Performance of the EQ-5D in Patients with Irritable Bowel Syndrome

Donald M. Bushnell, MA,[1] Mona L. Martin, RN, MPA,[1] Jean-François Ricci, PhD,[2] Andrea Bracco, MSc[2]

[1]Health Research Associates, Inc., Mountlake Terrace, WA, USA; [2]Novartis Pharma AG, Basel, Switzerland

ABSTRACT

Objective: The EQ-5D is a standardized, nondisease-specific instrument for evaluating patients' preference-based valuations of health-related quality of life (HRQoL). This study's purpose was to determine the psychometric properties of EQ-5D in patients with irritable bowel syndrome (IBS).
Methods: Data from four European IBS studies were assessed: UK (n = 161 and n = 297), Spain (n = 503), and Germany (n = 100). The EQ-5D is a five-item health state descriptive system used to develop health states (EQ-5D$_{INDEX}$) and a visual analog scale (VAS) (0–100 from worst to best imaginable health state, EQ-5D$_{VAS}$). Measures used with the EQ-5D included the SF-36, Irritable Bowel Syndrome—Quality of Life (IBS-QOL), and both subjective and clinical global assessments of IBS. Convergent validity was assessed using SF-36 and IBS-QOL data, discriminant validity using global ratings of IBS severity, and responsiveness by subjective and physician assessment of condition.

Results: Moderate-to-high associations ($r \geq 0.33$) were seen between the EQ-5D$_{VAS}$ and the SF-36 and IBS-QOL subscales. Mean response scores to EQ-5D$_{INDEX}$ dimensions and the EQ-5D$_{VAS}$ score were significantly better for control patients than for patients with IBS (all $P < 0.01$). The EQ-5D$_{VAS}$ was able to discriminate between levels of pain severity (quartiles, $P < 0.001$; mild/moderate/severe, $P < 0.05$) and general health severity (mild/moderate/severe, $P < 0.001$). The EQ-5D$_{VAS}$ and the EQ-5D$_{INDEX}$ were responsive in patients using both a self-perceived (Subject's Global Assessment) and physician-rated (Clinic Global Assessment) improvement.
Conclusions: The EQ-5D performs well in comparison to general and disease-specific outcomes. It is a valid and responsive measure that can be used to generate preference-based valuations of HRQoL in patients with IBS and useful for comparisons in clinical and cost-effectiveness studies.
Keywords: EQ-5D, irritable bowel syndrome, quality of life, reliability, validity.

Introduction

Irritable bowel syndrome (IBS) is a chronic gastrointestinal (GI) dysmotility disorder characterized by abdominal pain/discomfort, bloating and altered bowel habit (constipation, diarrhea or alternating periods of both) [1–3]. IBS has a broad spectrum of symptom severity, ranging from mild to severe and intractable. IBS is a common condition with an estimated symptom prevalence of 10% to 15% in Western countries [1–4].

Patients with IBS often experience symptoms for many years, with an average duration of 10 years or more [5]. IBS causes significant impairment to the quality of life (QoL) for those patients having this condition [6,7]. Patients with IBS experience physical role limitations, greater pain and a lower perception of their general health than those not having IBS. Epidemiological studies show that IBS accounts for 50% of

visits to gastroenterologists in the United States and 41% of visits in the UK [8,9]. Nevertheless, only 30% of patients with IBS in North America and Europe seek medical treatment [8–13].

Most people can control their symptoms with diet, stress management, and medications prescribed by their physician. Nevertheless, traditional pharmacotherapies may not provide adequate relief of symptoms [14] because these treatments target only one of the multiple symptoms of IBS and may aggravate the others [15,16]. For some people, IBS has a major impact on QoL, affecting their work, social life and ability to travel even short distances.

The assessment of health-related quality of life (HRQoL) using patient-reported outcome (PRO) measures has evolved greatly over the last decade. One measure, the EuroQoL (EQ-5D), was developed jointly by a group of European-based researchers with the intent of constructing a simple, self-administered instrument that provided a composite index score representing the preference for a given health state [17]. The EuroQoL group designed the new instrument to be quick and easy to use, standardized and to be used alongside other measures of health status. This instru-

ment provides both a health profile and index for individuals or groups that allow clinical and economic evaluation of medical interventions [18].

Cardiovascular and oncology are two areas where the EQ-5D has been used quite often, but new studies in musculoskeletal, respiratory, and GI diseases included the EQ-5D as generic questionnaire [19]. Furthermore, the EQ-5D is one of a handful of measures recommended for use in cost-effectiveness analyses by the Washington panel on cost-effectiveness in health and medicine [20].

Although one published study has evaluated IBS populations using the EQ-5D [21], it did not specifically address whether the EQ-5D is an appropriate and meaningful tool to use in patients with IBS. Using data from four separate studies of IBS (two in the UK, one in Spain, and one in Germany), psychometric properties were assessed to determine the validity (focusing on convergent and discriminant validity) and responsiveness of the EQ-5D in patients with IBS.

