Review

Quality of life measurement in gastrointestinal and liver disorders

Summary
Modern medicine has had a considerable impact on mortality rates for serious illness. Many chronic diseases which have previously been associated with an increased mortality now have survival rates approaching those of the background population. However, chronic diseases such as cancer, chronic pain syndromes, and chronic inflammatory conditions impose a considerable burden on families, the health care system, and society. Health related quality of life (HRQOL) is a concept that has developed from the need to estimate the impact of such chronic diseases. HRQOL measurement is a conceptual framework which attempts to predict daily function and well being based on subjective attitudes and experiences of physical, social, and emotional health. It has been evaluated predominantly from the patient's viewpoint as proxy respondents appear to underestimate the full effect of chronic illness on functional status. Measuring HRQOL in clinical research is most frequently undertaken using multi-item questionnaires to estimate daily function. Factors which affect HRQOL can be broadly classed as disease related and disease independent. The use of different assessment techniques permits comparisons between and within disorders. Generic and disease specific instruments used together enhance the ability to direct treatment for individuals and patient populations. Psychometrically sound questionnaires must be used. However, the type of instrument and research methods adopted depend on the question of interest. We have attempted to catalogue and critically assess the disease specific instruments used in the assessment of chronic gastrointestinal disease.

Introduction

Chronic gastrointestinal disorders (GID) such as gastro-oesophageal reflux disease (GORD), non-ulcer dyspepsia (NUD), irritable bowel syndrome (IBS), and inflammatory bowel disease (IBD) have mortality rates similar to the general population. Hospitalisation and surgical rates for these disorders are easily predicted by disease severity while daily functioning, well being, and life satisfaction, important features of HRQOL, are better predictors of ambulatory health services used.[1] Direct costs in Canada for chronic GID were $3.32 billion in 1997, fourth after cardiovascular, respiratory, and mental disorders.[2] HRQOL assessment thus provides an important yardstick to assess these conditions by promoting patient involvement in management, fuller measurement of disease impact, and implementation of the most cost effective strategies.

The number of publications in gastroenterology claiming to address quality of life (QOL) and HRQOL has increased dramatically in recent decades, as shown in fig 1. However, most reports merely pander to the sensitive new age approach to chronic illness and do not truly evaluate HRQOL. We have therefore attempted to catalogue and critically evaluate the published HRQOL instruments pertaining to gastrointestinal diseases, particularly addressing their psychometric properties and clinical applications.

Health related quality of life

HEALTH RELATED QUALITY OF LIFE: A WORKING DEFINITION

HRQOL is a concept which reflects the physical, social, and emotional attitudes and behaviours of an individual as they relate to their prior and current health state.[3] HRQOL assessment describes health status from the patients' perspective and serves as a powerful tool to assess and explain disease outcomes.[4] For example, two patients with ulcerative colitis (UC) may well have identical disease extent, severity, and medical therapy, yet one may hold a full time job with a vigorous social and family life while the other is unemployed, depressed, and receiving a disability pension. The functional domains that comprise HRQOL are outlined in table 1. Physical symptoms for a particular GID are more likely to be disease dependent, while the psychological and social effects are disease independent and are better predicted by cognitive function, knowledge, socioeconomic status, education, personality, coping strategies, social support network, culture, beliefs, and so on.[5]

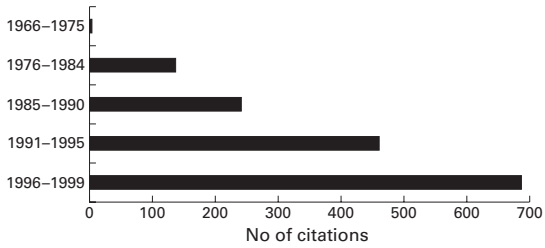

Figure 1 Number of quality of life related citations in the fields of gastroenterology and hepatology obtained from MEDLINE searches over different time intervals.

