Application of the general health status questionnaire SF36 to patients with gastrointestinal dysfunction: initial validation and validation as a measure of change

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Abstract

***Objective*:** To determine whether the Short Form (SF36) Health Status Survey is a valid measure of health status and health change for patients with irritable bowel syndrome (IBS).

***Methods*:** The SF36 was self-administered by 116 patients with IBS at the commencement and end of a controlled clinical trial. Patients were recruited through two Sydney teaching hospitals and through private gastroenterologists during 1997 and treated with Chinese herbal medicine.

***Results*:** The SF36 health concepts demonstrated internal consistency, construct validity and concurrent validity when applied to patients with significant bowel dysfunction. Patient scores on two health scales of the SF36 (bodily pain, general health) correlated significantly with the bowel symptom scores recorded by patients and gastroenterologists at the beginning and end of the trial period. Actively treated patients significantly improved their scores in four out of eight of the health scales of the SF36 and reported overall improvement compared with inactively treated patients.

***Conclusions*:** The SF36 is a valid measure of general health status in IBS patients, is sensitive to the presence of IBS, and is adequately sensitive to gastrointestinal change in IBS patients.

***Implications*:** While the SF36 general health measure is used by the Australian Bureau of Statistics and widely overseas, until recently no data have been available on the sensitivity of the SF36 to gastrointestinal dysfunction or numerous other disorders. The SF36 is not only sensitive to the presence of IBS, it also provides a useful adjunct to current methods of evaluating treatment outcomes for IBS, and potentially other disorders.

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General health questionnaires are increasingly used as survey instruments across population groups as a means of assessing health status. The principal assumption is that the questionnaires are sufficiently sensitive to determine variation in health status in the general population.

The SF36 is a self-reported measure of health status that has been extensively validated in overseas English-speaking countries and in Australia for adult age groups.[1-7] It has also been translated and validated in numerous other languages.[8] Other commonly used broader measures of health status include the Sickness Impact Profile (SIP)[9] and the Nottingham Health Profile (NHP).[10] However, the SF36 has become an increasingly popular choice among generic health status measures and for the purposes of this study was chosen over the SIP and NHP for a number of reasons. The SIP takes longer to complete, and both have been demonstrated to be less sensitive to lower levels of morbidity than the SF36.[5,11] The NHP also appears less sensitive than the SF36 on the majority of sub-scales of physical and emotional health.[5,12] The SF36 is now frequently recommended as the generic core in disease specific batteries.[13]

The SF36 is a 36-item questionnaire that consists of eight health concepts or scales. Each scale is made up of a number of distinct questionnaire items in the SF36. One separately reported item also assesses change in a respondent's health over the past year. The eight health scales are summarised in Table 1. Each of the scales is reported as a score from 0 (worst possible) to 100 (best possible).

The SF36 has been applied widely to clinical trials. Analyses of the physical and mental health scales of the SF36 have demonstrated that they are capable of discriminating between groups of persons: healthy patients and those with moderate levels of psychiatric or physical illness.[2,3,7,14] The clinical validity of the instrument has been tested on samples with a range of chronic disorders including low back pain, menorrhagia, suspected peptic ulcer, varicose veins,[3,15] asthma,[16] migraine,[17] HIV,[18]

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Table 1: Health concepts, number of items and levels, and summary of content for eight SF36 sub-scales and the health transition item (summarised from Medical Outcomes Trust, 1994).[30]

Concepts	No. of items	Summary of content
Physical functioning (PF)	10	Extent to which health limits physical activities
Role limits – physical (RP)	4	Extent to which physical health interferes with work or other daily activities
Bodily pain (BP)	2	Intensity and effect of pain on normal work
General health (GH)	5	Personal evaluation of health
Vitality (VT)	4	How energetic or tired
Social functioning (SF)	2	Extent to which physical health or emotional problems interfere with normal social activities
Role limits – emotional (RE)	3	Extent to which emotional problems interfere with work or other daily activities
Mental health (MH)	5	General mental health
Reported health transition (HT)	1	Evaluation of health compared with one year ago

post-operative functioning[19,20], and more recently, functional digestive disorders.[21,22] This paper presents further validation of the SF36 in IBS patients and new evidence of its capacity to measure health change following intervention.

