal pain, the restrictions on social life and leisure, and the obligation to take drugs.⁸ QoL assessment explores the repercussions of the disease and the treatments as perceived by the patient.³ Like any other outcome criterion, a QoL questionnaire has to include psychometric data such as reliability, and content and construct validity.^{4,5,9} When planning a clinical trial involving quality of life, the major concern is to select the most relevant, valid, and responsive questionnaire, which should be available in several languages. Generic instruments are designed to compare health status among different populations, whatever the underlying condition.¹⁰ Their main drawback is their failure to stimulate responsiveness, as they do not focus specifically on the impact of a particular disease. They have rarely disclosed small but significant health status changes over time or during therapeutic trials. A disease specific questionnaire seems more pertinent to discrimination of the effect of a particular therapy on the QoL.¹⁰ An analysis of the literature did not show the existence of any specific questionnaire devoted to FDD when we started to elaborate our questionnaire. Our objectives were to draft and validate a specific questionnaire, which would be available in French, English, and German. Besides a short description of the initial steps in devising this functional digestive disorders quality of life questionnaire (FDDQL), we report here the results of the international psychometric validation study in 401 patients with FD or IBS.

Patients and methods

INITIAL DEVELOPMENT

A French self administered questionnaire of 74 items was generated by clinicians (O C, J F B, and C C) on the basis of the literature, from

Abbreviations used in this paper: FD, functional dyspepsia; FDD, functional digestive disorders; FDDQL, functional digestive disorders quality of life; IBS, irritable bowel syndrome; QoL, quality of life.

Service de Médecine,
Hôpital Lariboisière,
75010 Paris, France
O Chassany
J F Bergmann
C Caulin

MAPI Values, 27 rue
de la Villette, 69003
Lyon, France
P Marquis

Institut de Recherche
Jouveinal, 3-9 rue de la
Loge, 94265 Fresnes,
France
B Scherrer
B Fraitag
J Geneve

Northern General
Hospital, Herries
Road, Sheffield
S5 7AU, UK
N W Read

Quali-team,
Frankfurter Strasse 47,
D 35037 Marburg,
Germany
T Finger

Correspondence to:
Dr O Chassany, Service de
Médecine, Hôpital
Lariboisière, 2 rue Ambroise
Paré, 75475 Paris Cedex 10,
France.

Accepted for publication
9 October 1998

Figure 1 Stepwise procedure for the elaboration of the functional digestive disorders quality of life (FDDQL) questionnaire. FDD, functional digestive disorders; IBS, irritable bowel syndrome; QoL, quality of life.

symptoms of FDD reported by patients, and from their consequent worries about daily activities. The successive steps in its elaboration (fig 1) are briefly described below for each section.

Table 1 Percentage distribution of gastrointestinal symptoms in the study population (n=391)

	Dyspepsia (n=189)	IBS (n=202)
<i>Functional dyspepsia: Rome criteria^{13*}</i>		
Upper abdominal pain or discomfort	87	63
Epigastric burning	62	23
Pain relieved by food or antacid	49	17
Postprandial pain	58	33
Night pain waking the patient from sleep	37	19
Postprandial fullness	89	56
Postprandial upper abdominal bloating	81	77
Feeling of slow digestion	70	48
Early satiety	38	28
Nausea, vomiting	50	26
Excessive burping/belching	68	40
Heartburn	51	17
<i>Irritable bowel syndrome: Rome criteria^{14†}</i>	IBS (n=202)	Dyspepsia (n=189)
Abdominal pain or discomfort relieved by defecation	91	25
Altered bowel frequency	87	34
Altered form of stool	88	39
Altered stool passage	82	27
Bloating or feeling of abdominal distension	97	70
Passage of mucus	28	14

*All differences between the dyspepsia and IBS groups were significant ($p < 0.05$) except for early satiety; †All differences between IBS and dyspepsia groups were significant ($p < 0.05$). IBS, irritable bowel syndrome.

Acceptability and item selection

A total of 31 patients with FDD and 11 healthy subjects filled in the first version of the questionnaire. On the basis of the results of patient testing and clinicians' decisions, some items were reformulated, deleted, or added, leading to a 59 item questionnaire.