Abbreviations used in this paper: HRQOL, health related quality of life; QOL, quality of life; IBD, inflammatory bowel disease; GORD, gastro-oesophageal reflux disease; NUD, non-ulcer dyspepsia; IBS, irritable bowel syndrome; CDAI, Crohn's disease activity index; SF, short form; SIP, sickness impact profile; PGWB, psychological general well being; GID, gastrointestinal disorder; GI, gastrointestinal; GIQLI, gastrointestinal quality of life index; ICC, intraclass correlation coefficient; GSRS, gastrointestinal symptom rating scale; PUD, peptic ulcer disease; GORQ, gastro-oesophageal reflux questionnaire; MOS, medical outcomes study; HBQOL, heartburn quality of Life; QPD, quality of life in peptic disease; FDDQL, functional digestive disorders quality of life questionnaire; DU, duodenal ulcer; QOLRAD, quality of life in reflux and dyspepsia; QLDUP, quality of life in duodenal ulcer patients; HPAG, *Helicobacter pylori* associated gastritis; SCL90-R, symptom checklist; IBSQ, irritable bowel syndrome questionnaire; RFIPC, rating form of inflammatory bowel disease patient concerns; UC, ulcerative colitis; CD, Crohn's disease; IBDQ, inflammatory bowel disease questionnaire; STAI, state-trait anxiety inventory; NTC, normal transit constipation; STC, slow transit constipation; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer core quality of life questionnaire; TG, total gastrectomy; SG, subtotal gastrectomy; TG+R, total gastrectomy plus gastric reconstruction; RSC, Rotterdam symptom checklist; HPN, home parenteral nutrition; QALY, quality adjusted life year; CLDQ, chronic liver disease questionnaire; HCV, hepatitis C virus; HBV, hepatitis B virus; IFN, interferon.

Table 1 Specific problems, issues and domains of health related quality of life (HRQOL) instruments

Leisure and recreation	*Mobility and self-care*
●Travel	●Walking
●Food/drink	●Running
●Visit friends' homes	●Climbing
●Vacation	●Eating
●Nearness to toilet facilities	●Grooming
●Hobbies and sports	●Physical endurance
Relationships	*Emotional*
●Intimacy and sexual function	●Anger
●Body image	●Embarrassment
●Understanding from others	●Anxiety
●Coping and support	●Irritability
●Relations with children and extended family	●Happiness
●Friendships	●Worries or fears
Pain and discomfort	●Ability to relax
●Chest pain	●Frustration
●Abdominal pain	●Depression/sadness
●Abdominal cramps	●Satisfaction
●Abdominal discomfort	*Job-education*
●Rectal pain	●Satisfaction
●Back pain	●Attendance
●Headaches	●Concentration
●Extraintestinal pain	Task completion
●Joint pain	●Achievement/promotion
Well being	●Financial reward
●Energy	*Treatment*
●Fatigue	●Efficacy
●Sleep	●Adverse effects
●Self-control	

APPLYING HRQOL MEASUREMENT

HRQOL measurement is important to patients, clinicians, researchers, and policy makers. Potential applications include identification of the problems of individuals or populations, assessment of quality of health care delivery, enhancement of disease related knowledge, and measurement of treatment efficacy or disease outcome.[6] HRQOL assessment is also a critical component of pharmacoeconomic evaluation.

HRQOL MEASUREMENT

The development and full psychometric testing of a new HRQOL instrument generally takes several years to complete. Excellent review articles[4–7] have addressed the detailed methodological process, which we will briefly summarise.

The three main types of HRQOL instrument are *global*, *generic*, and *disease specific* and the benefits of each are shown in table 2.[8] The g*lobal* assessment measures a single attribute using a visual analogue or graded scale to summarise overall function. For example, 80% of patients have "good" HRQOL. These assessments, although easy to perform, do not identify specific areas of dysfunction.[3] *Generic* instruments are multi-item questionnaires addressing various aspects of health and well being and have been derived in the general population, which includes both healthy subjects and people with acute or chronic illnesses. They are the most likely to detect an unexpected disease impact but may be unable to quantify clinically important dysfunction or change in function.[4] For example, a generic instrument will not address abdominal pain, urgency, or fear of leaving the house, problems experienced by many IBS patients, but does emphasise mobility and grooming, which are not common IBS problems. Until recently, generic assessments have represented the predominant method of measuring HRQOL in GID. Instruments such as the sickness impact profile (SIP),[9] psychological general well being (PGWB) scale,[10] and short form 36 (SF-36)[11] are the most commonly used and allow a direct comparison between individuals or populations with different diseases. Several, together with their psychometric properties, are listed in table 2. *Disease specific* instruments are designed for patients with a particular disease to identify the most relevant problems. Such instruments are generally more sensitive to patient concerns and changes in health status.[4] The major disadvantages are that no specific instrument is available for many disorders and that some unanticipated problems may be easily overlooked. To optimise HRQOL assessment, many studies now use both generic and disease specific instruments.