Methods

Data Sources

UK1 (n = 161) [21]. A study to identify the impact of IBS on HRQoL, time off work, and the utilization and cost of health services took place from February to November 1998. A sample of patients with IBS diagnosed by their general practitioners (GPs) was recruited from six practices in the Trent Region of the UK. The GP practices were chosen to be representative geographically and on the basis of deprivation level and social class. The GPs selected patients from their practice lists based on those prescribed antispasmodics or bowel regulators and/or diagnosed with IBS. The project researcher applied the Rome I criteria [22] to diagnose patients with IBS and only those meeting the criteria were included in the study in the IBS group.

UK2 (n = 297) [23]. A follow-up study to the UK1 was conducted, from May to September 2001, to further assess the quality of life (QoL) and resource use by patient-perceived IBS severity. The same enrollment, inclusion, and exclusion criteria were used. IBS patients were identified from GP records from 13 practices in the Sheffield area of the UK. In addition to the IBS sample, using the same methodology, 326 control subjects were recruited, case matched, by their GPs, on age, sex, and social characteristics. The IBS sample consisted of male or female patients aged 20 to 65 years who were currently on antispasmodics/bowel regulators, and/or had been diagnosed with IBS.

Spain (n = 503) [24]. This nationwide, multicenter observational, prospective, cohort study, initiated in October 2000, compared the impact of IBS on patients with the three IBS subtypes: constipation, diarrhea or alternating between constipation and diarrhea. The study assessed GI symptoms, QoL, psychological well-being, use of resources and environmental stress. Eighty-five gastroenterologists and 25 primary care doctors were involved. Subjects meeting Rome II criteria [25] were recruited from primary health-care centers, external hospital clinics, specialized medical centers, and other outpatient care sites.

Germany (n = 100) [26]. This observational study aimed at assessing the impact of IBS on QoL and the utility benefits of tegaserod began in 1999. This study used the EQ-5D and the disease-specific QoL questionnaire (IBS-QOL) to design a decision model to link the QoL benefits of tegaserod based on IBS pain severity. Patients with a diagnosis of IBS, and who had been treated for IBS for at least 12 months prior to enrollment, were interviewed by a random selection of private practice physicians.

QoL Assessment (Table 1)

EQ-5D. The EQ-5D consists of two parts: the health states descriptive system and the visual analog rating scale (VAS). The descriptive system records the level of self-reported problems on each of the five dimensions of the classification (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). For each dimension the respondent is asked to choose between three options: no problem, some/moderate problems, or extreme problems/unable. Health states defined by the five-dimensional descriptive system can be converted into a weighted health state index by applying scores from value sets elicited from general population samples [27]. Respondents then describe their own health status using a VAS. A 20-cm vertical VAS has become the standard means of obtaining valuations for health states. The endpoints of the VAS are labeled "best imaginable health state" and "worst imaginable health state" anchored at 100 and 0, respectively. Respondents are asked to indicate how they rate their own health state by drawing a line from an anchor box to that point on the VAS that best represents their own health on that day [18]. UK English, Spanish, and German versions have been adapted culturally and translated [28].

SF-36. The Medical Outcomes Trust Short Form 36-Item Health Survey (SF-36) is a generic measure of functional status and well-being [29]. It contains 36 questions that measure health across eight dimensions—physical functioning (PF), role limitations because of physical health (RP), role limitation because of emotional health (RE), social functioning (SF), bodily pain (BP), mental health (MH), vitality or energy (VT), and general health perception (GH). Responses

Table I Instruments used in the quality of life questionnaires

Instrument	Number of questions	Issues covered	Measurement
SF-36	36	Eight dimensions: physical functioning, role limitations because of physical health, role limitation because of emotional health, social functioning, bodily pain, mental health, vitality or energy and general health perception	Responses to each question within a dimension are combined to generate a score from 0 to 100, where 100 indicates good health and 0 indicates poor health
EQ-5D*	5	Mobility, self-care, usual activities, pain, and anxiety	−0.6 to 1 scale that was multiplied by 100 for compatibility with the SF-36 and IBS-QOL: −60 to 100. A value of 100 indicates good health, 0 death and negative values health states worse than death
IBS-QOL	34	Overall score, 8 subscale scores including: dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, sexual, and relationships	100 indicates highest possible QoL and 0 indicates worst possible HRQoL

*The EQ-5D includes the EQ-5D visual analog rating scale.
EQ-5D, EuroQOL instrument; HRQoL, health-related quality of life; IBS-QOL, Irritable Bowel Syndrome—Quality of Life questionnaire; QoL, quality of life; SF-36, Medical Outcomes Study 36-item Short Form health survey.

to each question within a dimension are combined to generate a score from 0 to 100, where 100 indicates "good health" and 0 indicates "poor health." The SF-36 survey was included only in the UK studies presented in this article.

IBS-QOL. The Irritable Bowel Syndrome—Quality of Life questionnaire (IBS-QOL) is a 34-item condition-specific instrument allowing the evaluation of QoL of patients with IBS by means of eight domains (dysphoria, interference with activity, body image, health worry, food avoidance, social reactions, sexual, and relationships). This questionnaire has proved to be valid and reliable for IBS patients [30,31] and has been used in a wide range of clinical trials.