Test-retest procedure

Fifty eight patients with FDD completed the questionnaire twice within a mean interval of 31 (9) days. Reproducibility was good as 16 stable patients who had the same pain score on both completions also had the same QoL score leading to an intraclass correlation coefficient of 0.98.¹¹ For the 42 patients whose pain score either worsened or improved during the survey, the QoL changed in the same direction (analysis of variance, $p = 0.0005$).

Therapeutic trials

The questionnaire was tested in two randomised double blind placebo controlled trials. In one trial, 277 patients with IBS were randomised into two groups, receiving either fedotozine (a peripheral kappa agonist) or placebo for six weeks. The mean improvement in lower abdominal pain was significantly greater with fedotozine than with placebo (analysis of variance, $p = 0.038$). QoL analysis of the data for 193 patients who filled in the questionnaire correctly showed a significant improvement with fedotozine over placebo ($p = 0.033$).¹² In the second trial, the results for several doses of acetorphan (an enkephalinase inhibitor) were compared with those for placebo in 151 patients with IBS. There was no efficacy effect of acetorphan on symptom or QoL scores compared with placebo, but both QoL and abdominal pain scores improved significantly over time in all the treatment groups ($p = 0.0001$).

Aggregation of items into scales

Items expected to explore the same concepts were combined into 12 scales according to the meaning of each item and to the results of a factorial analysis. Data were derived from the questionnaire filled in by the 277 patients with IBS in the fedotozine trial.

Content analysis

Sixty five patients with FDD and a panel of experts verified that the questionnaire correctly sampled the full range of concepts on FD and IBS and its clarity. Nine items that were of no concern or worry to 50% or more of patients were deleted, resulting in a 68 item questionnaire.

Translation for international use

The French version was translated into English and German by using the forward-backward translation method.

INTERNATIONAL PSYCHOMETRIC VALIDATION

In a cross sectional study, the proposed aggregation of items to form the different scales was verified, scores were calculated for each scale, and the reliability and validity of the FDDQL

Table 2 Demographic data and percentage distribution of the onset and severity of digestive disorders among 391 patients with dyspepsia and irritable bowel syndrome

	Dyspepsia (n=189)*	IBS (n=202)†	Controls (n=97)
Age (mean (SD))	50 (15)	46 (15)	46 (15)
Women	52	70	62
Current digestive therapy	74	72	
Duration of disease			
> 1 year	79	86	
> 5 years	30	43	
Number of symptoms			
< 5	9	13	
5–10	38	41	
> 10	53	46	
Handicap reported by the investigator			
None	8	4	
Mild	33	27	
Moderate	39	48	
Severe	19	17	
Extreme	1	4	

*Initial number 191 (two French questionnaires missing); †initial number 210 (six French questionnaires missing and two French and German erroneous inclusions).
IBS, irritable bowel syndrome.

questionnaire was checked. The study was performed in France, United Kingdom, and Germany. General practitioners and gastroenterologists each had to recruit two consulting patients with FD or IBS, defined by the occurrence several times a week for at least six months of at least two Rome symptoms (table 1).^{13 14} Exclusion criteria were a visual, linguistic, or mental disability preventing correct completion of the questionnaire, and a severe event that had occurred during the preceding three months that was likely to impair the QoL. Consulting patients without FDD were also included as controls by the same practitioners.

Procedure adopted for the study

Eligible dyspeptic and patients with IBS who gave informed consent to participate were asked to complete the specific FDDQL questionnaire alone in the waiting room, immediately after the consultation, and to hand it back to the practitioner in a sealed envelope. The questionnaire contained 68 items divided into 12 scales with five point Likert scale answers,

expressed in terms of intensity, frequency, or agreement. The recall period about which patients were asked was the preceding two weeks. Patients also had to complete the generic health status SF-36 questionnaire, validated in several languages.¹⁵ This questionnaire comprises 36 items which evaluate nine domains: physical functioning, social functioning, role limitation by physical problems, role limitation by emotional problems, mental health, energy and vitality, bodily pain, general perception of health, and changes in health over the past year. Answer options are dichotomic (yes/no) or comprise three, five, and six point Likert scales. The recall period is the preceding four weeks. In both the FDDQL and SF-36 questionnaires, the score for each scale was obtained by the non-weighted sum of the scores for each item (ranging from 0 to 4 for a five point Likert scale) and was linearly transformed into a range extending from 0 (poor QoL) to 100 (good QoL).^{16 17} Control patients, with disorders other than FDD, were asked to complete the SF-36 questionnaire only.

