The UFS-QOL, a New Disease-Specific Symptom and Health-Related Quality of Life Questionnaire for Leiomyomata

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OBJECTIVE: To create and validate a questionnaire for assessing symptom severity and symptom impact on health-related quality of life for women with leiomyomata.

METHODS: The questionnaire was derived from focus groups of women with leiomyomata. Content validity was established through cognitive debriefings of women with leiomyomata and review by expert clinicians. Patients for the validation study were recruited from five gynecologists' offices, an interventional radiology department, and a University campus. Instruments used for validation were the Short Form-36, Menorrhagia Questionnaire, the Revicki-Wu Sexual Function Scale, and a physician and a patient assessment of severity. Item and exploratory factor analysis were performed to assess the subscale structure of the questionnaire. Psychometric evaluation was conducted to assess reliability and validity. Test-retest was performed on a random subset of the sample within 2 weeks of the initial visit.

RESULTS: A total of 110 patients with confirmed leiomyomata and 29 normal subjects participated in the validation. The final questionnaire consists of eight symptom questions and 29 health-related quality of life questions with six subscales. Subscale Cronbach's α ranged from 0.83 to 0.95, with the overall health-related quality of life score $\alpha = 0.97$. The Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire subscales discriminated not only from normal controls but also among leiomyomata patients with varying degrees of symptom severity. Test-retest reliability was good with intraclass correlation coefficients of 0.76–0.93.

CONCLUSION: The UFS-QOL appears to be a useful new tool for detecting differences in symptom severity and health-related quality of life among patients with uterine leiomyomata. Additional study is underway to determine the responsiveness of the UFS-QOL to therapies for leiomyomata. (Obstet Gynecol 2002;99:290–300. © 2002 by the American College of Obstetricians and Gynecologists.)

Despite the prevalence of uterine leiomyomata and the symptoms they may cause, there has been relatively little study of the impact of symptoms on patients' health-related quality of life. As the effects of uterine leiomyomata are primarily symptomatic, the subjective outcome, namely symptom alleviation, cannot objectively be measured, which highlights the need for validated symptom and health-related quality of life assessments. Currently, no published, validated symptom and health-related quality of life questionnaires specific to uterine leiomyomata are available.

Previous research on hysterectomy, the most widely studied treatment for leiomyomata, has used generic health status questionnaires and found improvements in symptoms and health-related quality of life after surgical intervention.[1–3] Lamping et al developed a menorrhagia outcomes questionnaire[4] to assess hysterectomy outcomes, and Ruta et al developed the Menorrhagia Questionnaire[5] to use as a guide for treatment selection and outcomes assessment. Although these are useful tools to assess menorrhagia, the nonbleeding symptoms of uterine leiomyomata, such as pelvic pressure, urinary frequency, and back and pelvic discomfort (bulk symptoms) are not assessed, nor is the impact of symptoms on health-related quality of life fully assessed.

A leiomyomata-specific questionnaire designed to assess the impact of uterine artery embolization on leiomy-

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omata symptoms has been previously developed[6] and was able to detect a statistically significant change in symptom and health-related quality of life 3 months after embolization. However, this questionnaire did not incorporate a patient perspective and used a generic health status questionnaire and a questionnaire that was originally created to assess the hormonal effects of a pharmacologic agent. Consequently, we undertook this project to create and validate a symptom and health-related quality of life instrument that was specific for women with uterine leiomyomata while integrating a patient perspective. The result of this effort, the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire, is presented here.

MATERIALS AND METHODS

Instrument Development

The UFS-QOL was developed from focus groups, clinician opinion, and a thorough literature review. Focus group participants were recruited from a newspaper advertisement with all respondents screened for eligibility to ensure the presence of uterine leiomyomata symptoms. Two focus groups ($n = 17$) were held on the campus of Georgetown University Medical Center. The questionnaire was derived from comments and issues discussed in the focus group sessions using standard instrument development techniques.[7]

The preliminary questionnaire was sent to all focus group participants for comments on the applicability and administrative ease of the questionnaire as well as to verify that the questionnaire reflected the group discussions. Five women with uterine leiomyomata were also interviewed after completing the questionnaire to ascertain the feasibility and acceptability of the UFS-QOL. Additionally, three gynecologists reviewed the questionnaire for content validity. Minor revisions were made after the focus group review and cognitive debriefings.