Clinical Variables

To aid the evaluation of validity of the EQ-5D in IBS patients, both subjective and clinical (physician) global assessments of pain were used. In the UK studies, a 0- to 100-point VAS item was given to the patient to rate their assessment of IBS-related pain severity on abdominal pain and discomfort (VAS-ADP). In the Spanish study, a similar VAS item was given to both subjects and physicians to rate IBS severity. In the study from Germany, the severity was defined by subject's rating of severity as mild, moderate or severe.

Data Analyses

Participants who completed the QoL assessments at baseline in all studies were included in the analysis. EQ-5D scores from each study were described by their mean, standard deviation, median, interquartile range, and the percent of scores at the floor and ceiling of the distribution. All analyses were conducted using SPSS® for Windows, Release 11.5 [32].

The validity of the EQ-5D was tested by means of comparisons with validated instruments used to measure various characteristics of health status. Construct validity of the five individual EQ-5D items and EQ-

$5D_{VAS}$ was tested using Spearman correlations with the SF-36 domains and the IBS-QOL subscales and total score. Using a correlation between 0.3 and 0.5 as the definition for moderate correlation and correlations of at least 0.5 for strong correlations [33], the following relationships were hypothesized:

1. Correlations between EQ-5D and the SF-36 would be stronger than those between EQ-5D and IBS-QOL because the EQ-5D and the SF-36 are both generic measures of health status and the IBS-QOL is an IBS-specific measure.
2. EQ-5D mobility would be strongly associated with the SF-36 physical function domain and moderately correlated with the SF-36 social functioning domain.
3. EQ-5D pain/discomfort would be strongly correlated with SF-36 bodily pain domain and moderately correlated with the SF-36 physical functioning domain.
4. EQ-5D anxiety/depression item would be strongly associated with the SF-36 mental health domain and moderately correlated with the SF-36 vitality domain.
5. $EQ-5D_{VAS}$ would be moderately to-strongly correlated with the SF-36 general health domain.
6. EQ-5D pain/discomfort would have stronger associations with the IBS-QOL domains and total score than the other EQ-5D items.

Known-groups construct (discriminant) validity of the $EQ-5D_{VAS}$ (all studies) and the $EQ-5D_{INDEX}$ (in UK studies only) was examined by testing the hypothesis that as IBS severity increases (or worsens), the EQ-5D scores decrease (health status also becomes worse). Results from the subject's global assessment and VAS-ADP item (available in the UK2 study) were divided into tertiles and used to graph the mean $EQ-5D_{VAS}$ scores. Results were investigated for the German study by graphing the $EQ-5D_{VAS}$ mean scores against the subject's response of mild, moderate, and severe IBS pain;

Table 2 Sample characteristics

Sample	Description	Age (year) (mean, SD)	Sex (% female)
UK1 (n = 161)	To identify impact of IBS on HRQoL, work, and utilization	47.1 (11.9)	86.3
UK2 (n = 297)	To compare HRQoL, utilization, and cost by self-perceived IBS severity	48.2 (11.6)	83.9
Spain (n = 503)	Observational study to assess impact of IBS in Spain	42.7 (15.2)	75.9
Germany (n = 100)	Observational study to assess impact of IBS in Germany	53.8 (15.6)	80.0

HRQoL, health-related quality of life; IBS, irritable bowel syndrome.

and for the Spanish study using the subject's response on a seven-point severity of IBS scale (very good to very bad). No assessment of severity was available in the UK1 study. Analysis of variance was used to evaluate differences between groups. Group differences were identified using Scheffe post hoc procedures.

To assess responsiveness, data from Spain were used because this study included a 1-year follow-up measurement. Mean change scores (between baseline and 1 year) were calculated for both subjective and physician global ratings of IBS severity. Based on these change scores, subjects' IBS was identified as having improved, remained the same, or declined in severity. EQ-5D$_{VAS}$ and EQ-5D$_{INDEX}$ scores were then compared across the change in IBS severity. Responsiveness was reported in terms of the effect size statistic (mean change score divided by the standard deviation of baseline score) [34]. This effect size identified the differences in EQ-5D scores associated with the change in IBS severity over time.

Results

The study samples included: UK1, 161 subjects; UK2, 297 subjects; Spain, 503 subjects; and Germany, 100 subjects. The majority of subjects were female in all studies (Table 2) with a mean age of between 43 and 54 years. As seen in Figure 1, the mean scores for each of the five EQ-5D dimensions were very similar across the different studies. Median scores were 1.00 for mobility, self-care, and usual activities, and 2.00 for pain/discomfort and anxiety/depression in all studies. On individual questions, fewer people reported problems with EQ-5D self-care (8.1% in UK1, 12.8% in UK2, 5.2% in Spain, and 0% in Germany). The majority of subjects reported experiencing pain/discomfort

(83.2% in UK1, 84.2% in UK2, 77.0 in Spain, and 93.0% in Germany). The mean EQ-5D$_{VAS}$ score ranged from 55.3 in Germany to 62.4 in UK1 and the EQ-5D$_{INDEX}$ scores ranged from 0.62 in UK2 to 0.70 in Spain (Fig. 2). Figure 2 also includes mean EQ-5D scores for the control group (n = 326) included in the UK2 study. The scores (VAS = 81.0, INDEX = 0.84) indicate that the EQ-5D is able to detect differences between individuals with IBS and controls ($P < 0.001$).

