# Impact of Irritable Bowel Syndrome on Quality of Life

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The aims of this study were to determine the impact of irritable bowel syndrome on quality of life using a well-standardized measure, the SF-36, and to determine whether apparent impairments may be due to neuroticism. Undergraduate students with irritable bowel syndrome who had consulted a physician (41 females, 42 males), students with irritable bowel who had not consulted a physician (91 females, 74 males), and asymptomatic controls (52 females, 70 males) completed questionnaires on quality of life, neuroticism, and psychological distress. Patients showed greater impairment in quality of life than nonconsulters, who in turn showed greater impairment than controls. Neuroticism and psychological distress were correlated with all quality-of-life measures. However, when neuroticism and psychological distress were statistically partialed out, irritable bowel syndrome still had a significant negative impact. The SF-36 may be a useful outcome measure in treatment studies, but investigators will need to correct for confounding influences of neuroticism.

KEY WORDS: quality of life; irritable bowel syndrome; neuroticism; psychological distress; outcome.

Measuring the impact of irritable bowel syndrome (IBS) on quality of life may provide a method for comparing patients with respect to the severity of the disorder and for judging the efficacy of treatment. The Gastroenterology Division of the Food and Drug Administration has taken the position that improvements in quality of life are an important criterion for judging whether new drugs have acceptable costbenefit profiles in IBS because this disorder is associated with low mortality and morbidity.

To date, however, there has been very little research on the measurement of quality of life in patients with IBS. It is well documented that these patients report more illness-related absenteeism than

healthy people (1), but this provides only a crude measure of the impact of IBS on people's lives. In a postal survey, 148 IBS patients reported that all aspects of their lives were affected, including work, leisure, travel, and relationships (2). However, this was an uncontrolled study, and the subjects were self-selected; they had all voluntarily joined an IBS self-help group.

The Medical Outcomes Study Short Form (SF-36) is a well-standardized questionnaire for assessing quality of life (3). Steward et al (3) tested 9385 medical clinic patients with this instrument, of whom 696 (7.4%) reported that they had chronic gastrointestinal complaints. These complaints included duodenal, stomach, and peptic ulcer; "chronic inflamed bowel"; enteritis; and colitis. The authors reported that patients with these gastrointestinal complaints scored among the lowest (ie, most impaired) on quality of life scales out of eight medical conditions studied. Although the proportion of patients in this sample who had IBS was not reported, these data suggest

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	Patients		Non-Consulters		Controls	
	Females	Males	Females	Males	Females	Males
Number of Subjects	41	42	91	74	52	70
Race						
Caucasian	33	38	72	63	40	56
Black	5	3	12	3	9	3
Asian	0	0	1	I	0	2
Unknown	3	1	6	7	3	9
Average age (yr)						
Mean	24.07	23.17	22.79	23.35	21.08	21.00
SD	7.82	4.32	6.01	5.33	5.36	6.07

TABLE 1. DEMOGRAPHIC CHARACTERISTICS OF STUDY GROUPS

that the SF-36 may be useful as an outcome measure in IBS.

The principal aims of this study were: (1) to assess the impact of IBS on quality of life using a standardized scale, the SF-36 (3, 4); and (2) to determine whether the impact of IBS on quality of life is independent from neuroticism. Neuroticism is a psychological trait shared by many IBS patients (5), which is characterized by emotional lability and a negative outlook on life (6). This negative outlook could explain reports of poor quality of life in IBS patients (7). A secondary aim of the study was to determine whether the SF-36 includes all the areas of life that IBS patients identify as being affected by their bowel symptoms.

### MATERIALS AND METHODS

Subjects. The goal was to recruit 50 male and 50 female subjects in each of three groups: IBS patients, IBS nonconsulters (ie, people meeting symptom criteria for IBS but who had not consulted a physician about these symptoms), and asymptomatic controls. The strategy was to administer a previously described (8) 21-item bowel symptom questionnaire to all undergraduates taking introductory psychology at the University of Alabama at Birmingham during a two-year period in order to identify students with symptoms of IBS and to determine whether they had consulted a physician for these symptoms in the last year. The diagnosis of IBS required that subjects report abdominal pain that was relieved by defecation plus at least two of the remaining Manning symptoms (8). These diagnostic criteria are similar to but more stringent than the recommendations of Thompson et al (9). A total of 2405 students completed this screening questionnaire.