IBS is a common bowel disorder that affects 10-20% of the general population.[23-26] A recent UK survey found that approximately one in three patients with gastrointestinal complaints who attended a general practitioner were judged to have IBS.[27] Approximately 30% of patients with IBS take sick leave as a consequence of the symptoms, and it accounts for up to 50% of referrals to gastroenterologists.[28,29] IBS represents significant morbidity and economic cost to the community. If the SF36 is to be broadly applicable and reliable as a general health status measure it ought to be able to discriminate patients with any of a wide range of health disorders from healthy patients. IBS, with both affective and physiological aspects, is ideally suited to testing the SF36 health measure.

Objectives

The present research sought to determine whether the Short Form (SF36) Health Status Survey is a valid measure of health status in patients with irritable bowel syndrome (IBS), a common gastrointestinal disorder. In addition, the study sought to determine whether the SF36 is a valid measure of health change following intervention for IBS.

Methods

The SF36 was self-administered by patients who were presenting for treatment of their IBS with Chinese herbal medicine (CHM). Patients completed the SF36 at the beginning and end of a 16-week intervention period. It took approximately five minutes to complete the questionnaire.

All subjects were recruited and screened in two public hospital gastroenterology units and by private gastroenterologists in Sydney during 1997. Patients between the ages of 18 and 75 years (inclusive) were assessed by routine clinical workup for IBS and according to the established Rome criteria for IBS (see Table 2).[31,32] Symptom presentations were more than trivial – patients interested in participating in the clinical trial had to undergo referral to a specialist gastroenterologist and have a recent bowel examination (generally a colonoscopy). Patients were subsequently referred to receive CHM treatment at specified centres for 16 weeks continuously. At the CHM centres, patients were randomly allocated into active (both standard and individualised herbal) treatment or a placebo and were reviewed regularly by a traditional Chinese herbalist and by a gastroenterologist. Patients, gastroenterologists and herbalists were all blinded to treatment group. The trial protocol was approved by the ethics committees of the University of Western Sydney Macarthur and the two participating hospitals. The clinical outcomes of the trial intervention have been reported elsewhere.[33]

Patients and gastroenterologists completed bowel symptom scales at the start and end of the 16-week treatment period. The bowel scales consist of four 100 mm visual analogue scales related to each symptom of IBS (pain/discomfort, bloating,

Table 2: Inclusion criteria for IBS.

Age 18-75 years inclusive
Colonic evaluation (colonoscopy or barium enema) within the previous five years (for 18-60 year olds) or within the previous three years (for 61-75 year olds)
IBS by Rome criteria: At least three months of continuous or recurrent symptoms of: Abdominal pain or discomfort with at least some discomfort present within the last two weeks and two or more of the following on at least one-quarter of occasions or days: i. abdominal distension that is visible or felt by tight clothing ii. pain relief with bowel action iii. more frequent stools with onset of pain iv. looser stools with onset of pain v. mucous in stools vi. feeling of incomplete evacuation
Bowel symptom scale: At least one marking on the visual analogue scales for IBS symptoms to be at least 20 mm from the 'not present' end of the scale.
Normal liver function tests and full blood count, urea and creatinine (within the last two weeks).

Table 3: Mean scores for SF36 health scales and internal consistency measures (average intra-scale correlations) at commencement and end of intervention period (all patients).

	At start			At end		
Health scale	Mean score (SE)	n	Cronbach's alpha	Mean score (SE)	n	Cronbach's alpha
Bodily pain	50.9 (2.3)	114	0.87	59.7 (2.4)	95	0.89
General health	56.8 (2.3)	106	0.84	61.0 (2.7)	85	0.89
Mental health	60.7 (1.9)	112	0.82	63.1 (2.3)	93	0.89
Physical functioning	80.2 (2.1)	102	0.87	80.4 (2.2)	90	0.89
Role limits – emotion	58.4 (4.1)	113	0.87	64.2 (4.3)	95	0.86
Role limits – physical	53.9 (3.9)	108	0.85	59.6 (4.1)	96	0.83
Social functioning	62.2 (2.5)	115	0.87	66.8 (2.7)	95	0.81
Vitality	45.9 (2.0)	112	0.82	45.9 (2.4)	92	0.88

constipation, diarrhoea). Validation of the bowel symptom scale, used as a means of assessing response to treatment intervention, was previously reported.[33] Further evaluation items administered at the end of the trial included patient and gastroenterologist ratings of overall improvement.