The hypothesized relationships were confirmed between the EQ-5D and the SF-36 (Table 3) and IBS-QOL domain scores (Table 4). The correlations between the EQ-5D and SF-36 were generally stronger than those found between the EQ-5D and IBS-QOL. The EQ-5D mobility item correlated strongly with the SF-36 physical function domain (−0.70 and −0.71). The EQ-5D pain/discomfort item correlated strongly with the SF-36 bodily pain domain (−0.63 and −0.66). The EQ-5D anxiety/depression item was strongly correlated with the SF-36 mental health domain (−0.65 and −0.60). The EQ-5D$_{VAS}$ item was most strongly associated with the SF-36 general health domain (−0.71 and −0.67). Correlations between the EQ-5D items and the IBS-QOL total score were all moderate (−0.30 to 0.51) in the UK2 study. In the Spanish study, the EQ-5D usual activities, pain/discomfort and anxiety/depression items had moderate correlations with the IBS-QOL (−0.31 to 0.47), but the EQ-5D mobility and self-care items were smaller, but still significant (−0.12). Associations in UK1 and German studies were similar (Table 4).

Figure 3 shows that the predicted relationship between the EQ-5D$_{VAS}$ score and the VAS-ADP (defined in quartiles) was confirmed in the UK2 study. EQ-5D$_{VAS}$ scores decreased as levels of subjective severity increased ($F = 22.1$; $P < 0.001$). Similar results were
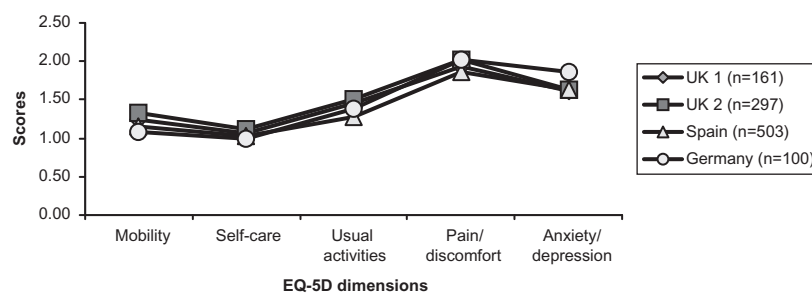
Figure 1 EQ-5D descriptive system mean scores. Note: Higher scores indicate greater negative impacts.
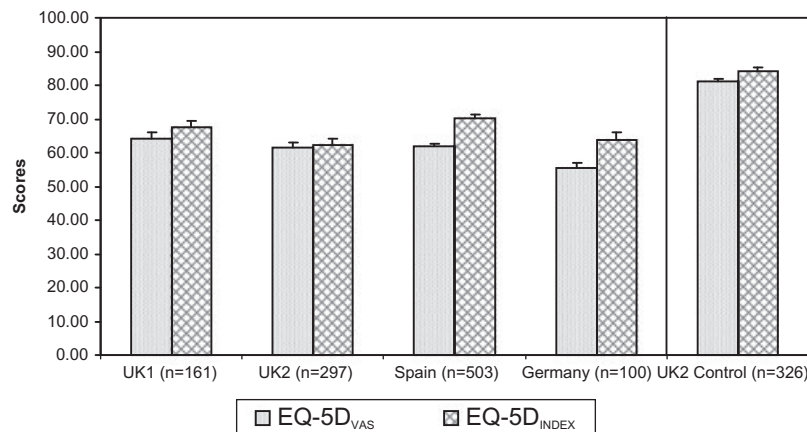
Figure 2 EQ-5D$_{VAS}$ and EQ-5D$_{INDEX}$ scores by study. Note: EQ-5D$_{INDEX}$ scores have been multiplied by 100 for comparison; Error bars represent standard error of the mean. VAS, visual analog rating scale.
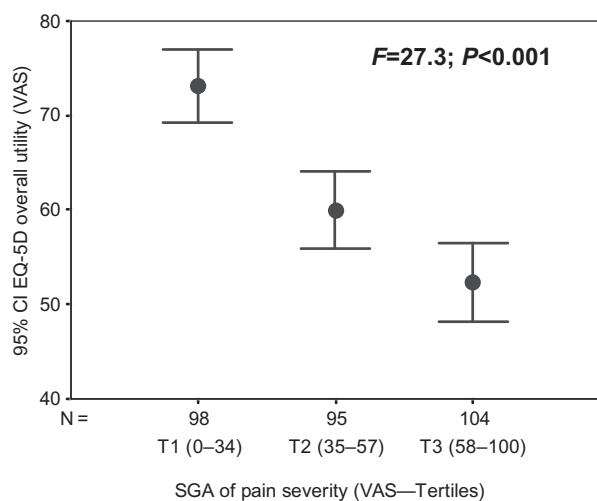
Figure 3 EQ-5D$_{VAS}$ by subject's global assessment (SGA) of pain severity (VAS scale). Data source: UK2 (n = 297). CI, confidence interval; VAS, visual analog rating scale.