The initial UFS-QOL consisted of 72 items (18 symptom, 54 health-related quality of life) and was designed for self-administration. Symptom items addressed both the frequency and severity of uterine leiomyomata symptoms. Health-related quality of life items addressed were: fatigue, sleep, self-image, mood disturbances/psychologic distress, fear of embarrassment, interference with daily activities, relationships with family and friends, and sexual functioning. Response options were presented as five-level Likert scales ranging from "none of the time" to "all of the time" for the symptom frequency and health-related quality of life items and "not at all" to "a very great deal" for the symptom severity items (in response to "how distressed were you"). A recall period of 3 months was chosen because of the variability in the severity and duration of menses in women with uterine leiomyomata while trying to minimize recall burden.

Participants and Procedures

Both normal volunteers and women with uterine leiomyomata were recruited to participate in the validation study. Enrollment was targeted to be a total of 100 women with a clinical diagnosis of uterine leiomyomata and 30 women without uterine leiomyomata. Normal volunteers were recruited from the Georgetown campus and women with uterine leiomyomata were recruited from five Washington, DC, area gynecologists' offices and an interventional radiologist's office to complete the questionnaire packet. Women recruited from the interventional radiologist's office were being evaluated for uterine artery embolization.

After providing written consent, women were asked to complete a series of questionnaires. Using a block randomization scheme of 1:4, approximately 25% of the participants were randomized to the test-retest component of the study in which they were asked to complete the UFS-QOL 2 weeks after the initial questionnaire completion.

This study was reviewed and approved by Georgetown University's Institutional Review Board, and all participants provided written informed consent before study entry. Participants were paid a nominal fee to offset costs of their participation.

Instruments

In addition to the UFS-QOL, participants completed the following questionnaires:

1. *Medical Outcomes Study Short-Form 36 (SF-36) Health Survey*: This 36-item self-administered generic health status questionnaire is comprised of eight domains: physical function (PF), role limitations–physical (RP), vitality (VT), general health perceptions (GH), bodily pain (BP), social function (SF), role limitations–emotional (RE), and mental health (MH).[8] The SF-36 has been used extensively as an indicator of health-related quality of life, and its reliability and validity are well documented.[8,9]
2. *Menorrhagia Questionnaire*: As excessive menstrual blood loss (menorrhagia) is one of the more frequent symptoms of uterine leiomyomata, the 15-item Menorrhagia Questionnaire developed by Ruta et al[5] was used to evaluate construct validity. The questions are similar to those asked during a gynecology history; responses are captured on an ordinal scale, summed, and converted to percentages to produce a single menorrhagia severity score between 0 to 100. Patients

are asked to answer questions on duration of period and menstrual cycle, amount of menstrual flow, pain related to menstrual flow, and the effect of symptoms on daily activities.[5]

3. *Revicki-Wu Sexual Function Scale*: The Sexual Function Scale is a 12-item questionnaire designed to measure health interference with sexual relations or ability, satisfaction with sexual relations, decrease in sexual activity, and intimate relations with a partner. It includes five items from the Medical Outcomes Study sexual problems scale.[10] Because sexual dysfunction is a frequent occurrence in this patient population, this scale was included to further characterize the extent of the dysfunction and to be an ancillary measure for the construct validity assessment.
4. *Clinical Variables*: Physicians rated patient severity of uterine leiomyomata symptoms on a scale of 1–10 as well as provided clinical data regarding duration of symptoms and current treatments. Such data were not available for normal volunteers.
5. *Self-Rated Symptom Severity*: All participants were asked to rate the severity of their uterine leiomyomata symptoms on a scale of 0–10 with 0 being not severe and 10 being very severe symptoms experienced.

