Fecal Incontinence Quality of Life Scale

Quality of Life Instrument for Patients with Fecal Incontinence

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PURPOSE: This goal of this research was to develop and evaluate the psychometrics of a health-related quality of life scale developed to address issues related specifically to fecal incontinence, the Fecal Incontinence Quality of Life Scale. METHODS: The Fecal Incontinence Quality of Life Scale is composed of a total of 29 items; these items form four scales: Lifestyle (10 items), Coping/Behavior (9 items), Depression/Self-Perception (7 items), and Embarrassment (3 items). RESULTS: Psychometric evaluation of these scales demonstrates that they are both reliable and valid. Each of the scales demonstrate stability over time (test/retest reliability) and have acceptable internal reliability (Cronbach alpha >0.70). Validity was assessed using discriminate and convergent techniques. Each of the four scales of the Fecal Incontinence Quality of Life Scale was capable of discriminating between patients with fecal incontinence and patients with other gastrointestinal problems. To evaluate convergent validity, the correlation of the scales in the Fecal Incontinence Quality of Life Scale with selected subscales in the SF-36 was analyzed. The scales in the Fecal Incontinence Quality of Life Scale demonstrated significant correlations with the subscales in the SF-36. CONCLUSIONS: The psychometric evaluation of the Fecal Incontinence Quality of Life Scale showed that this fecal incontinence-specific quality of life measure produces both reliable and valid measurement. [Key words: Fecal incontinence; Quality of life; Health surveys; Reproducibility of results; Outcome assessment (health care)]

Fecal incontinence (FI) can dramatically disrupt the lives of people who suffer from it. Inability to control the passage of stool or flatus can produce embarrassment, and fear of such episodes may limit a person's activities. Therefore, one measure of the effectiveness of therapy to correct fecal incontinence is the degree to which a patient's quality of life (QOL) is enhanced. Prior efforts to create quality of life scales relied on clinicians' opinions of the salient elements.[1-5] Some severity scales for FI include lifestyle issues,[6,7] but to our knowledge there is no validated QOL instrument for fecal incontinence. This article describes the development and psychometric evaluation of a QOL measure specifically designed to assess the impact of treatment for fecal incontinence.

Two approaches to measuring QOL are possible. One can use generic measures that are designed to tap aspects of health-related effects of care across a broad population, or one can look for indications that address the specific elements that will affect the lives of persons with a given condition.[8] The former offers the advantage of allowing comparability across conditions, but it is not likely to be as sensitive to the effects of a given health problem.[9] In this case we sought a measure of QOL that specifically addressed the impositions caused by a potentially socially disruptive condition. We then used the overall correlation with the more generic measure, the SF-36,[10] to establish the validity of the new condition-specific measures.

PATIENTS AND METHODS

Scale Development and Evaluation Procedures

A panel of experts, including colon and rectal surgeons and health service researchers, was convened to identify QOL-related domains adversely affected by FI. This process focused on specific state and trait characteristics and activities and behaviors that are related to FI. Out of this process, fundamental areas such as altering dietary habits and behavioral adaptations and emotional areas such as anxiety and embarrassment were identified as being the primary domains that are relevant to assessing QOL in the FI population. Based on these domains, questions were written and compiled into a 41-item questionnaire, the Fecal Incontinence Quality of Life Scale (FIQL).[11] The questionnaire was pretested in 50 patients with FI. This evaluation focused on clarity and readability and patient acceptance of the items. We sought patient feedback on the relevance of the items in the instrument to assessing QOL in a population that suffers from FI. All issues identified were resolved before developing a final test version.

The psychometric assessment of the FIQL evaluated both the reliability and validity of the instrument. Two aspects of reliability were examined, test/retest and internal,[11] and two different types of validity were assessed, discriminant and convergent.[11, 12]

In the evaluation of the reliability of an instrument, the reproducibility (stability) of the measurement properties were assessed. Test/retest reliability focuses on the stability of measurement over time; within a given period of time, in which no change is expected, a reliable instrument will provide the same measurement. A matched pair *t*-test was used to evaluate the test/retest reliability. Internal reliability evaluates the consistency of a set of items (scale) with each other. It is expected that items which comprise a scale will demonstrate strong consistent correlations with the total scale score. Cronbach's alpha was used to evaluate internal reliability.[13]

Discriminant validity (also referred to as construct validation by extreme groups, see Streiner and Norman,[11] Chapter 10) was evaluated by comparing the responses of patients with FI to those of a control group. The control group for this study was composed of patients with known gastrointestinal (GI) problems other than FI. A control population with no known GI problems could have been selected, but

such a comparison would be of little value because of the specificity of some of the questions. The use of a control population with known GI problems provides a better comparison population to evaluate the validity of the FIQL. (Appropriate changes were made to the control version of the questionnaire, *i.e.*, wording focusing specifically on FI such as "Due to FI. . . " was changed to read "Due to stomach or bowel problems. . . . " for administration in the control sample.) Analysis of variance was used to evaluate differences between the FI and control populations, so that gender and education could be controlled for in the analysis.