observed in the German study where EQ-5D$_{VAS}$ scores decreased as subject's assessment of their IBS pain increased ($F = 4.4$; $P < 0.05$) (Fig. 4) and in Spain where EQ-5D$_{VAS}$ scores decreased as IBS severity increased ($F = 16.8$; $P < 0.001$) (data not shown). The EQ-5D$_{INDEX}$ discriminated between tertiles of subjective pain severity, decreasing as levels of severity increased (data from the UK2, $F = 29.3$; $P < 0.001$) (Fig. 5).

Figure 6 shows the responsiveness of the EQ-5D$_{VAS}$ score for different levels of subjective and physician global assessments of IBS severity from the data collected in Spain. Subjects who reported a decline or worsening in IBS severity also experienced a decline in EQ-5D$_{VAS}$ scores. Subjects for whom IBS severity remained the same experienced slight improvements in EQ-5D$_{VAS}$ mean scores, whereas those who improved reported large improvements in EQ-5D$_{VAS}$ scores. The clinician rating of severity resulted in smaller amounts of patient-reported levels of improvement and decline in EQ-5D$_{VAS}$ scores. Effect size statistics were 0.64 for VAS-

Table 3 Correlations between the EQ-5D and the SF-36

EQ-5D	SF-36 domains							
	Social function	Role—emotional	Mental health	Vitality	Physical function	Role—physical	Bodily pain	General health
UK1 (n = 161)								
Mobility	−0.479†	−0.169	−0.117	−0.366†	−0.704†	−0.182	−0.501†	−0.479†
Self-care	−0.342†	−0.220*	−0.051	−0.300†	−0.568†	−0.097	−0.377†	−0.314†
Usual activities	−0.593†	−0.240†	−0.230†	−0.491†	−0.575†	−0.402†	−0.606†	−0.588†
Pain/discomfort	−0.434†	−0.150	−0.207*	−0.441†	−0.436†	−0.278†	−0.626†	−0.456†
Anxiety/depression	−0.458†	−0.452†	−0.598†	−0.389†	−0.199*	−0.155	−0.316†	−0.364†
EQ-5D$_{VAS}$	0.562†	0.135	0.352†	0.676†	0.550†	0.330†	0.534†	0.669†
UK2 (n = 297)								
Mobility	−0.559†	−0.363†	−0.276†	−0.394†	−0.711†	−0.555†	−0.618†	−0.556†
Self-care	−0.483†	−0.334†	−0.191†	−0.347†	−0.587†	−0.368†	−0.438†	−0.473†
Usual activities	−0.608†	−0.461†	−0.361†	−0.448†	−0.554†	−0.683†	−0.565†	−0.567†
Pain/discomfort	−0.509†	−0.342†	−0.307†	−0.410†	−0.536†	−0.438†	−0.662†	−0.560†
Anxiety/depression	−0.443†	−0.487†	−0.645†	−0.433†	−0.268†	−0.296†	−0.332†	−0.358†
EQ-5D$_{VAS}$	0.613†	0.485†	0.477†	0.536†	0.588†	0.565†	0.609†	0.710†

*Correlation is significant at the 00.05 level (2-tailed).
†Correlation is significant at the 00.01 level (2-tailed).
VAS, visual analog rating scale.