Statistical Analysis

Data were analyzed both individually and as a single data set using SAS 8.0 (SAS Institute, Cary, NC) and MAP-R (Health Assessment Lab, Boston, MA). Descriptive analyses on demographic and clinical variables were performed. For categorical comparisons where cells contained fewer than five respondents, Fisher exact test was used. Psychometric analyses were conducted separately for the symptom and health-related quality of life scales of the UFS-QOL as these scales were designed to be individual scales. Decision rules for item reduction were: 1) nonresponse if greater than 60% of participants denied the occurrence or impact of the item; 2) poor item discrimination (unable to discriminate between normal and uterine leiomyomata women); 3) low item to total correlations (less than or equal to 0.40); or 4) the item did not adequately load on any factor (less than or equal to 0.40 or greater than 0.40 on more than one factor).

Exploratory factor analysis was used to empirically identify potential subscales within the questionnaire, which is accomplished by analyzing the pattern of covariance (or correlation) among the questions.[11,12] An oblique rotation was performed as the subscales were assumed to be correlated. Questions that are more strongly interrelated to one another than other groups will tend to form factors (or subscales), indicating that these items are assessing similar concepts.

When performing exploratory factor analysis, any questionnaires with missing items were excluded from the analysis. For the subscale and subsequent analyses, if less than 50% of the subscale items were missing, the subscale was retained with the mean subscale score of the items present used to impute a score for the missing items. If greater than or equal to 50% of the items were missing, no subscale score was calculated. The health-related quality of life total score was calculated by summing the subscale scores excluding the symptom subscale. Each subscale and total health-related quality of life score were transformed into a 0–100 scale. For the health-related quality of life total and subscale scores, higher scores indicated better health-related quality of life. The opposite occurs with the symptom severity scale where higher scores are indicative of increasing symptom distress.

Item and subscale performances were examined with items assessed for floor and ceiling effects and subscales evaluated for scaling success (defined as an item correlating significantly higher with its hypothesized subscale than with other subscales) or scaling error (defined as the correlation of an item with other subscales, which exceeds the correlation of its own scale by two standard errors).[13]

Internal consistency reliability was assessed by Cronbach's α.[14] Concurrent validity was evaluated by Pearson correlation coefficients with the three previously validated questionnaires (SF-36, Menorrhagia Questionnaire, Sexual Function Scale). Cohen's guidelines for the interpretation of correlation coefficients were used with a correlation of 0.10 being small, correlation of 0.30 moderate, and a correlation of 0.50 being large.[15] In the behavioral sciences, validity coefficients (correlation with a criterion) are generally in the range of 0.00–0.60. Patient-perceived severity ratings of uterine leiomyomata symptoms and physician ratings of patient symptom severity were used as additional indices of validity; analysis of variance was used to ascertain differences between these ratings. Discriminant validity was determined by using *t* tests to compare normal participants with women with uterine leiomyomata.

Test-retest reliability was assessed by using intraclass correlation coefficients to compare scores obtained at baseline (visit 1) with those obtained 2 weeks later (visit 2) for the randomized subsample. Pearson correlation coefficients and paired *t* tests were calculated to identify systematic or mean value differences, respectively.

RESULTS

A total of 110 women with uterine leiomyomata and 29 normal volunteers were recruited into the validation study from July 1, 2000, through December 1, 2000. The

Table 1. Demographic Characteristics

	Normal $N = 29$	Uterine Fibroid $N = 110$	P
Age, mean (y) (SD)	31.2 (6.1)	37.9 (8.4)	.001
Race (%)			
White	7 (24.1)	36 (32.7)	
Black	22 (75.9)	69 (62.7)	
Hispanic	0	2 (1.8)	.81
Asian	0	2 (1.8)	
Other	0	1 (0.9)	
Employment status			
Full-time/part-time work	27 (93.1)	103 (94.5)	
Unemployed	0	3 (2.8)	
Homemaker	0	1 (0.9)	
Full-time/part-time student	2 (6.9)	1 (0.9)	.43
Retired	0	0	
Disabled	0	0	
Other	0	1 (0.9)	
Education			
≤ High school	13 (44.8)	25 (22.7)	
College	12 (41.4)	55 (50.0)	
Graduate school	3 (10.3)	29 (26.4)	.03
Other	1 (3.5)	1 (0.9)	
Marital status			
Living alone	6 (20.7)	38 (34.6)	
Living with spouse/partner	17 (58.6)	63 (57.3)	.10
Other*	6 (20.7)	9 (8.2)	
Ever pregnant (% yes)	75.9	68.8	.50
Self-rated symptom severity (mean) (SD)	1.25 (2.7)	5.6 (3.1)	.001