Convergent validity is the correlation of the measure(s) being evaluated with other instruments that presumably measure the same construct. To evaluate this aspect, a subsample within the study received both the FIQL and the SF-36. Comparisons between the scales within the FIQL and the SF-36 were then made to establish convergent validity. Pearson correlation coefficients were used for this analysis.

Study Design

To accomplish the goals of this research, two distinct populations had to be included in the research: a patient population known to have FI and a patient population known *not* to have FI, but which had to have other GI problems (controls). To minimize response burden, we used two subgroups within the FI population. One of these populations received both the FIQL scale and the SF-36 (for the convergent validity analysis). The other subgroup was asked to complete the survey at two points in time separated by 10 to 14 days (for the test/retest analysis). Controls completed only the survey and only once.

To recruit an adequate number of patients for the study, five colon and rectal surgery clinics were invited to participate in the research (Minneapolis, MN, Omaha, NE, St. Louis, MO, Cleveland, OH, and Ft. Lauderdale, FL). Participants (FI and controls) were sequentially recruited into the study during the course of one year, starting in October 1996 and ending in October 1997. For the fecal incontinence population, the inclusion criterion was the diagnosis of FI. The criteria for the controls were 1) be seen in clinic for a GI problem other than FI and 2) not be living with a person who had a diagnosis of FI. Patients in the FI group were randomly assigned to either the test/retest group or the validation group. Overall, a total of 269 surveys were distributed with 190 completed surveys

Table 1.
Basic Demographic Information for Fecal Incontinent and Control Populations

	Fecal Incontinent	Control	P Value
No.	118	72	
Age (yr)	58.7/16.6*	59.5/16.5*	NS
Gender			.01
Female	89	57	
Male	11	43	
Education			.05
Less than high school	18	10	
High school	21	19	
Some college	46	38	
B.S./B.A. or graduate	15	33	
Ethnicity			NS
Nonwhite	7	10	
White	93	90	

NS = not significant.
Figures are percentages unless otherwise specified.
* Age data are mean/standard deviation.

returned (response rate, 71 percent). The control population had the highest response rate, 79 percent (n = 72), whereas the FI population that received the validation version had the lowest, 61 percent (n = 55).

The administration of the surveys used a drop-off mail-back technique.[14] Patients were approached in clinic and asked to participate in the research; on securing informed consent, they were given a packet that contained one of the versions of the questionnaire and asked to fill it out and mail it to the University of Minnesota when completed. Each of these packets contained a cover letter, the appropriate questionnaire version, and a stamped return envelope. The test/retest packet contained two color coded copies of the questionnaire and instructions to complete the first survey and return it, and then complete the second survey 10 to 14 days after that. Phone call reminders and, when necessary, replacement questionnaires were sent out to nonrespondents.

Because only 9 of the 55 participants completing the retest version did so within the specified time frame (10–14 days), another sample of 61 patients was identified and the test/retest survey was conducted using the telephone mode. The response rate for this administration of the FIQL was 77 percent (N = 47). Given the goals of this research, reliability and validity evaluation, only the data collected from the telephone mode were used in the evaluation of test/retest reliability. (They have not been pooled with the data collected through self-administration, because of potential mode effects.)[15, 16]