The important steps to develop and psychometrically test a HRQOL instrument are outlined in tables 3 and 4.[4 7 12 13] We will focus primarily on disease specific instruments but highlight a few important studies that have used generic instruments.

Search methods

To identify all disease specific HRQOL measures used in gastrointestinal (GI) or liver disease, a thorough MEDLINE search from 1966 to September 1999 of fully published articles in English using the search terms "quality of life", "liver disease", and "gastrointestinal disease" was performed. Reference lists of relevant citations were also reviewed to ensure complete retrieval. Studies combining previously validated questionnaires were not considered as separate instruments.

The GIQLI

The gastrointestinal quality of life index (GIQLI) was developed by Eypasch and colleagues to measure HRQOL in multiple GIDs.[14] The questionnaire contains up to 36 items, scored on a five point Likert scale (range 0–144, higher score=better QOL), in which additional modules, specified by the particular GID, supplement a set of core questions. Construct validity was supported by demonstrating a reasonable correlation with the Spitzer quality of life index (r=0.53) and the Bradburn affect balance scale (r=0.42) in 204 German patients with a variety of GI illnesses. Patients with the most severe GID had a mean GIQLI score of 45 (14.8) compared with healthy controls

Table 2 Commonly used health related quality of life (HRQOL) instruments in gastrointestinal disorders

	Advantage	*Disadvantage*
Global assessment		
Visual analogue scale (10 cm line)	Simple summary	Reasons for dysfunction not clear
Graded scale (excellent, very good, good, poor, extremely poor)	Easily administered and scored	May not detect small but important differences
Utility (standard gamble or time trade off; 0.0 death to 1.0 perfect health)	Important for economic analysis	
Generic instrument		
Sickness impact profile[132] (136 items, 12 subscores; higher score=poorer HRQOL)	Permits comparison among diseases. May detect unanticipated effects	Complex to administer and score. May miss important clinical change
Short form 36[133] (36 items, 8 subscores; score 0, worst–100 best)		
Grogono and Woodgate[134] (20 items, 10 subscales)		
Psychological general well being[135] (22 items; 6 subscales (anxiety, depression, well being, self-control, health, vitality); reliability 0.61–0.89; score 22–132, lower score better)		
Euro-QOL[136] (5 items utility)		
Disease specific instrument		
See specific tables	Reflects problems most important to a specific population. May be more sensitive to change with time or treatment	Complex to administer and score. May miss unexpected effects

Table 3 Steps in developing a generic or disease specific health related quality of life (HRQOL) instrument

Step	*Method*
Item generation[12]	Identify all possible consequences of a particular disorder Literature review Patient focus groups Expert opinion
Item reduction[12]	Reduce items to a manageable number. Most prevalent issues (frequency) Greatest impact (important) Facilitated by factor analysis
Pre-testing[12]	Ensure clear wording, patient understanding, and acceptability
Psychometric assessment[4]	Validity Reliability Responsiveness
Cross cultural adaptation[13]	Independent forward and backward translation. Harmonisation among questionnaires. Pre-testing and examining score weighting.

who had a mean score of 125.8 (13). The GIQLI also discriminated well between patient groups when stratified by illness severity. The test-retest reliability was excellent (intraclass correlation coefficient (ICC) 0.92), as was internal consistency (Cronbach's alpha >0.90). In 194 patients who underwent laparoscopic cholecystectomy for biliary colic, a significant improvement (responsiveness) was observed from a mean score preoperatively of 87.3 (17.3) to 111.7 (14.6) six weeks postoperatively ($p<0.001$), although changes in specific subscores were not reported. The concept of a modular questionnaire, similar to combining disease specific and generic instruments, holds promise if it is shown to be psychometrically robust in other GIDs.

HRQOL in gastro-oesophageal reflux disease

Symptoms of GORD occur monthly in approximately 40% and daily in 7% of the adult population.[15] Twenty four per cent of sufferers will consult a physician, often fearing a serious condition such as cancer.[16] Specific symptoms, such as heartburn, regurgitation, or chest pain, substantially impair HRQOL and over half of patients require intermittent or continuous therapy.[17] McDougall *et al* assessed long term HRQOL in GORD using a postal survey.[11] After 10 years, 70% of 101 respondents reported persistent symptoms or the need for ongoing therapy. The mean SF-36 *physical function* subscore was significantly worse in GORD patients than in the general population (65.4 *v* 79.7; p=0.038) but was similar to that of patients with acute myocardial infarction (69.7). The mean *social function* was even lower for GORD than for congestive heart failure (71.3)[18] and was significantly impaired compared with the general population (62.5 *v* 83.3; $p<0.001$). These results suggest that patients with GORD feel as seriously affected as do patients with important cardiovascular disease.