Statistical analysis

The SF36 was tested for validity and reliability in its application to IBS sufferers. Internal consistency was assessed using inter-item correlations (and Cronbach alphas calculated) for the individual health scales. To test construct validity the student t-test was used to compare SF36 scores for IBS patients and normative data for the Australian and UK populations. Factor analysis was also applied to determine the construct validity of the individual health scales of the SF36. Tests for concurrent validity were used to determine which health scales in the SF36 most clearly reflect the reported gastrointestinal dysfunction. Pearson product moment correlation was employed in this analysis to identify the degree of correlation between the patients' SF36 scores and their bowel symptom scores.

The sensitivity of the SF36 to change in health status of IBS patients was tested by examining changes in SF36 scores from beginning to end of the treatment period (paired sample t-tests). Changes in bowel symptom scores from beginning to end of treatment (recorded by gastroenterologists and patients) were also compared against item 2 responses of the SF36 which asks 'Compared to one year ago, how would you rate your health in general now?' Similarly, responses to this item were compared against categorical responses to a bowel symptom questionnaire item asking both gastroenterologists and patients about the extent of overall improvement (Kendall's rank correlation coefficients). Chi-square was used to examine the differences in categorical responses to the SF36 item 2 between active and inactive treatment groups at the end of treatment. *p* values were all 2-tailed unless otherwise indicated, a level of significance was set at 0.05. Missing scale and item scores were not replaced.

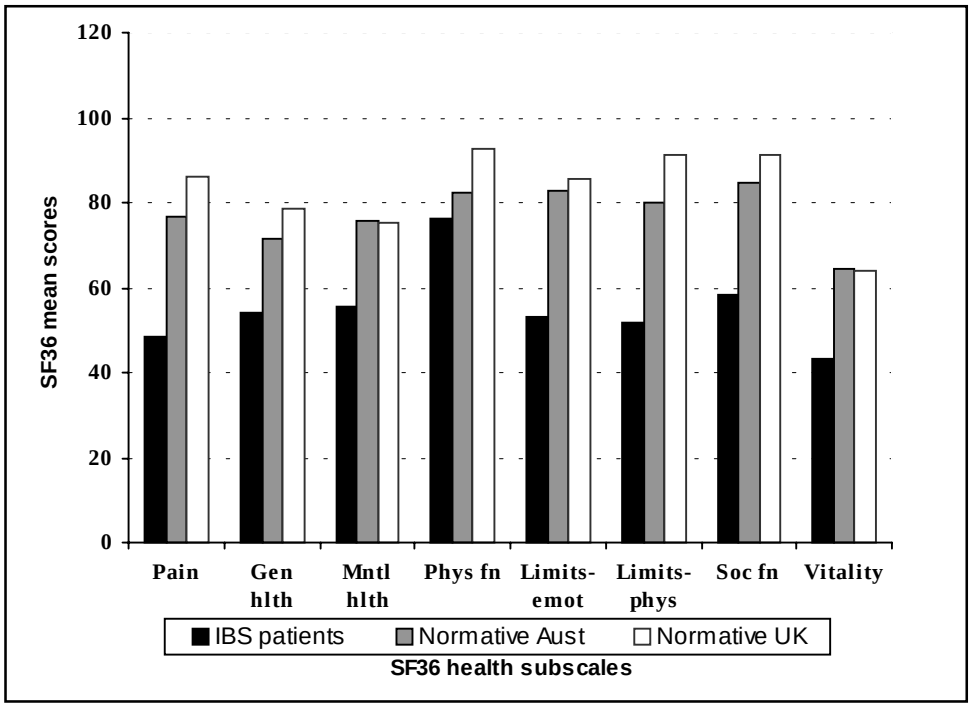

Figure 1: Comparison of age and sex standardised SF36 scores for the IBS cohort against age and sex standardised normative population data for Australia[1] and unstandardised normative population data for the UK[6] at the commencement of the trial.

