Development of a Fibroid-specific Quality-of-Life Instrument

Despite the prevalence of uterine leiomyomata and the symptoms they cause, until recently, there has been no disease-specific measures available in the public domain that provided a means of assessing symptom status and impact on health-related quality of life of women with symptomatic fibroids.

Previous research on hysterectomy, the most widely studied treatment for leiomyomata, has utilized generic health status questionnaires and found improvements in symptoms and HRQL post surgical intervention (1-3). Lamping developed a menorrhagia outcomes questionnaire (4) to assess hysterectomy outcomes and Ruta 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 non-bleeding 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 HRQL fully assessed.

With this in mind, we undertook a study to develop a fibroid-specific quality of life instrument to meet the needs of the researchers in this field. This project was funded by the Society of Interventional Radiology (SIR) Foundation, the research and education foundation of the SIR. The intent of this effort was to design a questionnaire that would be short, easily administered and easily scored. We hoped to have a 2 part instrument, with separate scores for symptoms and overall quality of life. The questionnaire which resulted from that effort, called the uterine fibroid symptom and quality of life questionnaire (the UFS-QOL) was published in 2002 (6).

The UFS-QOL was developed from focus groups, clinician opinion and a thorough literature review, using standard instrument development techniques. The validation study was conducted in both normal volunteers and women with uterine fibroids. Normal volunteers were recruited from Georgetown University campus and women with uterine leiomyomas were recruited from five Washington, DC-area gynecologists' offices and an interventional radiologist's office to complete the questionnaire packet.

In addition to the UFS-QOL, participants completed several other validated instruments, including (a) the Medical Outcomes Study Short-Form 36 (SF-36) Health Survey, (b) the Ruta Menorrhagia Questionnaire, (c) the Revicki-Wu Sexual Function Scale, and two additional measures of severity: (d) a physician-rated severity scale (1-10), and (e) subject self-rated symptom severity (0-10), with 0 being not severe and 10 being very severe symptoms experienced.

A total of 110 women with uterine leiomyomata and 29 normal volunteers were recruited into the validation study. African-American women made up 63% of the patients with fibroids and 76% of the normal population. Internal consistency was high, with Cronbach's alpha levels of 0.83-0.97 for individual subscales.

The UFS-QOL was able to discriminate between normal participants and women with leiomyomata (Table 1). Women with leiomyomata experienced significantly higher levels of symptom distress and lower health-related quality of life than normal controls. In addition, the subscale scores were able to discriminate between both patient-reported and physician-reported symptom severity ratings. The patient-rated severity scores were then categorized into 3 groups (<or = 4, >4 but < 8, = or > 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 was also good, with intraclass correlation coefficients of 0.76-0.93.

Table 1: Discriminant Validity of UFS-QOL

	Subscale Score Mean (Standard Deviation)		
UFS-QOL Subscale	**Normal (N=29)**	**Fibroids (N=110)**	**P**
Symptom severity	22.5(21.1)	44.0(22.5)	<0.001
Concern	84.0(23.5)	55.2(34.6)	<0.001
Activities	90.8(14.7)	67.1(30.0)	<0.001
Energy / mood	83.9(20.6)	64.1(26.1)	<0.001
Control	93.3(17.2)	62.3(31.6)	<0.001
Self-consciousness	79.0(29.0)	57.2(30.5)	<0.001
Sexual function	80.2(32.0)	65.0(34.9)	0.04
HRQOL	86.4(17.7)	62.6(25.5)	<0.001

The UFS-QOL demonstrated excellent discriminative validity in distinguishing not only normals from leiomyomata patients but also 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 (F). 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 final UFS-QOL was comprised of 37 questions, 8 symptom questions and 29 quality of life questions. There are 6 quality of life subscales, listed in Table 1. These are summarized to yield an HRQOL Total score. Both the symptom score and the quality of life score are on scales from 0 to 100, but inversely. A lower score for symptoms (fewer symptoms) indicates a better score, while a higher score for quality of life is indicates a better quality of life.

The UFS-QOL is a reliable and reproducible measure with evidence of construct and discriminant validity. The UFS-QOL has been translated into six languages (Spanish, French, Canadian French, Hebrew, German, and UK English), with equivalent psychometric properties to the original. The instrument is currently being used in several prospective cohort studies, including the FIBROID Registry and several industry-sponsored trials, under licensing agreements with the SIR Foundation.

References:

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