Harris and colleagues used decision modelling to compare three medical strategies for preventing recurrence of erosive oesophagitis.[19] They determined that the degree of QOL impairment could be used to select the optimum therapy; that subjects with poor QOL could be treated more cost effectively with an initial proton pump inhibitor and those with less impaired QOL should receive a H_2 receptor antagonist first. Such findings, using generic measures, can be greatly complemented by applying disease specific instruments. To date, five disease specific HRQOL instruments for GORD have been published and are shown in table 5.

The gastrointestinal symptom rating scale (GSRS) was developed by Svedlund *et al* in 1988 to discriminate between several GIDs.[20] Items were selected primarily from IBS and peptic ulcer disease (PUD) symptoms, using clinical experience and a literature review. Initial validation was performed for a physician administered 15 item questionnaire, with items such as epigastric pain, heartburn, and eructation scored on a four point Likert scale. A subsequent self-administered version, using a seven point Likert scale, was shown to have good internal consistency, and factor analysis identified five important domains: *abdominal pain syndrome*, *reflux syndrome*, *indigestion syndrome*, *diarrhoea syndrome*, and *constipation syndrome*.[21] In a mixed patient population, the GSRS discriminated well between patients with PUD, oesophagitis, and a normal endoscopy on all domains ($p<0.01$) except the *constipation syndrome*, with the most marked difference being noted in the *reflux syndrome* ($p<0.00001$).[21] Revicki *et al* recently undertook further validation and responsiveness testing in 516 GORD patients before and six weeks after administration of ranitidine 150 mg twice daily.[22] They observed significant correlations between subscores of the GSRS, SF-36, and PGWB index ($r = -0.43$ to -0.21; $p<0.0001$). Mean subscores in all five domains significantly discriminated between responders and non-responders (2.79 *v* 3.24, respectively; $p<0.0001$). The greatest improvement occurred in the *reflux domain*, with therapy producing a mean decrease in score of 1.23 in responders and 0.46 in non-responders ($p<0.0001$). This identified a clinically important score change of approximately 1.0 and suggested the *reflux subscore* as the most important for GORD.

Galmiche *et al* used the GSRS as an outcome in a double blind trial of omeprazole 10 mg or 20 mg daily versus cisapride 10 mg four times daily in 424 patients with mild GORD.[23] The global GSRS score improved in all treatment groups while the *reflux domain* improved significantly in the omeprazole 20 mg group compared with the cisapride group (-1.50 *v* -0.98; p=0.001). In a similar trial, Havelund *et al* compared omeprazole 10 mg or 20 mg daily with placebo in 408 endoscopically normal GORD patients.[24] After four

Table 4 Key properties of a methodologically robust health related quality of life (HRQOL) instrument

Property	*Definition*	*Method of assessment*
Validity		
Face[12]	Measures what it is supposed to measure	Full literature review, expert opinion, patient input (eg focus groups)
Content[12]	Adequately samples most important areas of interest	Pre-testing with item reduction or augmentation
Construct[12]	Relationship between score and a hypothesis of what is being measured	Instrument compared with another marker of illness to determine if it behaves as predicted
Criterion[12] (convergent)	Relationship between new questionnaire and an accepted reference	Instrument compared to an accepted reference measure that evaluates the same or similar features
Discriminative[4]	Instrument can distinguish between two groups of dissimilar patients	QOL scores for patients with different disease severity or different patterns of disease should differ significantly
Reliability		
Test-retest[4]	Ratio of between patient variation to total variation in score	Patients who remain stable should have little change in QOL scores on repeated measures. Described by intraclass correlation coefficient (ICC) (0–1, 1 perfect agreement)
Internal consistency[4]	Correlation of items within same domain or with the full questionnaire score	Cronbach's alpha coefficient (0–1, 1 excellent)
Responsiveness[4]	Signal to noise ratio of change with time	Patients with clinically important change (improve or deteriorate) should have significant change in QOL score

Table 5 Gastro-oesophageal reflux disease (GORD) specific health related quality of life (HRQOL) instruments