SD = standard deviation.
* Other reflects living with other family members or friends.

demographic and clinical characteristics for each group are displayed in Table 1. The normal participants were significantly younger than the leiomyomata participants (31.2 versus 37.9 years, $P = .001$), and there was a marginal difference in education level, with leiomyomata patients more likely to have attained a higher educational level ($P = .05$). A significant difference in self-rated symptom severity was also present with patients with leiomyomata more likely to have symptoms than normals ($P = .001$). No differences in comorbid conditions were present between the groups.

Item Reduction

Item reduction was an iterative process based on excluding items with high nonresponse rates, inability to discriminate between normal and uterine leiomyomata participants, low item-total correlations, and low factor loadings. Ten symptom and 25 health-related quality of life items were deleted according to the above criteria, whereas eight symptom and 29 health-related quality of life items were retained. As the symptom frequency and severity (distress) items were highly correlated (individual items $r = 0.70–0.84$, subscale $r = 0.88$, all $P < .001$), the symptom frequency Likert scale was eliminated, whereas the symptom severity scale items were retained because of the clinical importance of symptom severity.

Table 2. Reliability Estimate of UFS-QOL: Internal Consistency

Subscale	Number of items (κ)	Cronbach's alpha (α)
Symptom severity	8	0.86
Concern	5	0.95
Activities	7	0.94
Energy/mood	7	0.92
Control	5	0.93
Self-consciousness	3	0.83
Sexual function	2	0.95
HRQL total	29	0.97

UFS-QOL = uterine fibroid symptom and quality of life; HRQL = health-related quality of life.

Instrument Performance

Exploratory factor analysis revealed a single subscale for symptom severity, and six subscales for health-related quality of life were identified: concern, activities, energy/mood, control, self-consciousness, and sexual function. Factors were retained based on eigen values greater than 1 and factor loadings greater than 0.40. (Factor loadings are the correlations of each variable with each factor, and eigen values indicate the proportion of variance accounted for by each factor.) Internal consistency reliabilities for each subscale are displayed in Table 2. Subscale-to-subscale correlations were high and ranged from $r = 0.45–0.75$.

Concurrent Validity

The UFS-QOL subscales had small-to-moderate correlations with the SF-36 subscales ranging from 0.10 to 0.64. The bodily pain subscale of the SF-36 had the strongest correlation with the activities subscale of the UFS-QOL ($r = 0.64$), whereas the lowest correlations were among the general health perception SF-36 subscale and the UFS-QOL subscales. Moderate correlations between the UFS-QOL subscales and the Menorrhagia Questionnaire scales ($r = 0.44–0.76$) and Revicki-Wu Sexual Function Scale ($r = 0.14–0.78$) were present.

Discriminant Validity

The UFS-QOL was able to discriminate between normal participants and women with leiomyomata (Table 3). Women with leiomyomata experienced significantly higher levels of symptom distress and lower health-related quality of life than normal controls. More importantly, the subscale scores were able to discriminate between both patient and physician symptom severity

Table 3. Discriminant Validity of the UFS-QOL

UFS-QOL subscale*	Normal ($N = 29$)	Uterine leiomyomata ($N = 110$)	P
Symptom severity	22.5 (21.1)	44.0 (25.5)	<.001
Concern	84.0 (23.5)	55.2 (34.6)	<.001
Activities	90.8 (14.7)	67.1 (30.0)	<.001
Energy/mood	83.9 (20.6)	64.1 (26.1)	<.001
Control	93.3 (17.2)	62.3 (31.6)	<.001
Self-consciousness	79.0 (29.0)	57.2 (30.5)	<.001
Sexual function†	80.2 (32.0)	65.0 (34.9)	.04
HRQL total†	86.4 (17.7)	62.6 (25.5)	<.001

Abbreviations as in Table 2.

* High HRQL scores indicate better HRQL, whereas high symptom severity scores indicate increasing symptom severity.