Statistical analysis

Mean values were compared by Student's *t* test, and categorical data by the χ^2 test. The level of significance was 0.05. Acceptability of the FDDQL questionnaire was estimated from the number of missing data. The psychometric properties of the FDDQL questionnaire were analysed in five ways. (a) Factorial analysis used the principal component method to explore item aggregation into scales. (b) Confirmation of the structure of the FDDQL questionnaire scales was achieved using multi-trait scaling analysis,^{3 5} which is based on item scale correlation (Pearson coefficient). Item convergent validity was defined as a correlation of 0.4 or more between an item with its own scale, and item divergent validity as a stronger correlation of an item with its own scale than with other scales. (c) Reliability of the scales was assessed by internal consistency (Cronbach's α coefficient) which measures the overall correlation between items within a scale. A level of 0.7 or higher is considered desirable.^{16 17} (d) Discriminant validity explores the ability of the instrument to discriminate between groups of patients whose health status differs, according to the characteristics of their disease—for example, its severity.¹⁸ (e) Concurrent validity was analysed by correlating the scores for the specific FDDQL scales with those for the SF-36 scales, using Spearman's non-parametric correlation coefficient test. The concurrent validity was fulfilled when the scale scores for related concepts—that is, physical—showed close correlation (Spearman >0.4).^{3 16 17}

Results

The study was conducted from June to November 1995. A total of 187 practitioners, 55 from France, 60 from the United Kingdom, and 72 from Germany, participated in the study. In all, 498 eligible patients attending consultations were included: they comprised

Table 3 Scale reliability and content of the final FDDQL questionnaire (43 items, eight scales)

Domains of the FDDQL scales	Cronbach's α coefficient	Content
Daily activities (8 items)	0.89	Impact of FDD on daily activities such as running, leisure activities, and usual housework
Anxiety (5 items)	0.80	Impact of FDD on anxiety, fear of digestive cancer, apprehensions (e.g. while on holiday)
Diet (6 items)	0.82	Impact of FDD on diet
Sleep (3 items)	0.78	Impact of FDD on quality of sleep
Discomfort (9 items)	0.84	Impact of FDD symptoms like flatulence, bloated stomach, stomach rumbling on evenings out. Satisfaction of digestion
Coping with disease (6 items)	0.78	Impact of FDD on situations like having a hearty meal with friends or family, minimising the importance of digestive pain, and perception of health status
Control of disease (3 items)	0.69	Impact of FDD on conditions like not being in control of the situation, having no idea what to do, and the feeling that nothing will change the digestive problems
Stress (triggering factors, 3 items)	0.81	Impact of triggering factors like stress on FDD
Total	0.94	

FDD, functional digestive disorders; FDDQL, functional digestive disorders quality of life.

Figure 2 Distribution among dyspeptic and irritable bowel syndrome patients of mean scores for the functional digestive disorders quality of life (FDDQL) questionnaire scales. Scores for each scale ranged from 0 (poor quality of life) to 100 (good quality of life). Differences between dyspeptic and irritable bowel syndrome patients were significant for the diet, discomfort, and stress scales ($p < 0.05$, Mann-Whitney U test).

401 patients with either FD ($n = 191$) or IBS ($n = 210$) and 97 matched control patients. Of the patients with FD and IBS, 152 were included in France, 126 in the United Kingdom, and 123 in Germany. The rate of questionnaire return was 100% for United Kingdom and Germany and 95% for France. Eight French patients did not fill in the questionnaire. Except for two patients (one French and one German), all the eligibility criteria were met. Statistical analysis was therefore performed on 391 patient and 97 control questionnaires.