Table 4 Correlations between the EQ-5D and the IBS-QOL

|	Dysphoria	Interference with activity	Body image	Health worry	Food avoidance	Social reaction	Sexual	Relationship	Overall score
UK1 (n = 161)									
Mobility	−0.177*	−0.291†	−0.114	−0.209†	−0.205*	−0.174*	−0.116	−0.210†	−0.191*
Self-care	−0.125	−0.175*	−0.201*	−0.120	−0.077	−0.118	−0.106	−0.239†	−0.149
Usual activities	−0.383†	−0.460†	−0.371†	−0.379†	−0.266†	−0.401†	−0.260†	−0.323†	−0.442†
Pain/discomfort	−0.318†	−0.388†	−0.362†	−0.395†	−0.264†	−0.336†	−0.251†	−0.260†	−0.380†
Anxiety/depression	−0.418†	−0.342†	−0.278†	−0.352†	−0.287†	−0.358†	−0.260†	−0.357†	−0.433†
EQ-5D$_{VAS}$	0.391†	0.406†	0.325†	0.423†	0.263†	0.347†	0.305†	0.369†	0.470†
UK2 (n = 297)									
Mobility	−0.268†	−0.301†	−0.212†	−0.195†	−0.242†	−0.270†	−0.280†	−0.230†	−0.304†
Self-care	−0.283†	−0.325†	−0.207†	−0.221†	−0.216†	−0.234†	−0.351†	−0.251†	−0.311†
Usual activities	−0.311†	−0.340†	−0.246†	−0.257†	−0.214†	−0.240†	−0.325†	−0.248†	−0.335†
Pain/discomfort	−0.444†	−0.441†	−0.395†	−0.375†	−0.329†	−0.350†	−0.384†	−0.343†	−0.484†
Anxiety/depression	−0.367†	−0.323†	−0.308†	−0.289†	−0.206†	−0.277†	−0.207†	−0.309†	−0.363†
EQ-5D$_{VAS}$	0.536†	0.532†	0.392†	0.425†	0.401†	0.420†	0.396†	0.433†	0.519†
Spain (n = 503)									
Mobility	−0.092*	−0.133†	−0.142†	−0.113*	−0.064	−0.031	−0.109*	−0.067	−0.117†
Self-care	−0.109*	−0.104*	−0.071	−0.114*	−0.088*	−0.084	−0.070	−0.052	−0.117†
Usual activities	−0.385†	−0.332†	−0.266†	−0.247†	−0.255†	−0.330†	−0.385†	−0.310†	−0.408†
Pain/discomfort	−0.287†	−0.242†	−0.257†	−0.222†	−0.261†	−0.224†	−0.250†	−0.192†	−0.314†
Anxiety/depression	−0.358†	−0.242†	−0.268†	−0.271†	−0.335†	−0.297†	−0.283†	−0.287†	−0.380†
EQ-5D$_{VAS}$	0.460†	0.304†	0.319†	0.318†	0.349†	0.360†	0.373†	0.364†	0.466†
Germany (n = 100)									
Mobility	−0.149	−0.154	0.075	−0.143	−0.152	−0.071	−0.136	−0.134	−0.150
Self-care	0‡	0‡	0‡	0‡	0‡	0‡	0‡	0‡	0‡
Usual activities	−0.319†	−0.269†	−0.166	−0.201*	−0.303†	−0.124	−0.322†	−0.149	−0.313†
Pain/discomfort	−0.271†	−0.074	−0.071	−0.181	−0.303†	−0.301†	−0.016	−0.047	−0.236*
Anxiety/depression	−0.545†	−0.386†	−0.292†	−0.426†	−0.323†	−0.364†	−0.381†	−0.457†	−0.549†
EQ-5D$_{VAS}$	0.396†	0.188	0.192	0.322†	0.279†	0.079	0.220*	0.145	0.322†

*Correlation is significant at the 00.05 level (2-tailed).
†Correlation is significant at the 00.01 level (2-tailed).
‡Cannot be computed because the "Self-Care" item is constant (all responses are "1").
IBS-QOL, Irritable Bowel Syndrome—Quality of Life questionnaire; VAS, visual analog rating scale.

ADP and 0.48 for the Clinician's Global Assessment (CGA). Mean group comparisons showed each of these differences to be significant ($P < 0.001$). Similar trends were seen using the EQ-5D$_{INDEX}$ score with effect size of 0.33 and 0.29, respectively.