Successive students who met the inclusion criteria were recruited until approximately equal numbers of males and females in each group had completed the study (Table 1). Of those invited, 88.2% agreed to participate and completed the study.

**Procedures.** Subjects who agreed to participate were scheduled in small groups for a 3.5-hr session in which they were tested for lactose intolerance by the breath hydrogen technique. This involved testing breath hydrogen concen-

tration with a Jayco model EC60 (Mechanicsburg, Pennsylvania) portable hydrogen analyzer both before and at 30-min intervals for 3 hr after ingesting 50 g of lactose dissolved in 250 ml of water. An increase in breath hydrogen concentration of 20 ppm or greater constituted a positive test and caused the subject to be excluded from further participation. While being tested for lactose intolerance, subjects completed the following psychometric tests and questionnaires: the SF-36 (4), the NEO Personality Inventory (6), the Symptom Checklist 90 Revised (10), and a health care questionnaire developed for this study.

Medical Outcomes Study Short Form (SF-36). The SF-36 is a brief measure of functional status and well-being that was developed specifically for a large-scale epidemiological study (3, 4). It consists of eight scales: physical functioning (eg, walking, climbing stairs, carrying groceries), role physical (limitations in ability to work or perform usual activities), bodily pain (intensity of bodily pain or discomfort), general health (self-perception of current state of health, resistance to illness, and health outlook), vitality (energy level and fatigue), social functioning (impact of health or emotional problems on social activities), role emotional (impact of emotional problems on work or usual daily activities), and mental health (anxiety, depression, loss of control, sense of psychological well-being). Item 2 of the SF-36 asks subjects to indicate whether there has been a change in their health status in the last four weeks; it is sometimes included as a separate subscale labeled "health transition." Scores for the subscales were transformed following the recommendations of Ware (4) by dividing actual scores by the maximum score possible and expressing this ratio as a percent. Median internal consistency (ie, the extent to which the questions making up the subscales all measure the same constructs) and test-retest reliability (ie, the extent to which subjects give the same responses on separate occasions of testing in the absence of any intervention) for SF-36 scales range from 0.76 to 0.95 (3).

Health Care Questionnaire. This retrospective questionnaire included the following questions: "Do you experience symptoms of pain in the stomach area or abdominal discomfort, such as abdominal bloating, diarrhea, or constipation? If you do experience these symptoms, please list which areas of your life are most affected by these symptoms." Subjects were provided with six blank lines to write in their responses.

NEO Personality Inventory. The NEO Personality Inventory is a 182-item personality test that is scored for five

global domains: neuroticism, extroversion, openness, agreeableness, and conscientiousness. Previous research (7) suggests that the neuroticism scale is a predictor of symptom complaints and health care utilization, but the other four scales are not. Only the neuroticism scale was used in the data analyses for this study.

Symptom Checklist 90 Revised (SCL-90-R). The SCL-90-R (10) is a 90-item checklist of psychological symptoms that has been used in previous research on IBS (11). The SCL-90-R can be scored for nine clinical subscales, but for the purposes of this study, the global symptom index, which is an overall measure of the average severity of psychological symptoms, was used. Scores on the SCL-90-R were converted to T scores to allow comparison of males and females. The T-score scale is standardized so that the sample mean for the population is 50 and the standard deviation is 10. Thus, a T score of 70 corresponds to a raw score that is two standard deviations above the mean for a normative sample of 974 adults (10).

Data Analysis. To assess the relationship between IBS and quality of life (aim 1), a multivariate analysis of variance was initially used to compare the groups on all scales of the SF-36 simultaneously. This protects against errors in inference associated with making multiple comparisons. The multivariate analysis of variance was followed by univariate analyses of variance on the individual scales of the SF-36, and where appropriate, this was followed by pairwise comparisons of group means using Bonferroni-adjusted t tests.

To determine whether the impact of IBS on quality of life is independent of neuroticism (aim 2), we first computed Pearson correlation coefficients between the scales of the SF-36 and the two psychological scales: the neuroticism scale from the NEO Personality Inventory (6) and the global symptom index from the SCL-90-R (10). The criterion for statistical significance was set at a conservative 0.001 because a large number of correlations were tested. Having determined that these correlations were significant, the analyses described under aim 1 were repeated with the possible mediating effects of neuroticism and SCL-90-R partialed out. Analysis of covariance was used for these calculations.