† $N = 104$ because of missing data.

ratings (Figure 1). The patient-rated severity scores were then categorized into three groups (≤4, >4 but ≤8, >8) based on distribution of scores and clinical meaningfulness. The UFS-QOL discriminated between mildly, moderately, and severely symptomatic women, thus indicating sensitivity in the instrument. Similar results were found with the physician ratings of patient symptom severity.

Test-Retest Reliability

Twenty-seven participants completed the retest component of the study. The mean time to second visit was 21.3 days (range 7–33 days). The intraclass coefficients ranged from 0.76 to 0.93 indicating good test-retest reliablity. Paired t tests and Pearson correlation coefficients did not identify any mean value or systematic differences, providing further evidence of the reproducibility of the UFS-QOL.

DISCUSSION

We developed the UFS-QOL from a patient perspective to provide a simple, questionnaire-based tool to assess the symptom status and health-related quality of life impact of leiomyomata. The UFS-QOL, which is presented in Appendix A, was designed as two scales: a symptom severity scale and a health-related quality of life scale. The scales are scored separately (Appendix B) and may be used either separately or together. The rigorous development process of the UFS-QOL in conjunction with its sound psychometric properties make the UFS-QOL a useful tool for those engaging in research in this clinical condition.

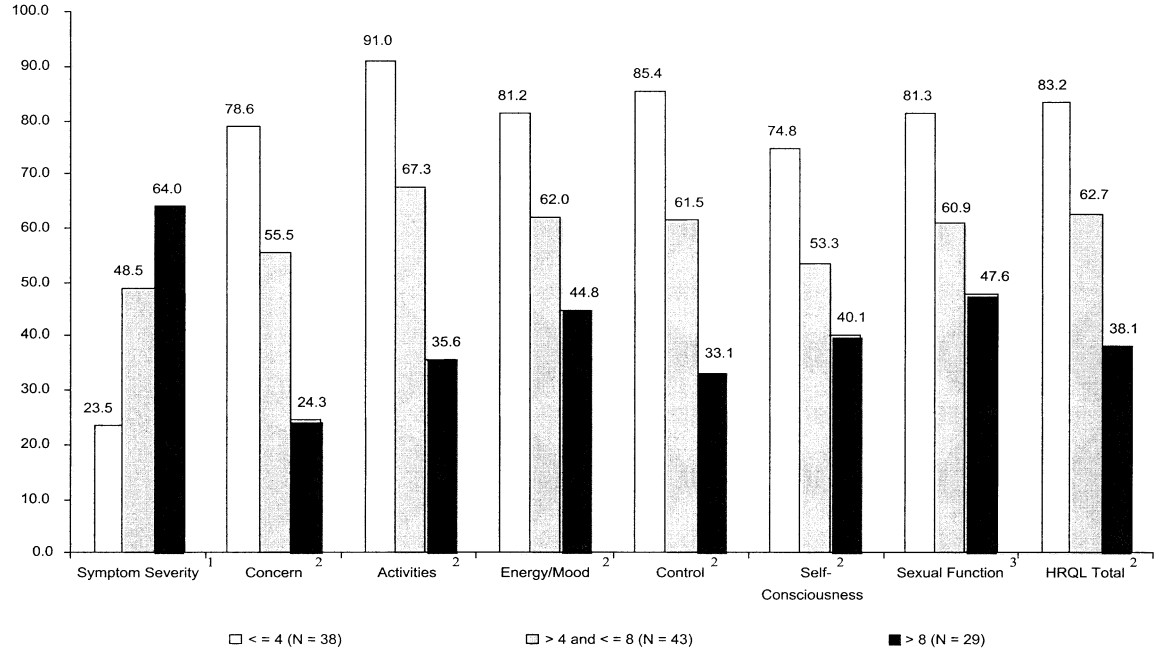

Figure 1. Discriminant validity. Comparison of patient-rated symptom severity and subscale and overall HRQL (health-related quality of life) scores. Symptom severity rated on a scale from 0 to 10 (0 not severe to 10 very severe), grouped into less than 4, greater than 4 and less than 8, and greater than 8. [1] $P < .02$ for all pairwise group comparisons. [2] $P < .0001$ for all pairwise comparisons. [3] $P < .01$ for <4 vs other groups only.