Discussion

Any PRO measure, such as the EQ-5D, should demonstrate satisfactory properties before being used in studies of specific populations, such as patients with
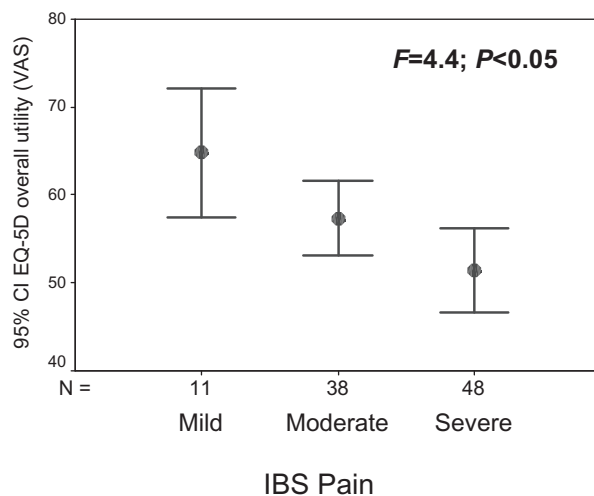
Figure 4 EQ-5D$_{VAS}$ by subject's global assessment of pain (Categorical scale). Data source: Germany (n = 100). CI, confidence interval; VAS, visual analog rating scale.
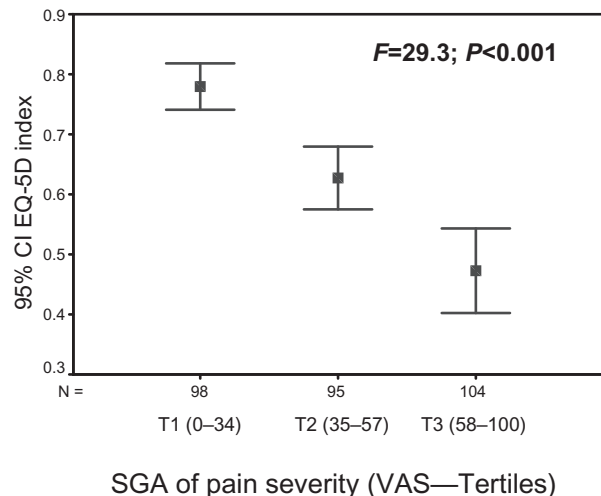
Figure 5 EQ-5D$_{INDEX}$ by subject's global assessment (SGA) of pain severity (VAS scale). Data source: UK2 (n = 297). CI, confidence interval; VAS, visual analog rating scale.
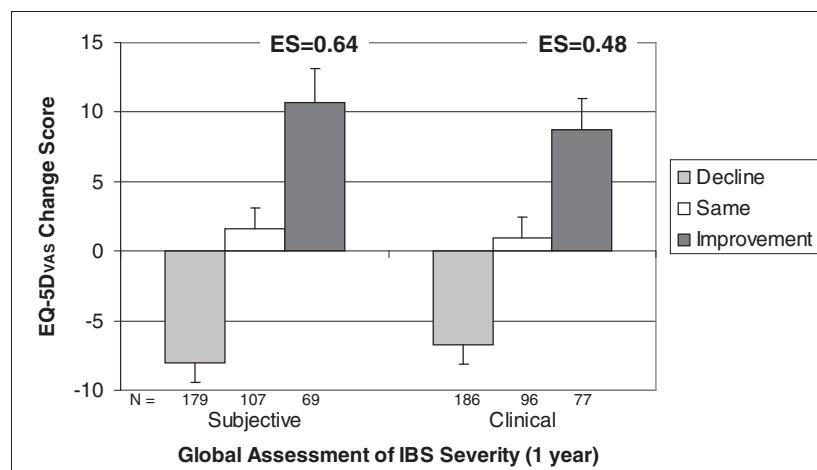
Figure 6 EQ-5D_{VAS} response using global assessment of IBS severity (after 1 year). Data source: Spain (n = 503). Effect size = change score divided by standard deviation at baseline. Note: Error bars represent standard error of the mean; number discrepancies relate to patients lost to follow-up. ES, effect size; IBS, irritable bowel syndrome; VAS, visual analog rating scale.

IBS. Although there have been studies exploring the health status of IBS patients [7,21,35], there is a lack of information regarding the applicability and sensitivity of these measures in determining the impact of IBS on patients.

The present study has certain limitations that need to be taken into account when considering the study and its contributions. In this research, data were obtained from several studies to provide evidence to support the use of the EQ-5D in an IBS population. Inclusion and diagnostic criteria varied across studies. For example, in the UK1 study, patients meeting the Rome I criteria for IBS were enrolled and the German sample consisted of constipation-predominant or alternating IBS patients). Another limitation in this analysis includes the variation in measures used. Although the data were collected from studies with divergent methodologies in several European countries, the EQ-5D scores remain similar with self-care having the least impact and pain/discomfort having the greatest effect on patients' QoL.

From the studies in the UK, we observed that each dimension of the EQ-5D was most highly associated with the corresponding dimension measured concurrently by the SF-36. The strongest relationships were seen between mobility (EQ-5D) and physical functioning (SF-36); the pain/discomfort dimension (EQ-5D) and bodily pain (SF-36); and anxiety/depression (EQ-5D) and mental health (SF-36).

The ability to convert EQ-5D scores to utility measures is advantageous because it provides a quantitative expression of an individual's preference for, or the desirability of, a particular state of health under conditions of uncertainty. These utility scores can then be used as the quality weights when computing a quality-adjusted life-year. This is a universal health outcome measure that is applicable to all individuals and all diseases, and enables comparisons across diseases and across programs. This feature of the EQ-5D provides greater support in cost-effectiveness studies where

more simple descriptive measures may not. It is noted that the VAS scale should not be used to measure utilities directly, rather health state evaluations are more relevant to obtain utility measures [36].

The EQ-5D performs well in comparison to general and disease-specific outcomes and data presented in this article demonstrate that it is a valid and responsive PRO measure that can be used to generate preference-based valuations of HRQoL in patients with IBS and useful for comparisons in clinical and cost-effectiveness studies.

References

1 Camilleri M, Choi MG. Review article: irritable bowel syndrome. Aliment Pharmacol Ther 1997; 11:3–15.
2 Talley NJ. Pharmacologic therapy for irritable bowel syndrome. Am J Gastroenterol 2003;98:750–8.
3 Drossman DA, Camilleri M, Mayer EA, Whitehead WE. AGA technical review on irritable bowel syndrome. Gastroenterology 2002;123:2108–31.
4 Hungin AP, Whorwell PJ, Tack J, Mearin F. The prevalence, patterns and impact of irritable bowel syndrome. an international survey of 40,000 subjects. Aliment Pharmacol Ther 2003;17:643–50.
5 Hahn BA, Yan S, Strassel S. Impact of irritable bowel syndrome on quality of life and resource use in the United States and United Kingdom. Digestion 1999;60:77–81.

6 Olden KW. Approach to the patient with severe refractory irritable bowel syndrome. Curr Treat Options Gastroenterol 2003;6:311–17.