To determine whether the SF-36 provided adequate assessment of the areas of subjects' lives affected by IBS (aim 3), the responses of subjects to an open-ended question about what areas of their lives were affected by IBS were separated into common categories and the number of items in each category was tabulated. These categories were compared to the items on the SF-36. The identification of areas not covered by the SF-36 would indicate that a more disease-specific quality of life instrument is needed.

# RESULTS

Demographic Characteristics of Study Groups. As shown in Table 1, the majority of the sample was Caucasian (88.6%), but 10.3% were African American and 1.2% were Asians. The preponderance of Caucasians was due in part to the exclusion of lactose malabsorbers, who were found more frequently among African Americans and Asians than among

Caucasians. There were no statistically significant differences between groups in age or ethnicity.

Group Differences in Quality of Life. Table 2 shows means and standard deviations for the SF-36 subscales. The multivariate analysis of variance showed a significant difference between groups  $[F_{\rm wilks}(18, 704) = 8.60, P < 0.001]$ , and subsequent univariate F tests were significant (P < 0.001) for all the SF-36 subscales except the Health Transition item [F(2, 360) = 0.80, P = 0.92].\* Patients differed significantly from control subjects, and nonconsulters differed significantly from control subjects on all eight standard SF-36 subscales. IBS patients reported significantly poorer quality of life than nonconsulters on the role physical, bodily pain, general health, vitality, and social functioning subscales.

To test the possibility that these results were confounded by the demographic characteristics of the sample, the multivariate analysis of variance was repeated after partialing out any differences related to age, gender, and race. The demographic variables were not significantly related to the dependent variables  $[F_{\rm wilks}(27,941)=0.80, P>0.76]$ , and the group effect remained at essentially the same magnitude  $[F_{\rm wilks}(18,644)=7.41, P<0.001]$ .

Relationship of Quality of Life Scales to Neuroticism and Psychological Distress. Neuroticism scores were similar in patients (97.16  $\pm$  2.51, mean  $\pm$  standard deviation) and nonconsulters (97.85  $\pm$  20.69). However, controls (78.88  $\pm$  19.91) were significantly less neurotic than both patients  $[t_{(203)}=6.11,\,P<0.0001]$  and nonconsulters  $[t_{(285)}=7.80,\,P<0.0001]$ . The SCL-90-R measure of overall psychological symptom severity showed a similar pattern: Patients (62.61  $\pm$  9.44) were not significantly different from nonconsulters (61.30  $\pm$  8.55), but controls (48.76  $\pm$  10.85) scored significantly lower than both IBS patients  $[t_{(203)}=9.45,\,P<0.0001]$  and IBS nonconsulters  $[t_{(284)}=10.56,\,P<0.0001]$ .

Table 3 shows the correlation of neuroticism and

<sup>\*</sup> The distribution of scores on the SF-36 scales were negatively skewed because many subjects obtained the highest score possible. The analysis of variance is a robust statistical test that is relatively insensitive to nonnormality of distributions. However, to ensure that nonnormality of distributions did not lead to a false impression of differences between groups, the univariate tests described above were all repeated using the non-parametric Kruskal-Wallis test. Results were almost identical to those shown in Table 2: there was a significant group effect (P < 0.0001) on all scales of the SF-36 except for the health transition scale, and paired comparisons (adjusted for multiple comparisons) showed the same between-group differences except for the bodily pain and social functioning scales, for which the IBS patients were no longer significantly different from the IBS nonconsulters.