Table 4: Principal components factor analysis on SF36 scales at pre- and post-treatment with percentage variance accounted for by principal factors (all patients).

Health scales	Pre-treatment Eigen-value	Pre-treatment % of variance accounted for by principal factor	Post-treatment Eigen-value	Post-treatment % of variance accounted variance principal factor
Bodily pain	1.7	85.8	1.8	88.4
General health	3.1	62.0	3.5	69.7
Mental health	3.0	59.0	3.5	70.5
Physical functioning	4.8	48.5	5.2	51.9
Role limits – emotion	2.4	79.3	2.4	78.5
Role limits – physical	2.7	68.5	2.6	65.8
Social functioning	1.8	88.4	1.7	83.9
Vitality	2.6	65.4	2.9	73.4

Table 5: Pearson-product moment correlation coefficients between patient responses on SF36 and gastroenterologist and patient interpretations of severity of bowel symptoms (all patients).

	Pre-treatment correlations Gastro-enterologist ratings	*Pre-treatment correlations* Patient ratings	*Post-treatment correlations* Gastro-enterologist ratings	*Post-treatment correlations* Patient ratings
Bodily pain	-0.31**	-0.43**	-0.28*	-0.44**
General health	-0.28**	-0.24*	-0.30*	-0.38**
Mental health	-0.18	-0.14	-0.12	-0.20
Physical function	-0.15	-0.21*	-0.02	-0.12
Role emotion	-0.18	-0.14	-0.31**	-0.24*
Role physical	-0.21*	-0.13	-0.25*	-0.40**
Social function	-0.25**	-0.17	-0.15	-0.30**
Vitality	-0.16	-0.21*	-0.18	-0.32**

Note:
** p<0.05, ** p<0.01*

Results

All 116 patients who entered the trial completed the SF36 on commencement (2.9% missing values), 99 patients completed it on exit or completion of the trial (3.2% missing values). The mean age of patients surveyed was 47.8 years (SD 14.1). Seventy-five participants were female (64.7%) and 41 male (35.3%). All subjects had a gastroenterologist-confirmed diagnosis of IBS.

Internal consistency

The internal consistency of the SF36 health scales were assessed using inter-item correlations within each of the eight health scales. Cronbach's coefficient alpha (representing average inter-item correlations) were high for all health scales of the SF36 on both occasions (see Table 3). Within each scale there were strong individual inter-item correlations, except for the items to do with 'bathing' or 'dressing and walking one block', which were both poorly correlated with other items representing the 'physical functioning' scale. This has been noted previously in other patient groups.[2]

Construct validity

Construct validity is reflected in the ability of the SF36 to distinguish a patient cohort with a significant health dysfunction from healthy patients. The IBS patient responses for each health scale of the SF36 were compared with responses in the general population (see Figure 1).

Mean scores for each of the eight health scales of the SF36 were standardised for age and sex for our IBS cohort of patients. This was achieved by adjusting mean scores for each age group and sex in the IBS group to reflect the normal population distribution figures provided by the Australian Bureau of Statistics.[1] A student t-test comparison of the standardised means between the known IBS group and normative data for the Australian population and an unstandardised UK population sample[6] showed significance at $p<0.01$ on all health scales.

A principal components factor analysis was also applied to each health scale for both the first and second administrations of the SF36. With the exception of the 'physical functioning' scale, on each occasion the scales revealed only one factor with an eigenvalue greater than 1. That is, all items within each scale (with the exception of the 'physical functioning' scale) had significant correlation with the first factor, confirming that items within each scale are measuring the same construct. For the 'physical functioning' scale on both occasions the items 'walking one block' and 'bathing or dressing oneself' were both more weakly correlated with the remainder of items in the scale. This contributed to a second factor in the 'physical functioning' scale. When compared with 'vigorous activity' also within the same scale, this would be expected given the vast difference in physical functioning these items signify.