7 Lea R, Whorwell PJ. Quality of life in irritable bowel syndrome. Pharmacoeconomics 2001;19:643–53.

8 Kellow JE. Treatment goals in irritable bowel syndrome. Int J Clin Pract 2001;55:546–51.

9 Thompson WG, Hungin AP, Neri M, et al. The management of irritable bowel syndrome: a European, primary and secondary care collaboration. Eur J Gastroenterol Hepatol 2001;13:933–9.

10 Borum ML. Irritable bowel syndrome. Gastroenterology 2001;28:523–38.

11 Zaman A. Irritable bowel syndrome. Clin Cornerstone 2002;4:22–32.

12 Drossman DA, Whitehead WE, Camilleri M, for the Patient Care Committee American Gastroenterology Association. Irritable bowel syndrome: a technical review for practice guideline development. Gastroenterology 1997;112:2120–37.

13 Camilleri M. Management of irritable bowel syndrome. Gastroenterology 2001;120:652–68.

14 Talley NJ. Evaluation of drug treatment in irritable bowel syndrome. Br J Clin Pharmacol 2003;56:362–9.

15 Fennerty MB. Traditional therapies for irritable bowel syndrome: an evidence-based appraisal. Rev Gastroenterol Disord 2003;3(Suppl. 2):S18–24.

16 Jailwala J, Imperiale TF, Kroenke K. Pharmacologic treatment of the irritable bowel syndrome: a systematic review of randomized, controlled trials. Ann Intern Med 2000;133:136–47.

17 Kind P. The EuroQol instrument. an index of health-related quality of life. In: Spilker B, ed., Quality of Life and Pharmacoeconomics in Clinical Trials (2nd ed.). Philadelphia, PA: Lippincott-Raven Publishers, 1996.

18 Brooks R. EuroQol: the current state of play. Health Policy 1996;37:53–72.

19 The EuroQoL database. Available from: http://www.euroqol.org. [Accessed October 5, 2005].

20 Weinstein MC, Siegel JE, Gold MR, et al. Recommendation of the panel on cost-effectiveness in health and medicine. JAMA 1996;276:1253–8.

21 Akehurst RL, Brazier JE, Mathers N, et al. Health-related quality of life and cost impact of irritable bowel syndrome in a UK primary care setting. Pharmacoeconomics 2002;20:455–62.

22 Drossman DA, Richter JE, Talley NJ, eds. et al. The Functional Gastrointestinal Disorders: Diagnosis, Pathophysiology and Treatment (1st ed.). McLean, VA: Degnon Associates, 1994.

23 Ricci JF, Walters S, Ward S, Akehurst R. Quality of life of IBS patients in the United Kingdom compared with a general population sample. Gastroenterology 2003;123:A518.

24 Badia X, Mearin F, Caballero A, et al. Economic burden of irritable bowel syndrome (IBS): one year results. RITMO study. Value Health 2003; 6:684.

25 Drossman DA, ed. Rome II: The Functional Gastrointestinal Disorders—Diagnosis, Pathophysiology, and Treatment: a Multinational Consensus (2nd ed.). McLean, VA: Degnon Associates, 2000.

26 Grüger J, Schultes HJ, Pirk O, van Assche D. The utility benefits of tegaserod in irritable bowel syndrome. Gut 2001;49(Suppl. III):A3001.

27 Kind P. Guidelines for value sets in economic and non-economic studies using EQ-5D. In: Brooks R, Rabin R, de Charro F, eds., The Measurement and Valuation of Health States Using EQ-5D: A European Perspective. Dordrecht: Kluwer Academic Publishers, 2003; 29–41.

28 Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med 2001;33: 337–43.

29 Ware JE, Snow KK, Kosinski M, Gandek B. SF-36 Health Survey Manual and Interpretation Guide. Boston, MA: New England Medical Center, The Health Institute, 1993.

30 Patrick DL, Drossman DA, Frederick IO, et al. Quality of life in persons with irritable bowel syndrome: development and validation of a new measure. Dig Dis Sci 1998;43:400–11.

31 Drossman DA, Patrick DL, Whitehead WE, et al. Further Validation of the IBS-QOL: a disease-specific quality-of-life questionnaire. Am J Gastroenterol 2000;95:999–1007.

32 SPSS, Inc. Statistical Package for the Social Sciences Base 10.0 User's Guide. Chicago, IL: SPSS, Inc., 1999.

33 Cohen J. Statistical Power Analysis for the Behavioral Sciences (Revised Edition). New York: Academic Press, 1997.

34 Fayers PM, Machin D. Quality of Life: Assessment, Analysis and Interpretation. Chichester: John Wiley & Sons, 2000.

35 Granlek IM, Hays RD, Kilbourne A, et al. The impact of irritable bowel syndrome on health-related quality of life. Gastroenterology 2000;119:654–60.

36 Dolan P, Gudex C, Kind P, Williams A. A Social Tariff for EuroQoL: Results from UK General Population Survey. CHE Discussion Paper 138. York: Centre for Health Economics, University of York (UK), 1997.