Instrument	Items/scoring*	Domains	Validity			Reliability	
			Face	Content	Construct	IC	TR
GSRS[20 22]	15/105–15	Reflux, diarrhoea, constipation, pain, indigestion	L, E	Factor analysis	SF-36, PGWB	0.60–0.85	ICC 0.42–0.6
GORQ[26]	76/NS	Heartburn, regurgitation, effect of heartburn, pain, dysphagia, UGI, respiratory, past history, medications, past treatments, miscellaneous	L, E	3 field tests	NT	NT	κ 0.70
GORD-HRQL[27]	10/45–0	NS	E	NT	Endoscopic oesophagitis	NT	NT
HBQOL[30]	15/0–100	Role physical, pain, sleep, diet, social, mental health	L, E	NT	SF-36	0.75–0.91	NT
QOLRAD[32]	25/25–175	Emotional, sleep, eating problems, physical/social, vitality	L, E, P	Factor analysis	SF-36, GSRS	0.89–0.94	NT

*Scores range from worst to best QOL.
NS, not stated; NT, not tested; IC, internal consistency (Cronbach's alpha); TR, test-retest.
L, literature review; E, expert opinion; P, patient interviews.

weeks, the *reflux dimension* improved significantly in both omeprazole groups (p=0.003—10 mg, p=0.0001—20 mg) as well as in the omeprazole 20 mg compared with the 10 mg group (p=0.04). These data provide further evidence that the GSRS, particularly the *reflux domain*, can measure clinically important changes in HRQOL.

Locke *et al* focused on GORD related symptoms from a general bowel questionnaire[25] adding the medical outcomes study (MOS) short form 20 (SF-20) to produce the gastro-oesophageal reflux questionnaire (GORQ).[26] The final 76 item instrument had acceptable test-retest reliability (kappa 0.70) but the authors have not yet fully examined the validity or responsiveness, thereby limiting the current usefulness of this instrument.

A third GORD specific instrument, the gastro-oesophageal reflux disease health related quality of life scale (GORD-HRQL), was developed by Velanovich and colleagues.[27] This 10 item questionnaire was drafted using clinician opinion (face validity), scored using a six point Likert scale, and administered to 72 patients with severe GORD before and after medical or surgical therapy. The GORD-HRQL score discriminated well between individuals based on their satisfaction with current symptoms (median score 26 in the unsatisfied *v* 5 in the satisfied group; p<0.0001). Surgical patients were more greatly improved than medical patients (median improvement 27.5 *v* 11, respectively; p=0.002). However, the scores correlated poorly with pretreatment 24 hour pH testing (r=0.09; p=0.7), lower oesophageal sphincter pressures (r= −0.21; p=0.24), and the SF-36 and subscores.[28] Although scores correlated moderately with the endoscopic oesophagitis grade (r=0.53; p<0.001),[29] further assessment is clearly needed before it can be recommended for clinical research.

A fourth disease specific instrument, the heartburn quality of life (HBQOL), was developed by Young and colleagues.[30] Validation of the 15 items against the SF-36 was undertaken but raw data supporting a claim of moderate correlation were not provided. A 12 item version with six domains was later used in a randomised trial.[31] Dimensional scores were significantly better than placebo in patients given ranitidine 150 mg twice daily for six weeks for *heartburn pain* (72.4 *v* 62.8; p<0.001), *sleep* (87.6 *v* 80.8; p<0.001), *diet* (83.7 *v* 76.0; p<0.001), and *mental health* (73.8 *v* 67.2; p<0.001). Unfortunately, the HBQOL was not administered before treatment thereby precluding full responsiveness assessment. This questionnaire will require further psychometric testing.

The final GORD specific HRQOL instrument is the quality of life in reflux and dyspepsia (QOLRAD), a 25 item questionnaire, with each item scored on a seven point Likert scale, and five subscores.[32] Items were generated using "focus groups" of patients with GORD or NUD and were then tested in 759 patients referred for endoscopy in five countries. Construct validity was supported by its correlation with almost all domains of the SF-36 (r=0.44–0.71), GSRS (r=0.29–0.63), and severity (r=−0.31 to −0.38) or frequency of symptoms (r= −0.27 to −0.34), as judged by clinicians. QOLRAD scores also significantly discriminated between patients who did or did not use concomitant sedatives for anxiety (mean emotional scores 3.4 *v* 4.2, respectively). Responsiveness of the QOLRAD has not yet been determined.