PATIENT CHARACTERISTICS

Mean age did not differ among patients with FD and IBS and controls (table 2). The duration of symptoms exceeded five years in 43% of patients with IBS compared with 30% of FD patients ($p = 0.028$). Patients were symptomatic, as most of them presented with five or more symptoms (table 2). Of the patients with IBS, 69% had a handicap that was scored by

Figure 3 Distribution of mean scores for functional digestive disorders quality of life (FDDQL) questionnaire scales according to the number of symptoms. Each scale score and global score ranged from 0 (poor quality of life) to 100 (good quality of life). Intrascale differences were significant for all scales except those for coping with and control of disease and stress, according to the number of symptoms ($p < 0.05$, Mann-Whitney U test). Differences between global scores, according to the number of symptoms were significant ($p < 0.001$, Kruskal-Wallis test).

the investigator as moderate to extreme, compared with 59% of FD patients ($p = 0.053$). The distribution of symptoms was different among patients with FD and IBS ($p < 0.05$) except for postprandial fullness (table 1). Control patients were recruited while consulting their general practitioner. They had no digestive disorders, but 43% had a chronic disease, most commonly arthritis, hypertension, and insomnia.

ACCEPTABILITY OF THE QUESTIONNAIRE

Of the 401 patients given the questionnaire, eight did not complete or return it. Of the returned FDDQL questionnaires, 10.9% ($n = 43$) had at least one missing item (FD 8% and IBS 14%). Missing items were reported for 11, 17, and 5% of French, British, and German patients respectively. Acceptability for the SF-36 questionnaire was similar, with a total of 11.5% ($n = 45$) incomplete questionnaires, which included 17, 9.5, and 6.5% of French, British, and German questionnaires respectively.

FACTORIAL ANALYSIS

Principal component analysis identified 17 factors with a relatively good distribution of variance, as the first four factors explained 38% of the variance. The factorial structure was similar for the three countries considered and for FD and IBS.

ITEM SCALE CORRELATION

Convergent and divergent validity were satisfied, as all items except five correlated more strongly with their own scales than with other scales.

Twenty five items were deleted for the following reasons: they only accounted for a very small fraction of the total variance; they did not form a factor as it was expected; they were not sufficiently well correlated with their own scale or they correlated with several other factors; there was a ceiling effect. A ceiling effect means that most patients are not worried by a particular item. The scale assignment of six items was changed. After the removal of these items, the scaling success was 98%, as all the items except one correlated well with their own scale. This resulted in a questionnaire of 43 items grouped into eight scales (four of the original scales were either combined or deleted because of lack of items).

RELIABILITY

The global Cronbach's α coefficient was 0.94, and scale coefficients ranged from 0.69 to 0.89 (table 3).

DISCRIMINANT VALIDITY

This was assessed by comparing FDDQL scores with descriptive and clinical patient data. There was no difference between the scores of the FDDQL scales for the three countries, except for the stress scale, for which the score was higher (better) in the United Kingdom (Mann-Whitney U test, $p = 0.0001$). The mean scores for all the FDDQL scales were higher for men than women (Mann-

Table 4 Discriminant validity. Mean values (SD) for FDDQL scales according to the handicap scored by the investigators. Scores for each scale ranged from 0 (poor quality of life) to 100 (good quality of life). All intrascale differences according to the handicap were significant except for the stress scale ($p < 0.05$, Mann-Whitney U test)

Handicap	Daily activities	Anxiety	Diet	Sleep	Discomfort	Coping with disease	Control of disease	Stress
None (n=24)	80 (17)	62 (18)	53 (23)	73 (17)	55 (21)	62 (22)	65 (16)	33 (24)
Mild (n=116)	72 (20)	59 (21)	54 (18)	68 (23)	52 (19)	59 (20)	60 (21)	31 (23)
Moderate (n=169)	64 (20)	53 (20)	44 (18)	62 (21)	42 (17)	52 (18)	55 (21)	29 (21)
Severe (n=71)	51 (22)	44 (24)	37 (26)	56 (24)	37 (19)	43 (19)	50 (23)	26 (24)
Extreme (n=11)	36 (19)	38 (24)	33 (25)	36 (20)	20 (9)	34 (25)	39 (25)	33 (31)