TABLE 2. MEANS	STANDARD DEVIATIONS, AND GROUP COMPARISONS OF S	F-36
	QUALITY OF LIFE SUBSCALES	

Subscale	Patients	Nonconsulters	Controls	
Physical Functioning	-		<del>-</del>	
Mean	90.66	92.12	97.05	$P = N < C^*$
SD	11.76	12.25	8.28	
Role physical				
Mean	67.77	83.13	92.62	P < N < C
SD	36.74	29.25	22.66	
Bodily pain				
Mean	52.11	55.78	65.85	P < N < C
SD	13.76	14.23	14.11	
General health				
Mean	62.29	70.52	85.61	P < N < C
SD	19.80	10.10	15.35	
Vitality				
Mean	45.96	52.35	66.15	P < N < C
SD	18.20	19.53	14.68	
Social functioning				
Mean	78.46	83.90	93.04	P < N < C
SD	18.79	16.86	12.16	
Role emotional				
Mean	59.44	68.51	86.61	P = N < C
SD	38.62	38.53	26.99	
Mental health	20.02	50.55	-0.77	
Mean	63.71	66.49	75.31	P = N < C
SD	17.66	16.70	14.11	
Health transition	27100	-5170		
Mean	54.82	54.45	55.12	P = N = C
SD	21.90	21.68	19.27	

<sup>\*</sup> P = patients, N = nonconsulters, C = controls. An equal sign indicates no significant difference between groups and a less than or more than sign indicates a significant difference in the indicated direction.

psychological symptom severity to each subscale of the SF-36. Neuroticism correlated significantly (P < 0.001) with seven of the eight standard SF-36 scales, but neuroticism did not correlate significantly with the role physical scale. The SCL-90-R correlated significantly with all SF-36 scales, but the correlations were lower for the physical functioning and role physical scales as compared to other SF-36 scales. When the multivariate analysis of variance described above was repeated with the global symptom index of the SCL-90-R and the neuroticism scales partialed out,

TABLE 3. CORRELATIONS BETWEEN PSYCHOLOGICAL SYMPTOMS AND QUALITY OF LIFE SUBSCALES

Scale	SCL-90R global symptom index	Neuroticism	
Physical functioning	-0.17*	-0.23*	
Role physical	-0.19*	-0.14	
Bodily pain	-0.35*	-0.24*	
General health	-0.47*	-0.47*	
Vitality	-0.54*	-0.47*	
Social functioning	-0.44*	-0.41*	
Role emotional	-0.48*	-0.46*	
Mental health	-0.60*	-0.66*	

<sup>\*</sup> P < 0.001.

the main effect for groups remained significant  $[F_{\rm wilks}(18, 698) = 4.58, P < 0.001]$ , although attenuated by about half. After partialing out the effects of neuroticism and psychological distress, the role emotional subscale was no longer significantly different between groups, but the group effects on the other subscales remained significant at P < 0.04 or greater (compared to P < 0.001 or greater prior to partialing).

Areas of Life Affected by IBS. The responses of IBS patients and nonconsulters to the question about what areas of their lives were affected by bowel symptoms were tallied and the results compared to the content of the SF-36. The commonest concerns were covered by the SF-36: social activities and home life (26.6% of subjects), work (20.2%), school (16.1%), and exercise (8.1%). Areas of concern to people with IBS that were not covered by the SF-36 included eating (7.7%), sleeping (6.0%), ability to concentrate (2.8%), time management or delays (3.2%), sex (1.6%), and physical appearance (0.8%). Fecal incontinence was not explicitly mentioned, although it is known to occur in 22% of IBS patients (12). However, four subjects referred to "personal" areas as

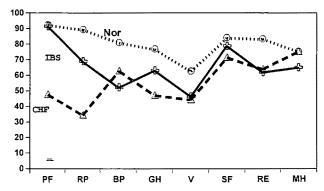


Fig 1. Comparison of quality of life in IBS patients (plus signs) to Ware's (4) published data for patients with congestive heart failure (triangles) and asymptomatic controls (circles). IBS patients showed less impairment in physical functioning and role physical but their quality of life was otherwise similar to that of patients with congestive heart failure. Definitions of SF-36 scales are PF for physical functioning, RP for role physical, BP for bodily pain, GH for general health, V for vitality, SF for social functioning, RE for role emotional, and MH for mental health.

being affected by IBS, one referred to insecurity, and one referred to going out in public without knowing where bathrooms were located. The responses of these four subjects may have related to concerns about fecal incontinence.

# DISCUSSION

IBS has a significant impact on the quality of life as measured by the SF-36. For illustration, Figure 1 shows how patients with IBS compare to patients with congestive heart failure, another chronic condition studied by Ware (4): IBS patients showed as great or greater impairment as patients with congestive heart failure on all scales of the SF-36 except physical functioning (ability to walk and dress), role physical (ability to work), and general health.