Disease specific instruments can therefore discriminate GORD from other disorders, can stratify patients by severity, and are useful as outcomes in clinical trials and decision modelling. Overall, the GSRS has been the most extensively evaluated of the GORD instruments and has favourable psychometric properties, making it more attractive currently than the other questionnaires.

Dyspepsia

Functional dyspepsia, or NUD, occurs in approximately 25% of the general population.[33] Despite normal investigations, subjects experience considerable anxiety and demonstrate health care seeking behaviour.[34] Patients with NUD describe abdominal pain, interruption of daily activities,[35] and decreased sexual drive.[36] An important barrier to dyspepsia research has been the difficulty in quantifying the severity of the subjective complaints,[37] which has led to the development of several disease specific instruments, shown in table 6.

An Italian group, led by Bamfi, developed the quality of life in peptic disease questionnaire (QPD).[38] Items were generated by patients with confirmed PUD, oesophagitis, or NUD. A 30 item questionnaire was then administered to several patient groups and validation by factor analysis

Table 6 Dyspepsia specific health related quality of life (HRQOL) instruments

Instrument	Items/scoring*	Domains	Validity			Reliability	
			Face	Content	Construct	IC	TR
QPD[38]	30/NS	Anxiety, social, symptom perception	L, E, P	2 field tests	SF-36	0.73–0.91	NT
FDDQL[39]	43/0–100	Activities, anxiety, diet, sleep, discomfort, coping, control, stress	L, E, P	3 field tests	SF-36	0.69–0.89	0.98
QOLRAD[32]	25/25–175	Emotional, sleep, eating problems, physical/social, vitality	L, E, P	Factor analysis	SF-36, GSRS	0.89–0.94	NT
QLDUP[40]	54/NS	SF-36 + PGWBI, family circle, food, drink, coffee-tobacco, pain	E, P	NT	NT	>0.70	0.73
Not named[42]	8/40–8	NS	L, E	1 field test	NT	NT	0.69–0.82

*Scores range from worst to best QOL.
NS, not stated; NT, not tested; IC, internal consistency (Cronbach's alpha); TR, test-retest.
L, literature review; E, expert opinion; P, patient interviews.

Table 7 Irritable bowel symdrome (IBS) specific health related quality of life (HRQOL) instruments

			Validity			Reliability	
Instrument	*Items/scoring**	*Domains*	*Face*	*Content*	*Construct*	*IC*	*TR*
IBS-QOL[51]	34/0–100	Dysphoria, activity, body image, anxiety, food avoidance, social, sexual relations, relationships	L, E, P	2 field tests	SF-36, PGWB, SCL90-R	0.65–0.92	0.69–0.89
IBSQ[52]	26/26–182	Symptoms, fatigue, activity, emotional	L, E, P	1 field test	NT	NT	NT
IBSQOL[49]	30/0–100	Emotional, mental health, health belief, sleep, energy, physical functioning, diet, social role, physical role, sexual relations	L, E	2 field tests	NT	0.66–0.93	NT
FDDQL[39]	43/0–100	Activity, anxiety, diet, sleep, discomfort, coping, control, stress	L, E, P	3 field tests	SF-36	0.69–0.89	0.98

*Scores range from worst to best QOL.
NT, not tested; IC, internal consistency (Cronbach's alpha); TR, test-retest.
L, literature review; E, expert opinion; P, patient interviews.

demonstrated three domains: *anxiety induced by pain*, *social restrictions*, and *symptom perception*. Low to moderate correlations were observed with all domains of the SF-36 (r=0.26–0.60) (construct validity). Responsiveness to change was shown by a significant improvement in the total score (mean change 11.5; p=0.001) and dimensional scores (mean change 2.8–4.9; p=0.001) four weeks after *Helicobacter pylori* eradication. Cross cultural adaptation in non-Italian patients has not yet been reported.

The functional digestive disorders quality of life questionnaire (FDDQL), developed by Chassany *et al* to measure QOL in patients with functional dyspepsia or IBS, has been assessed in French, German, and English patients with dyspepsia.[39] Seventy four items were later reduced to 43 and scored using a five point Likert scale within eight domains. The FDDQL discriminated well among patients with different degrees of handicap as assessed by the investigators. This was most marked for the *mean daily activity score* (80 in patients with no handicap *v* 36 for extreme handicap; p<0.05). Construct validity of the FDDQL was supported by significant correlations between its subscores and those of the SF-36. The correlation was strongest between the *daily activity* score and both the SF-36 *physical role limitation* and *bodily pain* subscores (r=0.63, p<0.0001). The FDDQL is currently being evaluated to determine its ability to detect change.