Whitney U test, $p < 0.05$), and higher for patients with FD than for those with IBS (fig 2). Differences were significant for the diet, discomfort, and stress scales, p ranging from 0.026 to 0.0001 (Mann-Whitney U test) (fig 2). The scores for all scales except those for coping with disease, control of disease, and stress decreased significantly ($p < 0.05$) when the number of symptoms was clustered into three groups (fig 3). The mean scores for all scales except the stress scale differed ($p < 0.05$) depending on the severity of the handicap reported by the investigator on a five point Likert scale. The largest differences were observed for the daily activities and sleep scales. Scores for the daily activities scale ranged from 80 (17) in the absence of a handicap to 36 (19) for an extreme handicap (table 4). Most of the scales, especially those for daily activities, discomfort, and sleep were significantly associated with many symptoms, indicating that the QoL score was higher when the symptom was absent. However, there was little or no association between the FDDQL scales and upper abdominal pain or epigastric burning in FD patients and abdominal pain in patients with IBS.

CONCURRENT VALIDITY

This was assessed by the correlations between scores for the scales of the FDDQL and SF-36 questionnaires. Except for the FDDQL stress scale, all the Spearman rank correlation coefficients were significant ($p < 0.0001$). The two most strongly correlated FDDQL scales with SF-36 scales were those for daily activities and coping with disease. The daily activities scale correlated closely with the scales for physical role limitation and bodily pain (0.63 for both) and less well with those for emotional role limitation and mental health (0.43 and 0.48 respectively). Similarly, the coping with disease scale correlated closely with the general health scale (0.69), but more weakly with that for physical functioning (0.51).

VALIDATION OF A GLOBAL SCORE FOR FDDQL ITEMS

Principal component analysis of the scores for the scales in the questionnaire yielded a correlation ≥ 0.4 on the first factor, for all except the stress scale. This factor explained 51% of the variance. A global score was thus computed from the sum of the scores for all the scales except the stress scale. Global scores ranged from 0 (poor QoL) to 100 (good QoL). Patients scored their digestive status over the preceding two weeks on a scale ranging from 0 (very bad) to 10 (very good). There was a sig-

nificant association (Kruskal-Wallis test, $p < 0.001$) between the global score for QoL and the score for digestive status, as the QoL ranged from the low level of 42 (14) for poor digestive status (scored 0–3), to an intermediate level of 55 (13) (scored 4–6), and thence to the high level of 64 (15) for good status (scored 7–10). Similar results were obtained for the number of symptoms. The larger the number of symptoms, the lower the global QoL score (Kruskal-Wallis test, $p < 0.001$): one to five symptoms corresponded to a QoL score of 59 (14), and six to ten symptoms to a score of 55 (16). For more than 10 symptoms, the QoL score was 48 (15) (fig 3).

Discussion

Functional digestive disorders are common as 10–40% of the general population report symptoms consistent with FD or IBS.^{19–22} These diseases are chronic, and their manifestations include recurrent bouts of digestive and non-digestive symptoms at unpredictable times. Some even regard FD and IBS as non-severe conditions that cause discomfort in all day to day activities and have a real impact on health care utilisation and working capacity.^{6, 22, 23}

According to a survey conducted with the SF-36 questionnaire, dyspeptic symptoms undermined vitality, mental health, and the emotional role contrarily to the status of the general population,²⁴ and resulted in more suspensions of daily activities.⁷ In a large survey of 1032 symptomatic patients with IBS, we recently reported that the impact of IBS symptoms was much stronger than expected. Even in the absence of symptoms, 68% of patients were apprehensive because they could not predict when the next bout of IBS would occur, and 69–85% said they experienced difficulties in carrying out their daily activities.⁸ These difficulties also affected their perception of general health status, sleep, and diet.⁸ The overall QoL scored by the generic schedule for evaluation of individual quality of life was significantly poorer in IBS than inflammatory bowel diseases.²⁵

In our study, the low scores for the FDDQL and SF-36 questionnaires reflect the physical and psychological repercussions of FD and IBS on QoL, the QoL in patients with IBS being worse than in FD. Thus SF-36 subscores changed significantly, by a mean 27% in dyspeptic patients and 30% in patients with IBS, compared with the control group composed of patients with disorders other than IBS or FD (fig 4).

Figure 4 Distribution of mean scores for the SF-36 questionnaire among dyspeptic and irritable bowel syndrome patients versus controls. Scores for each scale ranged from 0 (poor quality of life) to 100 (good quality of life).