Table 4 summarises eigenvalues and the percentage of variance accounted for by each principal factor.

Concurrent validity

The health scales were tested for concurrent validity at the commencement and end of treatment against both patients' and gastroenterologists' ratings of severity of bowel dysfunction. The Pearson correlation coefficient was in the range of -0.44 to -0.12 for each health scale against the total bowel symptom score as completed by patients and gastroenterologists (see Table 5). The only exception to this was the 'physical functioning' scale, which correlated poorly with the gastroenterologist measure of severity of bowel symptoms (r=-0.02).

The SF36 scales that correlate most closely with the severity of IBS as perceived by gastroenterologists and patients include 'bodily pain' and 'general health'. Limited health scales of the SF36 therefore exhibit concurrent validity with patient and gastroenterologist interpretation of the severity of the specific bowel symptoms. Other health scales demonstrated some correlation with severity of bowel symptoms, although these were

Table 6: Mean scores for health sub-scales of actively treated patients at commencement and end of intervention period.

Sub-scale	Pre-treatment Mean score (SE)	Post-treatment Mean score (SE)	n pairs
Bodily pain	51.7 (2.8)	63.4 (2.6)**	64
General health	60.3 (2.7)	67.2 (3.2) **	54
Mental health	62.4 (2.1)	65.9 (2.7)	59
Physical functioning	78.8 (2.6)	80.9 (2.9)	57
Role limits – emotion	57.8 (4.9)	68.7 (4.8)	62
Role limits – physical	56.7 (4.6)	66.5 (4.7) **	60
Social functioning	62.0 (3.0)	70.5 (3.3) **	64
Vitality	48.4 (2.5)	49.9 (2.8)	59

Note:
** p<0.05, ** p<0.01*

Table 7: Difference in overall health improvement reported by active and inactive treatment groups at end of treatment (chi-squared). Due to small cell sizes, the five categories of response to the SF36 item 2 have been collapsed into three. Percentages are within active or inactive groups.

Post-treatment SF36 item 2	Active no. (%)	Inactive no. (%)	*p* value
Much or somewhat better	27 (40.3)	6 (18.8)	
About the same	35 (52.2)	15 (49.9)	0.002
Much or somewhat worse	5 (7.5)	11 (34.4)	

neither sufficiently strong nor consistent. This is to be expected as the bowel symptom scales do not focus on activities specified in these items. The SF36 clearly assesses additional material to the bowel scales that focus on four key gastrointestinal symptoms.

The significant correlation with the 'bodily pain' and 'general health' scales also indicates the SF36 may be a valid, albeit weaker, measure of the severity of IBS presentations – with more severe bowel dysfunction correlating with lower scores on these two health scales of the SF36.

Sensitivity to change

As reported elsewhere, IBS patients receiving CHM improved significantly over those patients receiving placebo.[33] Hence, it was of interest to see if the SF36 was sufficiently sensitive to detect these changes in the active treatment group. The SF36 has not been previously tested as a measure of change in health status following intervention. It has, however, been reported as sufficiently sensitive over a 12-month period to note health changes in older patients with debilitating disease,[34] and over 12 to 18 months in patients with psoriatic arthritis.[35] The CHM intervention period was 16 weeks.

Paired sample *t*-tests were used to compare mean patient SF36 scores for each health scale from commencement to end of the trial for all actively treated patients (see Table 6). While patient mean scores on all scales showed improvement, changes in scale scores were statistically significant ($p<0.05$) for 'bodily pain', 'general health', 'role limits – physical' and 'social functioning'. No significant differences were noted in any of the scales for placebo patients over the duration of the trial.

At the end of the treatment period, the changes in the bowel symptom scores recorded by both gastroenterologists and patients correlated significantly with patient responses to item 2 of the SF36, which inquires about degree of overall health improvement compared with one year ago (patients τ=-0.31, gastroenterologists τ=-0.37) ($p<0.01$ on both occasions).