Spies. The UFS-QOL. Obstet Gynecol 2002.

The low-to-moderate correlations with the SF-36 are typical and are anticipated when comparing generic health-related quality of life or health status questionnaires with condition-specific instruments. Such relatively modest correlations confirm the need for this condition-specific questionnaire, as the UFS-QOL appears more sensitive to variation in symptom severity and health-related quality of life than the SF-36. The bodily pain subscale of the SF-36 had the highest correlation to the UFS-QOL activities scale, which strengthens the UFS-QOL's validity as the painful symptoms of leiomyomata would be anticipated to have an impact on activities, whereas the other SF-36 subscales, such as general health perception, would not likely be as affected by the presence of leiomyomata.

The moderate-to-strong correlations between the Menorrhagia Questionnaire and UFS-QOL subscales reflect the assessment of similar constructs and demonstrate the impact of menorrhagia as a symptom of leiomyomata. As expected, the Revicki-Wu Sexual Function Scale correlated highest with the sexual function scale of the UFS-QOL, providing strong evidence of concurrent validity.

The UFS-QOL demonstrated excellent discriminative validity in not only distinguishing normals from leiomyomata patients but among patients with varying self-rated and physician-rated symptom severities. Women with leiomyomata experienced significant decrements in health-related quality of life, particularly when experiencing severe symptoms. Although the subscale score differences were not as pronounced, the subscale scores significantly differed by physician ratings of patient symptom severity. This sensitivity in detecting differences in symptom distress and health-related quality of life impact lends promise for detecting treatment differences in longitudinal studies.

The UFS-QOL subscales of concern and control appear to be the most affected by symptoms followed by the subscale of activities and self-consciousness. The concern subscale focuses on concern regarding soiling garments, the inconvenience of always carrying sanitary protection, and anxiety about the unpredictable onset of menses. For women reporting severe leiomyomata symptoms, this concern was particularly detrimental. This information provides insight into the health-related quality of life impact of leiomyomata, which has been previously undocumented. The control subscale asks questions related to feelings of control over one's health, life, and future uncertainty. This was an area that was discussed frequently in the focus groups; women were quite distressed about their inability to control their symptoms and how the debilitating effects of leiomyomata symptoms could immediately alter all plans for travel, social engagements, or physical activities.

The activities subscale of the UFS-QOL pertains to a variety of activities including travel, exercise, social activities, usual daily activities, and the planning of these activities. The activities subscale had stronger correlations with the physical function, role-physical, bodily pain, and social function subscales of the SF-36 than with the emotional/mental health SF-36 subscales, which further indicates the validity of the activities subscale. During the focus group discussions, activities were affected not only by leiomyomata symptoms but also fatigue. Fatigue, which is captured in the energy/mood subscale, was a chronic complaint of women in the focus groups, particularly during their menses, but also as an underlying condition. The magnitude of the correlations of the energy/mood subscale among all of the SF-36 subscales is fairly equivalent reflecting the fatigue effects on activity and mood effects on mental/emotional health.

Although the severity scale contains items related to the bulk symptoms of leiomyomata, the self-consciousness subscale captures the effects of the bulk symptoms on health-related quality of life as this subscale pertains to appearance related to stomach appearance and bloating. (Stomach was the preferred term over "lower abdomen" in both the focus group and patient interviews.) Dissatisfaction with one's appearance also had an impact on sexual function as some women in the focus groups "did not feel attractive," although most stated that they only avoided sexual relations because of menorrhagia related to their leiomyomata.

Although the sample recruited for this initial psychometric validation was not unusually large, it was sufficiently large to allow *t* test comparisons and correlations to be performed. The sample recruited also experienced a wide range of symptoms and was ethnically diverse – both important characteristics when validating questionnaires. The sample size may have been underpowered to detect differences in baseline characteristics, particularly in living situations; however, this was not thought to impact the outcome of this analysis because of the magnitude of differences between the leiomyomata and control groups. The test-retest sample of 27 patients is adequate to identify differences in scores at different administration times.