Current clinical criteria for the assessment of FDD, such as abdominal pain, may not reflect the patient's subjective point of view on life satisfaction and function in day to day activities, and may not correlate with consulting behaviour.²⁰ In our psychometric study, abdominal pain severity correlated weakly with the scores for the FDDQL scales. In another large cohort of 1300 patients with IBS,²⁶ the improvement in symptoms over time was independent of change in the severity of handicap in daily life. Several authors therefore postulated that psychological factors, rather than the type or severity of symptoms, strongly affect the way in which gastrointestinal symptoms are perceived and acted upon.^{20 27 28} A poor correlation was recently shown between the SF-36 scores and subjective symptom scores for reflux and objective reflux measurements by 24 hour ambulatory oesophageal pH monitoring.²⁹ Consequently, current clinical criteria are not relevant to the evaluation of QoL in FDD.

When evaluating QoL in a clinical trial, one has to choose between a generic and a disease specific questionnaire. As generic measures are designed for general populations, they are less likely to detect small but clinically important changes induced by treatment.⁴ Thus, in a study of 185 dyspeptic patients,²⁴ the psychological general wellbeing questionnaire, a generic QoL instrument, was unable to detect any difference between the QoL of patients receiving omeprazole and those receiving placebo, even though there was a significantly greater improvement in dyspeptic symptoms in the omeprazole group. As disease specific instruments include items that are likely to be affected by the particular disease under study, they are expected to be more responsive than generic measures to clinical changes and therefore be more appropriate for clinical trials designed to evaluate specific treatments.^{5 10} In addition, some generic QoL questionnaires omit relevant topics; for instance, the SF-36 questionnaire contains no item relating to sleep, which is impaired in FDD.⁸

Our questionnaire is specific for patients with FD and IBS, because these are chronic functional diseases, which may have common physiopathological characteristics and triggering factors, and because dyspeptic and IBS patients exhibit very similar alterations in their personality patterns.³⁰ Moreover, many authors have underlined the overlap between FD and IBS symptoms. FD symptoms are present in 50–90% of patients with IBS.^{20 26 28 31} Talley *et al*²² reported that 34% of patients with FD had symptoms compatible with IBS. Thus, according to Agréus *et al*¹⁹, separation of functional gastrointestinal symptoms into those relating to FD, its subgroups, and IBS may be inappropriate. In our study, even if the Rome criteria eliciting major symptoms of FD and IBS were able to distinguish clearly FD from IBS patients, many dyspeptic and IBS patients exhibited such a symptom overlap (table 1). Therefore, on the basis of the similarities in demographic data, psychological profiles, possible underlying mechanisms, and frequent overlapping of the symptoms, it is desirable to elaborate a single QoL questionnaire for FD and IBS. The FDDQL questionnaire showed clearly an altered quality of life in the both groups of patients.

The patients who enrolled in our psychometric validation study were representative of the dyspeptic and IBS patients likely to be included in subsequent clinical studies. Patients were considered eligible for inclusion if they had a clinical diagnosis of FD or IBS,^{13 14} and if they were able to answer questionnaires correctly. Patients enrolled must present with at least moderately severe symptoms to be representative of consulting patients. Those who enrolled in our study were severe cases, for three reasons: they reported many symptoms (mean (SD) 9 (3)); most of the investigators rated their handicap as moderate to extreme; and their disease had lasted for several years. It has been shown that abdominal symptoms were more likely to limit various aspects of the lives of chronic IBS attenders than first time attenders.³²

To be valid, a questionnaire needs first to be understandable and easily completed by the population concerned.³¹ In our study, the low rate of missing data for the FDDQL questionnaire, which was similar to the rate for the validated generic SF-36 questionnaire, supports the feasibility of measuring health related QoL with this specific questionnaire in patients with FD or IBS. In all the studies combined, 983 patients were given the questionnaire, and most were interested in answering questions that directly concerned their daily life.