Table 2.
Fecal Incontinence Quality of Life Scale Composition

Question	Loading
Scale 1: Lifestyle	
I cannot do many of things I want to do	0.621
I am afraid to go out	0.639
It is important to plan my schedule (daily activities) around my bowel pattern	0.686
I cut down on how much I eat before I go out	0.698
It is difficult for me to get out and do things like going to a movie or to church	0.731
I avoid traveling by plane or train	0.755
I avoid traveling	0.773
I avoid visiting friends	0.800
I avoid going out to eat	0.804
I avoid staying overnight away from home	0.847
Scale 2: Coping/Behavior	
I have sex less often than I would like to	0.603
The possibility of bowel accidents is always on my mind	0.611
I feel I have no control over my bowels	0.668
Whenever I go someplace new, I specifically locate where the bathrooms are	0.735
I worry about not being able to get to the toilet in time	0.736
I worry about bowel accidents	0.737
I try to prevent bowel accidents by staying very near a bathroom	0.763
I can't hold my bowel movement long enough to get to the bathroom	0.766
Whenever I am away from home, I try to stay near a restroom as much as possible	0.768
Scale 3: Depression/Self Perception	
In general, would you say your health is	0.530
I am afraid to have sex	0.613
I feel different from other people	0.650
I enjoy life less	0.678
I feel like I am not a healthy person	0.708
I feel depressed	0.759
During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile	0.796
Scale 4: Embarrassment	
I leak stool without even knowing it	0.641
I worry about others smelling stool on me	0.790
I feel ashamed	0.813

Table 1 presents a summary of the demographic information for the self-administered survey. (Demographic data for the telephone sample are not presented, because they are not used in any analysis in which FI and controls are compared with each other.) No significant differences between the controls and FI population were found for age or ethnicity. However, significant differences were found in the distribution

of males and females between these two groups ($P <$ 0.01) and in educational status ($P < 0.05$). Therefore, both gender and educational status were controlled for in any comparison between the FI and control populations.

Scaling

Items (questions) were conceptually grouped *a priori* into six scales based on the state and trait characteristic or aspect of life that they were presumed to

Table 3.
Reliability Analysis of Fecal Incontinence Quality of Life Scales

	Test	Retest	P Value	Alpha
Lifestyle	3.28/1.02	2.23/0.99	NS	.96
Coping/Behavior	2.84/1.23	2.83/1.29	NS	.96
Depression/Self Perception	3.68/1.02	3.67/1.08	NS	.88
Embarrassment	2.87/1.13	2.82/1.22	NS	.8

NS = not significant.
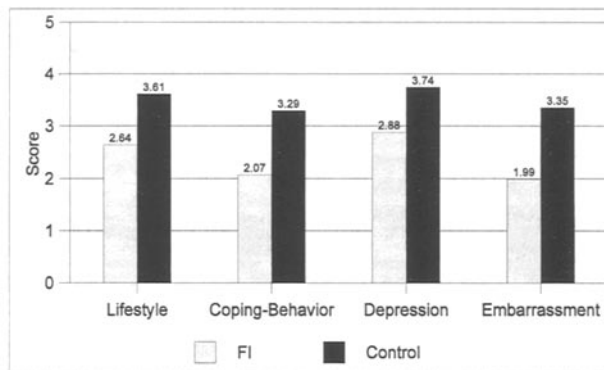Figures are mean/standard deviation unless otherwise specified.

Figure 1. Comparison of patients with fecal incontinence (FI) and controls for each scale (all significant at the 0.01 level, controlling for gender and education).

measure. Confirmatory factor analysis was used to evaluate the groupings.[17, 18] Two of the six original scales were eliminated because they were found to be composed of multiple factors (*i.e.*, more than one "scale." Subsequent analysis of these factors individually did not yield a grouping that achieved a single factor with acceptable item loadings.) Items from these scales were then evaluated for their fit with the four remaining scales. Of the 41 original questions developed, 29 were retained in the four scales. The exact question wording and factor loadings for each of the items in the four FIQL scales is presented in Table 2. A sample of the questionnaire itself and scale scoring procedures are shown in the appendix.

RESULTS

Reliability

Table 3 shows the reliability analysis. The test/retest analysis used a matched pairs *t*-test. On average, the test and retest administrations were completed eight days apart (standard deviation, ±3). As shown in the table, none of the scales show significant differences between the test and retest administrations. The four scales also demonstrate acceptable internal reliability; all alpha values are well over the traditionally accepted level of 0.70.

Discriminant Validity

The first test of validity is the ability of the FIQL scales to differentiate between the FI and control samples. If the FIQL is a well-designed, condition-specific QOL scale, the FI population should demonstrate a significantly lower QOL than the control population. Figure 1 shows that the FI population had a significantly lower QOL score than the controls for each of the four scales ($P < 0.01$, controlling for gender and education).

Table 4.
Correlation of Fecal Incontinence Quality of Life Scales (FIQL) with Selected SF-36 Scales

FIQL Scale	SF-36 Scale					
	Role: Physical	General Health	Vitality	Social Functioning	Role: Emotional	Mental Health
Lifestyle	.51*			.53*	.55*	
Coping						.35*
Depression/Self Perception		.52*	.46*			.65*
Embarrassment	.28†			.44*		.53*

Figures are Pearson correlation coefficients.
* Significant at $P < .01$.
† Significant at $P < .05$.

