UROGYNECOLOGY

Utility preference score measurement in women with fecal incontinence

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OBJECTIVE: The objective of the study was to evaluate the construct validity of 3 multiattribute health status classification system instruments, and a visual analog scale (VAS) for measuring utility scores for women with fecal incontinence (FI).

STUDY DESIGN: Utility scores were measured in 200 women with 1 or more of the following diagnoses: fecal or urinary incontinence or pelvic organ prolapse. Pelvic floor symptom severity was measured using the Pelvic Floor Distress Inventory (PFDI-20), and quality of life was assessed with the Pelvic Floor Impact Questionnaire (PFIQ-7). Construct and concurrent validity were evaluated.

RESULTS: After adjusting for age, comorbidities, urinary incontinence, and prolapse, utility scores were significantly lower for women with FI than women without FI for all health status instruments but not the VAS. All health status instruments had significant correlations with PFDI-20 and PFIQ-7 scores.

CONCLUSION: The health status instruments provide valid utility scores in women with FI and would be useful in clinical trials and cost-effectiveness research.

Key words: fecal incontinence, health-related quality of life, multiattribute health status classification system, pelvic floor disorders, utility score

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Fecal incontinence, defined as the involuntary loss of solid or liquid feces or mucus, is associated with significant adverse effect on quality of life.[1-3] The reported prevalence of fecal incontinence ranges from 7% in community-dwelling US women[4] to as high as 47% in the institutionalized elderly.[5] Fecal incontinence is common in women with pelvic floor disorders and affects approximately 20% of women presenting with urinary incontinence.[6]

A utility score is a measure of patient preference for a given health state, a standardized generic health-related quality of life (HRQOL) measure that summarizes morbidity on a scale from 0 (death) to 1 (optimum health). Utility scores are used to quantify the severity of a patient's condition and burden of illness and allow comparison across a wide range of disease states, populations and treatment modalities. Utility preference scores are required to calculate quality-adjusted life years, a unit of measure in quantifying the benefits of an intervention, and are key elements in cost-effectiveness research.

Several condition-specific instruments to measure quality of life in women with fecal incontinence exist such as the Fecal Incontinence Severity Index,[7] the Manchester Index,[8] the Pelvic Floor Distress Inventory,[9,10] and the Pelvic Floor Impact Questionnaire.[9,10] However, these instruments do not allow calculation of utility scores or comparison across different disease states.

Several general scales have been developed to measure utility scores for a wide variety of disease conditions and populations. These include the single-item generic visual analog scales (VAS)[11] and the widely used multiitem, multiattribute health status classification system instruments, Health Utilities Index Mark 3[12] (HUI-3), EuroQol[13] (EQ-5D), and Short Form 6D[14] (SF-6D). In women with urinary incontinence, the HUI-3[15] and EQ-5D[16,17] have been used to measure utility scores. The EQ-5D and VAS have been previously used in adults with fecal incontinence[18,19]; however the validity of scores on these instruments for measuring utilities in women with fecal incontinence has not been established. Also, the impact of fecal incontinence with concomitant urinary incontinence and pelvic organ prolapse needs to be explored given the common coexistence of these disorders.

The aim of the present study was to evaluate the construct validity of 3 multiattribute health status classification system instruments and the visual analog scale for measuring utility preference scores for women with fecal incontinence within a population of women with pelvic floor disorders.

Materials and Methods

This is a prospective observational study of 200 consecutive new women present-

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ing to the University of Pennsylvania urogynecology practice in the 12 month period between March 2008 and February 2009 with symptoms of pelvic organ prolapse, urinary incontinence, or fecal incontinence. Institutional review board approval was obtained from the University of Pennsylvania.

All women presenting for new visits were evaluated for eligibility. Women with urinary incontinence, fecal incontinence, or pelvic organ prolapse stage 2 or greater were invited to participate in the study. Additional inclusion criteria included ability to give consent and complete questionnaires in English. Exclusion criteria included age younger than 18 years, pregnancy, chronic pain conditions, neurologic diseases, current or recurrent urinary tract infections, and pelvic surgery within the last 6 months.