The comprehensive evaluation of medical and surgical treatments for uterine leiomyomata requires reliable and valid patient-reported outcome assessments. In the absence of objective clinical markers, patient-reported outcomes represent the most relevant approach to assessing the impact of disease and its treatment. The UFS-QOL is a reliable and reproducible measure with evidence of construct and discriminant validity. Al-

though the responsiveness of the UFS-QOL needs to be assessed within prospective trials of leiomyomata treatments (one of which is currently underway), disease-specific health-related quality of life instruments with good reliability and discriminant validity are also likely to be responsive to clinically meaningful changes in patient outcomes.[16] It was our intent to create a brief, self-administered questionnaire that would have sufficient detail to yield meaningful and usable scores for clinical trials, cohort studies, and other research efforts. Based on the findings of this study, the UFS-QOL appears to meet those goals.

REFERENCES

1. Carlson K, Miller B, Fowler F. The Maine women's health study: I. Outcomes of hysterectomy. Obstet Gynecol 1994;83:556–65.
2. Carlson K, Miller B, Fowler F. The Maine women's health study: II. Outcomes of nonsurgical management of leiomyomas, abnormal bleeding, and chronic pelvic pain. Obstet Gynecol 1994;83:566–72.
3. Dwyer N, Hutton J, Stirrat G. Randomised controlled trial comparing endometrial resection with abdominal hysterectomy for the surgical treatment of menorrhagia. Br J Obstet Gynaecol 1993;100:237–43.
4. Lamping D, Rowe P, Clarke A, Black N, Lessof L. Development and validation of the menorrhagia outcomes questionnaire. Br J Obstet Gynaecol 1998;105:766–79.
5. Ruta D, Garratt Y, Chadha Y, Flott G, GHall M, Russell I. Assessment of patients with menorrhagia: How valid is a structured clinical history as a measure of health status? Quality of Life Res 1995;4:33–40.
6. Spies J, Warren E, Mathias S, Walsh S, Roth A, Pentecost M. Uterine fibroid embolization: Measurement of health-related quality of life before and after therapy. JVIR 1999; 10:1293–303.
7. Streiner D, Norman G. Health measurement scales: A practical guide to their development and use. Oxford: Oxford University Press, 1989.
8. Ware J, Sherbourne C. The MOS 36-item short-form health survey (SF-36), I. Conceptual framework and item selection. Med Care 1992;30:473–83.
9. Ware J. SF-36 health survey manual and interpretation guide. 1st ed. Boston, MA: The Health Institute, 1993.
10. Sherbourne C. Social functioning; sexual problems scale. In: Stewart A, Ware J, eds. Measuring functioning and well-being: The Medical Outcomes Study approach. Durham, NC: Duke University Press, 1992:235–59.
11. Mulaik S. The foundations of factor analysis. New York: McGraw-Hill, 1972.
12. Nunnally J, Berstein I. Psychometric theory. New York: McGraw-Hill, 1994.
13. Hays R, Hayashi T. Beyond internal consistency reliability: Rationale and user's guide for Multitrait analysis program on the microcomputer. Behav Res Meth Instr Comp 1990;22:167–75.
14. Cronbach L. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297–334.
15. Cohen J. Statistical power analysis for the behavorial sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
16. Revicki D, Osoba D, Fairclough D, Barofsky I, Berzon R, Leidy L, et al. Recommendations on health-related quality of life research to support labeling and promotional claims in the United States. Quality of Life Res 2000;9:887–900.

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APPENDIX A

Pt. Initials: _____ **Pt. ID:** _____

Date: _____

UTERINE FIBROID SYMPTOM AND HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE (UFS-QOL)

Listed below are symptoms experienced by women who have uterine fibroids. Please consider each symptom as it relates to your uterine fibroids or menstrual cycle. Each question asks how much distress you have experienced from each symptom during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by checking (✓) the most appropriate box. If a question does not apply to you, please mark "not at all" as a response.