Convergent Validity

To test for convergent validity, the FIQL scales were correlated with comparable scales found in the SF-36. The goal of this analysis is to examine the scales relative to an established set of measures that have been demonstrated to be sensitive in similar domains. The condition-specific focus of the FIQL scale makes comparison of each scale with all eight scales in the SF-36 unwarranted. Ten comparisons between the FIQL scales and the SF-36 subscales were *a priori* identified for analysis. As shown in Table 4, the correlations range from a high of 0.65 (FIQL depression, SF-36 Mental Health) to 0.28 (FIQL embarrassment, SF-36 Role Physical) and all are significant.

DISCUSSION

The FIQL seems to have passed the requisite psychometric tests to establish its potential as a useful measure of quality of life for patients with FI. An examination of the content of the four scales suggests that they do indeed tap aspects of life for patients with FI that could pose problems and affect social functioning in addition to self-image. The test/retest and internal reliability evaluations show that the measure is stable over a specified period of time in which no change should occur and that the internal consistency between the items in each scale is acceptable. In the first validity analysis the scales differentiate between patients with FI and patients with other GI problems. In the second the FIQL scales correlate with appro-priate subscales from the SF-36. Thus, the FIQL seems ready to be used to assess the outcomes in therapeutic trials for this patient group.

A further refinement would be to collapse the four scales into a single summary measure. Although some people might object to this level of generalization, others would undoubtedly find such a summary useful. The cardinal issue surrounding such a condensation is how to weight the various component scales. There is no *a priori* reason to believe that each scale is of equal importance. Work is currently underway to examine the relative value patients with FI and clinicians place on each of the scales. These value weights can then be used to create the summary FIQL scale.

CONCLUSIONS

The FIQL has met the psychometric criteria for reliability and validity. The instrument provides a standardized instrument that can be used to assess QOL issues related to fecal incontinence. The remaining task is to establish the responsiveness of the scales.[8, 19] This task requires demonstrating that the scales are able to show a difference when there is a clinical reason to expect such a result. This test is ordinarily conducted when the scales are used in an intervention study. The focus of this research was to evaluate the fundamental psychometric principles of the FIQL. Follow-up research will focus on evaluating the responsiveness of the FIQL.

Appendix

Q 1:   In general, would you say your health is:

      1 ☐ Excellent
      2 ☐ Very Good
      3 ☐ Good
      4 ☐ Fair
      5 ☐ Poor

Q 2:   For each of the items, please indicate how much of the time the issue is a concern for you
due to accidental bowel leakage.   (If it is a concern for you for reasons other than
accidental bowel leakage then check the box under Not Apply, (N/A).)

Q2. Due to accidental bowel leakage:	Most of the Time	Some of The Time	A Little of the Time	None of the Time	N/A
a. I am afraid to go out	1	2	3	4	☐
b. I avoid visiting friends	1	2	3	4	☐
c. I avoid staying overnight away from home	1	2	3	4	☐
d. It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e. I cut down on how much I eat before I go out	1	2	3	4	☐
f. Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g. It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h. I avoid traveling	1	2	3	4	☐
i. I worry about not being able to get to the toilet in time	1	2	3	4	☐
j. I feel I have no control over my bowels	1	2	3	4	☐
k. I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l. I leak stool without even knowing it	1	2	3	4	☐
m. I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

Q 3:   <u>Due to accidental bowel leakage</u>, indicate the extent to which you AGREE or DISAGREE with each of the following items. (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Apply, N/A).

Q3. Due to accidental bowel leakage:	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree	N/A
a. I feel ashamed	1	2	3	4	☐
b. I can not do many of things I want to do	1	2	3	4	☐
c. I worry about bowel accidents	1	2	3	4	☐
d. I feel depressed	1	2	3	4	☐
e. I worry about others smelling stool on me	1	2	3	4	☐
f. I feel like I am not a healthy person	1	2	3	4	☐
g. I enjoy life less	1	2	3	4	☐
h. I have sex less often than I would like to	1	2	3	4	☐
i. I feel different from other people	1	2	3	4	☐
j. The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k. I am afraid to have sex	1	2	3	4	☐
l. I avoid traveling by plane or train	1	2	3	4	☐
m. I avoid going out to eat	1	2	3	4	☐
n. Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

Q 4:   During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?