After obtaining written informed consent, all women were asked to complete the following: (1) 4 general HRQOL questionnaires: the 3 multiattribute health status classification system instruments as well as a VAS and (2) 2 condition-specific symptoms and HRQOL questionnaires, the Pelvic Floor Distress Inventory short form (PFDI-20) and the Pelvic Floor Impact Questionnaire short form (PFIQ-7) (details given below). Elements of their physical examination and medical history were obtained from the medical chart. Prolapse was staged using the pelvic organ prolapse quantification system.[20]

Three common multiattribute health status classification system instruments were used to estimate utility preference scores: HUI-3 (Health Utilities Inc, http://www.healthutilities.com), EQ-5D (EuroQol Group, http://www.euroqol.org), and SF-6D (QualityMetric Inc, http://www.qualitymetric.com).

The HUI-3 classifies health status across 8 attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) with 5-6 levels each for a possible 972,000 unique health states. The EQ-5D has 5 attributes (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with 3 levels each for a possible 243 unique health states. The SF-6D is derived from 8 items of the Short Form 12 (SF-12) and has 6 attributes (physical functioning, role limitation, social functioning, pain, mental health, and vitality) with 5-6 levels each for a possible 7500 unique health states.

Women also completed a 100 point vertically oriented VAS with anchors of best imaginable health state and worst imaginable health state. VAS scores were divided by 100 prior to analysis to make them comparable with the utility score 0-1 scale. Higher scores on the health status instruments and VAS indicate better quality of life.

All women also completed the short form of the PFDI-20, a validated, condition-specific questionnaire with 3 subscales, designed to evaluate distress caused by specific pelvic floor symptoms including bowel, urinary, and pelvic organ prolapse complaints. Items on the PFDI first ask whether each symptom is experienced or not (yes or no response) and if yes, the degree of bother is assessed on a scale from 1 (not at all) to 4 (quite a bit).[9,10] Pelvic floor–related quality of life was measured by the PFIQ-7, a validated condition-specific HRQOL questionnaire also with bladder, bowel, and pelvic organ prolapse subscales. Items on the PFIQ assess the impact of symptoms on ability to do household chores, physical activities, entertainment activities, travel, social activities, emotional health, and feeling frustrated on a scale from 0 (not at all) to 3 (quite a bit).[9,10] Scores on the PFDI and PFIQ range from 0-300, with higher scores indicating worse symptoms and worse quality of life.

The diagnosis of urinary incontinence was based on the Questionnaire for Urinary Incontinence Diagnosis, a questionnaire validated for the diagnosis of urinary incontinence.[21] Comorbid medical conditions were measured by the Charlson Comorbidity Index.[22]

All questionnaires were self-administered on the same day during the baseline evaluation. The order of questionnaire administration was varied to minimize order effect.

Fecal incontinence was defined as leakage of solid or liquid stool with at least somewhat of a bother on the PFDI. Incontinence of flatus was not included in this definition and was measured separately.

Demographic data are presented as percentages, medians, or means ± SD. Categorical data were compared between women with and without fecal incontinence using Pearson χ^2 and Fisher's exact tests as appropriate. Continuous variables were compared between the 2 groups using parametric and nonparametric Student *t* tests as appropriate.

For the generic and condition-specific instruments, groups were first compared with nonparametric Student *t* tests. Then linear regression was used to adjust for confounding risk factors such as age, comorbidities, presence of coexistent pelvic organ prolapse, and urinary incontinence. Spearman correlations were used to assess relationships among instrument scores. Observed significant correlations below 0.3 were considered low, between 0.3 and 0.5 moderate, and 0.5 or above high.[23]

For construct validity, we first compared the utility scores as measured by the health status instruments and VAS between women with and without fecal incontinence. Next, utility scores were correlated to total and bowel, bladder, and pelvic organ prolapse subscale scores on condition-specific symptom severity and quality-of-life instruments (PFDI and PFIQ). Known group differences were explored by evaluating the effect of fecal incontinence with or without concomitant urinary incontinence and pelvic organ prolapse. We measured the association of utility scores with the severity of specific bowel symptoms on individual items of the PFDI, and we measured the association of utility scores with the impact of bowel symptoms on HRQOL on individual items of the PFIQ.

For discriminant validity, we examined the relationship of individual subscales of the utility instruments expected to be related to the severity of fecal incontinence (eg, anxiety, depression, and pain) and also the relationship of individual subscales of the utility instruments not expected to be related to the severity of fecal incontinence (eg, speech and hearing).

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