During the previous 3 months, how distressed were you by...	Not at all	A little bit	Some-what	A great deal	A very great deal
1. Heavy bleeding during your menstrual period	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. Passing blood clots during your menstrual period	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. Fluctuation in the duration of your menstrual period compared to your previous cycle	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. Fluctuation in the length of your monthly cycle compared to your previous cycles	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. Feeling tightness or pressure in your pelvic area	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. Frequent urination during the daytime hours	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. Frequent nighttime urination	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. Feeling fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions ask about your feelings and experiences regarding the impact of uterine fibroid symptoms on your life. Please consider each question as it relates to your experiences with uterine fibroids during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by checking (✓) the most appropriate box. If the question does not apply to you, please check "none of the time" as your option.

During the previous 3 months, how often have your symptoms related to uterine fibroids...	None of the time	A little of the time	Some of the time	Most of the time	All of the time
9. Made you feel anxious about the unpredictable onset or duration of your periods?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. Made you anxious about traveling?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. Interfered with your physical activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. Caused you to feel tired or worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
13. Made you decrease the amount of time you spent on exercise or other physical activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Made you feel as if you are not in control of your life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. Made you concerned about soiling underclothes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. Made you feel less productive?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
17. Caused you to feel drowsy or sleepy during the day?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Made you feel self-conscious of weight gain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Made you feel that it was difficult to carry out your usual activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Interfered with your social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Made you feel conscious about the size and appearance of your stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Made you concerned about soiling bed linen?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the previous 3 months, how often have your symptoms related to uterine fibroids...	None of the time	A little of the time	Some of the time	Most of the time	All of the time
23. Made you feel sad, discouraged, or hopeless?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Made you feel down hearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Made you feel wiped out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Caused you to be concerned or worried about your health?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Caused you to plan activities more carefully?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28. Made you feel inconvenienced about always carrying extra pads, tampons, and clothing to avoid accidents?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
29. Caused you embarrassment?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. Made you feel uncertain about your future?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. Made you feel irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. Made you concerned about soiling outer clothes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. Affected the size of clothing you wear during your periods?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34. Made you feel that you are not in control of your health?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35. Made you feel weak as if energy was drained from your body?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36. Diminished your sexual desire?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
37. Caused you to avoid sexual relations?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

APPENDIX B

UFS-QoL Scoring Manual

To calculate a symptom score for symptom severity, create a summed score from the items listed below and then use the formula below the table to transform the value. This will provide symptom scores where higher score values are indicative of greater symptom severity or bother and lower scores will indicate minimal symptom severity (high scores = bad).

Scale	Sum Item Values	Lowest and Highest Possible Raw Scores	Possible Raw Score Range
Symptom Severity	Sum 1 – 8	8, 40	32

Transformation for Symptom Severity raw scores ONLY:

$$\text{Transformed Score} = \frac{(\textit{Actual}\text{ raw score} - \textit{lowest}\text{ possible raw score})}{\textit{Possible raw score range}} \times 100$$

For the HRQL subscales (concern, activities, energy/mood, control, self-conscious, and sexual function), create summed scores of the items listed below for each individual subscale. To calculate the HRQL total score, sum the value of each individual subscale (do not sum individual items). Use the formula below the table to transform all values. Higher scores will be indicative of better HRQL (high = good).

Scale	Sum Item Values	Lowest and Highest Possible Raw Scores	Possible Raw Score Range
Concern	9+15+22+28+32	5, 25	20
Activities	10+11+13+19+20+27+29	7, 35	28
Energy/mood	12+17+23+24+25+31+35	7, 35	28
Control	14+16+26+30+34	5, 25	20
Self-conscious	18+21+33	3, 15	12
Sexual function	36+37	2, 10	8
HRQL TOTAL	Sum of 6 Subscale Scores	29, 145	116

Formula for transformation of HRQL raw scores ONLY:

$$\text{Transformed Score} = \frac{(\textit{Highest}\text{ possible score} - \textit{Actual raw}\text{ score})}{\textit{Possible raw score range}} \times 100$$

Missing Items

For the subscale analyses, if < 50% of the scale items are missing, the scale should be retained with the mean scale score of the items present used to impute a score for the missing items. If ≥ 50% of the items are missing, no scale score should be calculated, the subscale score should be considered missing. If a subscale score is missing, the HRQL total cannot be calculated.