The psychometric properties of the FDDQL questionnaire were found to be satisfactory. The structure yielded by factorial analysis confirms that the FDDQL questionnaire is relevant for both FD and IBS, in English, German, and French. Assessment of the within scale reliability was good, as Cronbach's α coefficient ranged from 0.69 to 0.89.¹⁰ The discriminant capacity of the FDDQL questionnaire was established, as the patients with the most severe disease in terms of handicap, the

number of symptoms, and digestive status reported significantly lower subscores and global scores than the others. Women reported poorer health in both the FDDQL and SF-36 questionnaires, as already stressed by others.³³ Concurrent validity was supported as the scales of the specific FDDQL and generic SF-36 questionnaires exploring the same concepts—that is, physical—were more closely related than scales exploring different concepts, the SF-36 questionnaire being taken as reference.^{3,16,17} These findings support the claim that the FDDQL questionnaire can be considered truly disease specific and not only symptom based.¹⁷ However, the correlation between the respective scales of the FDDQL and SF-36 questionnaires was not very close, as it ranged from 0.06 to 0.69. This is a quality rather than a defect, as the validation of a new questionnaire should only yield a moderately close correlation with a well established scale. If that correlation is very close, it means that the new QoL tool is redundant. The responsiveness of the preliminary version of the FDDQL questionnaire has been established, but that of the final version must still be confirmed in clinical trials.

Researchers are now focusing on the QoL associated with gastrointestinal disorders. Since the elaboration of the FDDQL questionnaire began, an American IBS specific QoL questionnaire has been published.³⁴ It consists of 30 items grouped into nine concepts (emotional role, mental health, sleep, energy, physical functioning, diet, social role, physical role, and sexual relations). It has been administered to more than 500 IBS patients during the validation process, but is only available in English, and its responsiveness remains to be evaluated.

The FDDQL questionnaire measures the specific physical, psychological, and perceptual impacts of dyspepsia and IBS. All the steps in its validation were designed to select items assumed to concern or worry most patients, so that changes could be detected over time or during a therapeutic trial. This 43 item self administered questionnaire provides a profile with eight subscores as well as a global score (table 3), is available in English, French, and German, and is ready for use in international clinical trials to evaluate its responsiveness. (Since this paper was first written, the FDDQL questionnaire has also been translated into Italian and Spanish, and adapted for US and English and French Canadian patients.)

This research was partially funded by the Institut de Recherche Jouveinal. We thank the 187 investigators from United Kingdom, Germany, and France who enrolled the 498 patients participating in the International Psychometric Study. Readers interested in the content of the FDDQL questionnaire should contact O C.

- 1 Farthing MJG. Irritable bowel, irritable body, or irritable brain? *BMJ* 1995;310:171–5.
- 2 Talley NJ. Functional dyspepsia: should treatment be targeted on disturbed physiology? *Aliment Pharmacol Ther* 1995;9:107–15.
- 3 Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Ann Intern Med* 1993;118:622–9.