While there were no significant differences in response to the SF36 item 2 between active and inactive treatment groups on commencement of the trial, patients in the active group reported significant improvement over those in the inactive group by the end of the trial (χ^2=12.9, df=2, p=0.002; see Table 7). This is consistent with the principal outcome measures used in this trial.[33]

Conclusions

The SF36 Health Status Survey has been demonstrated to have adequate internal consistency and both construct and concurrent validity when applied to patients with irritable bowel syndrome. It is capable of distinguishing between known groups (healthy and dysfunctional GIT) effectively. Given the variety of presentations of IBS (from constipation to diarrhoea predominant, and from presence to absence of discomfort and bloating), it appears the SF36 could be sensitive to most bowel dysfunction, despite it comprising no direct questions related to bowel function.

Of interest, IBS impacted significantly on all health scales of the SF36, in comparison with healthy populations (see Figure 1). This supports other findings in the US and Europe.[21,22,36] Importantly, these results indicate that IBS has a significant impact not only on the measures of physical health in the SF36 but also on other health measures to do with energy levels, and mental and social well-being. These findings demonstrate the real and diverse impact of IBS on patients' lives, an impact not restricted to the physical expressions of pain, bloating, constipation and diarrhoea.

The SF36 is a valid measure of general health status in IBS patients in that it is sensitive to the presence of IBS. An important caveat is that this cohort of patients on whom the SF36 was tested was generally at the more severe end of clinical presentation. The mean duration of symptoms was reported as between five and 10 years and all patients were required to have had a bowel examination within the previous five years. The ability of the SF36 to reflect changes in the health status of mild to moderate cases of IBS remains to be established.

The SF36 also appears adequately sensitive to gastrointestinal change in IBS patients, albeit within the limitations of the four health constructs: 'bodily pain', 'general health', 'role limits – physical' and 'social functioning'. This improvement had been separately confirmed by changes in bowel symptom scores.[33] All

four scales directly reflect important aspects of the IBS condition – bodily pain, general health, general physical well-being, and interference in social life. Sensitivity of the SF36 was restricted to these four scales. The scales insensitive to change include 'physical functioning', 'mental health', 'role limits-emotional' and 'vitality'. 'Physical functioning' has already been identified as problematic because of its item span across a wide range of contrasting activities. 'Mental health' and 'role limits-emotional' were understandably less sensitive to IBS symptom change, as they measure non-physical symptoms not recorded by the traditionally physical IBS symptom scales. Similarly, 'vitality' was neither directly measured by the IBS scale, nor does it correlate closely with severity of symptoms.

Following active treatment the SF36 recorded significant improvements, not only in 'bodily pain' and 'role limits – physical', but also for the 'general health' and 'social functioning' subscales. These latter two scales are distinct to the more physical changes commonly recorded by bowel symptom scores. Clearly, improvement in the IBS condition resulted in a perceived improvement in other aspects of patient lives. It can be argued that the SF36 added a degree of sensitivity to the changes in patient well-being not recorded by any physical measures of change in bowel function, and again reflects the broader health impact of IBS.

Implications

The SF36 general health measure is used widely internationally as a component of general and disease-specific health measures, and for the collation of Australian health data by the Australian Bureau of Statistics. For our cohort of patients, the SF36 has proved a consistent and valid measure of health. Despite its widespread use and validation in varying clinical circumstances, the SF36 general health measure has remained largely untested as a tool to evaluate treatment outcomes.

These findings indicate that specific health sub-scales of the SF36 (bodily pain, general health, role limits – physical, social functioning) registered improvement in patients consistent with determinations made by gastroenterologists and patients using symptom-specific bowel scores. Importantly, these findings also lend some support to the use of the SF36 in the evaluation of other clinical interventions. The limitations are that any particular clinical disorder may only register substantial changes in specific health sub-scales and not in all. It should be remembered that in our study while all health sub-scales improved by the end of treatment, only the four above registered significant improvement. These could be used as additional measures of clinical outcome in IBS.

Utilising the SF36 general health questionnaire offers the advantage that it allows patients to communicate the impact of their illness and assesses clinical outcomes across a broad range of health aspects. Disease specific measures do not usually provide this feature. The SF36 is a simple, easily administered instrument. Its suitability as a method of evaluating treatment outcomes should be explored for other clinical conditions.

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