     1 ☐ Extremely So - To the point that I have just about given up
     2 ☐ Very Much So
     3 ☐ Quite a Bit
     4 ☐ Some - Enough to bother me
     5 ☐ A Little Bit
     6 ☐ Not At All

Scale Scoring

Scales range from 1 to 5, with a 1 indicating a lower functional status of quality of life. Scale scores are the average (mean) response to all items in the scale (*e.g.*, add the responses to all questions in a scale together and then divide by the number of items in the scale. Not Apply is coded as a missing value in the analysis for all questions.)

Scale 1. Lifestyle, ten items: Q2a Q2b Q2c Q2d Q2e Q2g Q2h Q3b Q3l Q3m

Scale 2. Coping/Behavior, nine items: Q2f Q2i Q2j Q2k Q2m Q3d Q3h Q3j Q3n

Scale 3. Depression/Self Perception, seven items: Q1 Q3d Q3f Q3g Q3i Q3k Q4, (Question 1 is reverse coded.)

Scale 4. Embarrassment, three items: Q2l Q3a Q3e

REFERENCES

1. O'Keefe EA, Talley NJ, Tangalos EG, Zinsmeister AR. A bowel symptom questionnaire for the elderly. J Gerontol 1992;47:M116–21.
2. Shelton A, Madof R. Defining anal incontinence: establishing a uniform continence scale. Semin Colon Rectal Surg 1997;8:54–60.
3. Ludman L, Spitz L, Kiely EM. Social and emotional impact of faecal incontinence after surgery for anorectal abnormalities. Arch Dis Child 1994;71:194–200.
4. Ludman L, Spitz L. Psychosocial adjustment of children treated for anorectal anomalies. J Pediatr Surg 1995;30:495–9.
5. Ludman L, Spitz L. Coping strategies of children with faecal incontinence. J Pediatr Surg 1996;31:563–7.
6. Lunniss PJ, Kamm MA, Phillips RK. Factors affecting continence after surgery for anal fistula. Br J Surg 1994:81:1382–5.
7. Holschneider AM. Treatment and functional results of anorectal continence in children with imperforate anus. Acta Chir Belg 1983;82:191–204.
8. Fitzpatrick R. Advances in medical sociology. In: Albrecht GL, ed. Quality of life in health care. Vol 5. Greenwich: JAI Press, 1994.
9. Avis NE, Smith KW. Conceptual and methodological issues in selecting and developing quality of life measures. In: Fitzpatrick R, ed. Quality of life in health care. Vol 5. Greenwich: JAI Press, 1994:255–80.
10. Ware J, Snow K, Kosinski M, Gandek B. SF-36 health survey. Manual and interpretation guide. Boston: The Health Institute, New England Medical Center, 1993.
11. Streiner DL, Norman GR. Health measurement scales: a practical guide to their development and use. Oxford: Oxford University Press, 1989:vii,175.
12. Campbell DT, Overman ES, Methodology and epistemology for social science: selected papers. Chicago: University of Chicago Press, 1988:xix,609.
13. Cronbach L. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297–334.
14. Salant P, Dillman DA. How to conduct your own survey. New York: Wiley, 1994:xvi,232.
15. Dillman DA, Sangster RL, Tarnai J, Rockwood TH. Understanding differences in people's answers to telephone and mail surveys. In: Braverman MT, Slater JK, eds. Advances in survey research. San Francisco: Jossey-Bass, 1996:110.
16. Rockwood TH, Sangster RL, Dillman DA. The effect of response categories on questionnaire answers: context and mode effects. Sociol Methods Res 1997; 26:118–40.
17. Lawley DN, Maxwell AE. Factor analysis as a statistical method. 2nd ed. New York: American Elsevier, 1971: viii,153.
18. Kim JO, Mueller CW. Factor analysis. Statistical methods and practical issues. A Sage University paper. Beverly Hills: Sage Publications, 1978:88.
19. Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. J Chronic Dis 1987;40:171–8.

Invited Editorial

To the Editor—Although clinicians have always been interested in assessing the quality of life of their patients, it is only recently that quality of life has been measured objectively and quantitatively and has been an important outcome in assessing various surgical procedures. Quality of life is difficult to define, but there is general agreement that quality of life encompasses physical, psychological, and social well being. Furthermore, it is accepted that quality of life should be measured from the patient's perspective.[1]

This article by Rockwood and colleagues describes the development of a quality of life instrument for patients with fecal incontinence. It is an important contribution, because fecal incontinence is prevalent and has a major impact on quality of life. Furthermore, it is well known that function and quality of life do not necessarily correlate. For instance, the quality of life of some patients may be severely affected even with what seems to be minimal functional impairment, whereas the converse may also be true. Thus,