Talley and colleagues (13) used the SF-36 to characterize the quality of life of patients with functional dyspepsia. Their patients were older (average age 59), and they were recruited through their attendance at a tertiary referral center. These patients with functional dyspepsia showed greater impairment than our young patients with IBS on the SF-36 scales for physical functioning (mean of 74.4 for functional dyspepsia vs 90.7 for IBS), bodily pain (mean of 43.9 for functional dyspepsia vs 52.1 for IBS), and general health (mean of 39.3 for functional dyspepsia vs 62.3 for IBS). On other scales of the SF-36, they were similar to the IBS patients described in this study.

A concern about the use of quality of life measures for assessment of IBS patients is that they may be confounded with the psychological trait of neuroti-

cism. This would imply that quality-of-life scales may not be able to distinguish the effects of the illness on quality of life from the generally negative outlook on life that characterizes neuroticism. Moreover, because neuroticism is a relatively stable personality trait, this confounding could render quality-of-life measures less sensitive to improvements in physical symptoms. The data from this study reinforce these concerns: When the SF-36 was compared to a standard measure of neuroticism (the NEO Personality Inventory) and to a commonly used scale measuring psychological distress (the SCL-90-R), statistically significant and moderately strong correlations were observed (median correlation = -0.47; range = -0.14 to -0.66). This replicates earlier observations by our group showing that in patients attending a gastroenterology outpatient clinic, a visual analog scale rating of quality of life correlated significantly (r = -0.49) with scores on the SCL-90-R (14).

Although data such as these raise questions about the usefulness of quality-of-life measures for the assessment of treatment outcome in clinical trials, quality of life was significantly impaired among IBS patients and nonconsulters even after the effects of neuroticism and psychological distress were statistically removed. This implies that IBS symptoms have a measurable impact on quality of life that is independent of neuroticism, but it also emphasizes that the confounding influence of neuroticism on quality of life assessment must be taken into account. We recommend that future studies of the effect of chronic illness on quality of life include concurrent measures of neuroticism and assess illness effects only after partialing out neuroticism, as was done in this study.

This cross-sectional study does not enable us to determine what mechanisms account for the correlations among IBS, quality of life, and neuroticism. Neuroticism could contribute to these correlations through measurement error without having any "real" impact on bowel symptoms or on the quality of life. This would be the case if neuroticism predisposed subjects to adopt a low threshold for describing somatic sensations as illness or if it led subjects to report impairments in physical and role functioning on the SF-36 that are due to anxiety, depression, or secondary gain rather than the consequences of somatic symptoms. Alternatively, neuroticism could exert independent influences on the development of bowel symptoms and on quality of life. Neuroticism could also influence quality of life secondarily, as a consequence of its effects on bowel symptoms. By investigating the relationships among all these domains in both cross-sectional and longitudinal studies, future research may be able to specify the interrelationships between illness, psychological functioning, and behavior voth greater precision.

An unexpected finding in this study was that neuroticism and psychological distress in the nonconsulter group was similar to that of IBS patients and significantly greater than that of control subjects. Both our laboratory (11) and others (15, 16) have previously reported that IBS nonconsulters exhibit less psychological distress than IBS patients and that they are similar to controls in the level of psychological distress they exhibit. These differences appear to be related to the study of an undergraduate student population rather than older adults, since Gick and Thompson (personal communication, 1995) also found in an undergraduate student population that nonconsulters were similar to IBS patients and more psychologically distressed than healthy controls. The reasons for this cohort effect are not known.

The most important findings of this study are as follows: (1) IBS has a negative impact on the quality of life. This impact is independent from the tendency for many people with IBS to adopt a negative outlook on life due to the psychological trait, neuroticism. (2) The SF-36, which is the best validated quality-of-life measure currently available, is sensitive enough to detect differences among IBS patients, IBS nonconsulters, and asymptomatic controls; this implies that it can be used as an outcome measure in treatment studies. However, (3) investigators should be aware that the SF-36 scales are highly correlated with (ie, contaminated by) neuroticism. This confuses the interpretation of the SF-36 as a health outcome measure and strongly suggests the inclusion of concurrent measures of neuroticism in the design and analysis of data from outcome studies.

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