- 4 Wiklund I, Dimenäs E, Wahl M. Factors of importance when evaluating quality of life in clinical trials. *Control Clin Trials* 1990;11:169–79.
- 5 Testa MA, Simonson DC. Assessment of quality of life outcomes. *N Engl J Med* 1996;334:835–40.
- 6 Drossman DA, Li Z, Andruzzi E, et al. Householder survey of functional gastrointestinal disorders. Prevalence, sociodemography, and health impact. *Dig Dis Sci* 1993;38:1569–80.
- 7 Talley NJ, Weaver AL, Zinsmeister AR. Impact of functional dyspepsia on quality of life. *Dig Dis Sci* 1995;40:584–9.
- 8 Chassany O, Bergmann JF, Billardon M, et al. Quality of life in irritable bowel syndrome [abstract]. *Gastroenterology* 1996;110:A646.
- 9 Staquet M, Berzon R, Osoba D, et al. Guidelines for reporting results of quality of life assessments in clinical trials. *Qual Life Res* 1996;5:496–500.
- 10 Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Med Care* 1989;27(suppl):S217–32.
- 11 Deyo RA, Diehr P, Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. *Control Clin Trials* 1991;12:S142–58.
- 12 Chassany O, Geneve J, Abitbol JL, et al. Specific quality of life questionnaire in irritable bowel syndrome. Effect of fedotazine [abstract]. *Gastroenterology* 1995;108:A581.
- 13 Talley NJ, Colin-Jones D, Koch KL, et al. Functional dyspepsia: a classification with guidelines for diagnosis and management. *Gastroenterology International* 1991;4:145–60.
- 14 Thompson WG, Creed F, Drossman DA, et al. Functional bowel disease and functional abdominal pain. *Gastroenterology International* 1992;5:75–91.
- 15 Aaronson NK, Acquadro C, Alonso J, et al. International quality of life assessment (IQOLA) project. *Qual Life Res* 1992;1:349–51.
- 16 Fletcher A, Gore S, Jones D, et al. Quality of life measures in health care. II. Design, analysis, and interpretation. *BMJ* 1992;305:1145–8.
- 17 Marquis P, Fayol C, Joire JE, et al. Psychometric properties of a specific quality of life questionnaire in angina pectoris patients. *Qual Life Res* 1995;4:540–6.
- 18 Aaronson NK. Quality of life assessment in clinical trials: methodologic issues. *Control Clin Trials* 1989;10:S195–208.
- 19 Agréus L, Svärssudd K, Nyren O, et al. Irritable bowel syndrome and dyspepsia in the general population: overlap and lack of stability over time. *Gastroenterology* 1995;109:671–80.
- 20 Jones R, Lydeard S. Irritable bowel syndrome in the general population. *BMJ* 1992;304:87–90.
- 21 Penston JG, Pounder RE. A survey of dyspepsia in Great Britain. *Aliment Pharmacol Ther* 1996;10:83–9.
- 22 Talley NJ, Fett SL, Zinsmeister AR, et al. Gastrointestinal tract symptoms and self-reported abuse: a population-based study. *Gastroenterology* 1994;107:1040–9.
- 23 Wilhelmsen I. Quality of life in upper gastrointestinal disorders. *Scand J Gastroenterol* 1995;211:21–5.
- 24 Wiklund I, Glise H, Lauritsen K, et al. A placebo-controlled comparison of the effectiveness of omeprazole in relieving dyspeptic symptoms and improving quality of life in patients with functional dyspepsia [abstract]. *Gastroenterology* 1997;112:A330.
- 25 O'Sullivan M, Mahmud N, Lovett E, et al. Impaired quality of life in irritable bowel syndrome as compared to inflammatory bowel disease. *Gut* 1996;39(suppl 3):A33.
- 26 Danquechin Dorval E, Delvaux M, et al. Profil et évolution du syndrome de l'intestin irritable. *Gastroenterol Clin Biol* 1994;18:145–50.
- 27 Talley NJ, Zinsmeister AR, Schleck CD, et al. Dyspepsia and dyspepsia subgroups: a population-based study. *Gastroenterology* 1992;102:1259–68.
- 28 Drossman DA, McKee DC, Sandler RS, et al. Psychosocial factors in the irritable bowel syndrome. A multivariate study of patients and non patients with irritable bowel syndrome. *Gastroenterology* 1988;95:701–8.
- 29 Trus TL, Laycock WS, Branum GD, et al. Quality of life scores correlate poorly with subjective and objective measurements of gastroesophageal reflux [abstract]. *Gastroenterology* 1997;112:A1480.
- 30 Talley NJ, Phillips SF, Bruce B, et al. Relation among personality and symptoms in non-ulcer dyspepsia and the irritable bowel syndrome. *Gastroenterology* 1990;99:327–33.
- 31 Guyatt G, Mitchell A, Irvine EJ, et al. A new measure of health status for clinical trials in inflammatory bowel disease. *Gastroenterology* 1989;96:804–10.
- 32 Guthrie EA, Creed FH, Whorwell PJ, et al. Outpatients with irritable bowel syndrome: a comparison of first and chronic attenders. *Gut* 1992;33:361–3.
- 33 Dimenäs E, Carlsson G, Glise H, et al. Relevance of norm values as part of the documentation of quality of life instruments for use in upper gastrointestinal disease. *Scand J Gastroenterol* 1996;31(suppl 221):8–13.
- 34 Hahn BA, Kirschdoerfer J, Fullerton S, et al. Evaluation of a new quality of life questionnaire for patients with irritable bowel syndrome. *Aliment Pharmacol Ther* 1997;11:547–52.