Martin *et al* developed the quality of life in duodenal ulcer patients (QLDUP) by combining the SF-36, PGWB index, and 13 disease specific items derived from patient and clinician interviews.[40] The 54 item instrument with 15 dimensions was administered to French patients with acute duodenal ulcer (DU), a prior history of DU, or NUD, and showed good internal consistency (ICC >0.70) and test-retest reliability (Spearman's coefficient 0.73). Validity was claimed by identifying significant differences in scores between groups. However, the data to support this assertion were not provided. A subsequent trial by Rampal *et al* in 581 patients with a recently healed DU compared maintenance nizatidine (150 mg/day) with intermittent nizatidine therapy (300 mg/day as needed).[41] Patients receiving daily maintenance therapy had significantly better HRQOL compared with the intermittent treatment group in seven of the 15 dimensions at one year follow up (p<0.05). Although these studies support the construct validity of the QLDUP, responsiveness and assessment in other languages are lacking at this time.

A short eight item questionnaire using a five point response scale, developed by Veldhuyzen van Zanten *et al*, was pilot tested in 10 patients with NUD and 14 with *H pylori* associated gastritis (HPAG).[42] It was then administered to 55 patients with NUD or HPAG before and four weeks after antacid or *H pylori* eradication therapy, respectively. The instrument was responsive to change for both NUD (mean change −2.7; p=0.003) and HPAG (mean change −3.6; p=0.002) showing a significant improvement in scores, which correlated with the patient's self-reported global response (p<0.0001).

The QOL-RAD, discussed above, has also been validated in dyspeptic patients (table 6).

Each of the six disease specific HRQOL questionnaires for dyspepsia has undergone some psychometric evaluation supporting both validity and responsiveness. However, none has been satisfactorily assessed to warrant a recommendation for preferred use.

Irritable bowel syndrome

IBS is characterised by abdominal pain, altered bowel habit, and disturbed sensory and motor function with normal bowel morphology.[43] The prevalence ranges from 6.6% to 21.6% of the general population[44] and results in approximately 3.5 million physician visits and 2.9 million prescriptions annually in the USA.[45] Whitehead *et al* have shown that IBS patients have significantly poorer SF-36 scores than healthy controls (general health 62.3 *v* 85.6; p<0.001).[46] These patients have difficulty travelling, participating in sports, and attending social gatherings. Extraintestinal symptoms, such as back pain, headache, dyspareunia, urinary symptoms, and sleep disturbance are also more frequent in IBS patients than in healthy controls.[47] These symptoms result in work absenteeism, job changes, and premature termination of employment.[48] The lack of objective parameters to assess health status has prompted several groups to develop disease specific measures of HRQOL for IBS, as shown in table 7.

The first, the IBSQOL, was developed at UCLA by Hahn and colleagues.[49] Each of 30 items is scored on a five or six point Likert scale and summed in nine subscores. The IBSQOL discriminated well between a control group with non-IBS GI disorders and unselected patients with IBS. A later study showed that the IBSQOL could also discriminate between IBS patients with different disease severity.[50] However, no data regarding the construct validity or responsiveness have been published.

The IBS-QOL, a 34 item instrument developed by Patrick *et al*, was reviewed by European gastroenterologists in Britain, Germany, Italy, and France during the item reduction phase to ensure cross cultural validity.[51] A cross sectional survey of 169 patients with IBS demonstrated moderate construct validity with the SF-36 (r=0.30–0.44), PGWB (r=0.31–0.45), and the symptom check list (SCL90-R) (r =−0.27 to −0.46). The IBS-QOL discriminated well between patients with mild and high symptom frequency (mean score 69.7 *v* 55.0; p<0.0001) and symptom severity (mild *v* high, 72.2 *v* 53.8; p<0.0001). It could also discriminate between patients based on frequency of physician visits in the preceding six months (mean score 53.0 for greater or 65.6 for fewer; p < 0.05) and by the number of work days missed in the previous year (mean score 68.9 for 0 days missed *v* 54.6 for ⩾6 days missed; p<0.05). Eight different domains were identified by factor analysis. The IBS-QOL had excellent test-retest reliability and internal consistency. However, this study did not assess the responsiveness to change of the IBS-QOL.

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