GYNECOLOGY

Validity of utility measures for women with pelvic organ prolapse

Heidi S. Harvie, MD, MSCE, MBA; Daniel D. Lee, MD; Uduak U. Andy, MD; Judy A. Shea, PhD; Lily A. Arya, MD, MS

BACKGROUND: Pelvic organ prolapse is a common condition that frequently coexists with urinary and fecal incontinence. The impact of prolapse on quality of life is typically measured through condition-specific quality-of-life instruments. Utility preference scores are a standardized generic health-related quality-of-life measure that summarizes morbidity on a scale from 0 (death) to 1 (optimum health). Utility preference scores quantify disease severity and burden and are widely used in cost-effectiveness research. The validity of utility preference instruments in women with pelvic organ prolapse has not been established.

OBJECTIVE: The objective of this study was to evaluate the construct validity of generic quality-of-life instruments for measuring utility scores in women with pelvic organ prolapse. Our hypothesis was that women with multiple pelvic floor disorders would have worse (lower) utility scores than women with pelvic organ prolapse only and that women with all 3 pelvic floor disorders would have the worst (lowest) utility scores.

STUDY DESIGN: This was a prospective observational study of 286 women with pelvic floor disorders from a referral female pelvic medicine and reconstructive surgery practice. All women completed the following general health-related quality-of-life questionnaires: Health Utilities Index Mark 3, EuroQol, and Short Form 6D, as well as a visual analog scale. Pelvic floor symptom severity and condition-specific quality of life were measured using the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire, respectively. We measured the relationship between utility scores and condition-specific quality-of-life scores and compared utility scores among 4 groups of women: (1) pelvic organ prolapse only, (2) pelvic organ prolapse and stress urinary incontinence, (3) pelvic organ prolapse and urgency urinary incontinence, and (4) pelvic organ prolapse, urinary incontinence, and fecal incontinence.

RESULTS: Of 286 women enrolled, 191 (67%) had pelvic organ prolapse; mean age was 59 years and 73% were Caucasian. Among women with prolapse, 30 (16%) also had stress urinary incontinence, 39 (20%) had urgency urinary incontinence, and 42 (22%) had fecal incontinence. For the Health Utilities Index Mark 3, EuroQol, and Short Form 6D, the pattern in utility scores was noted to be lowest (worst) in the prolapse + urinary incontinence + fecal incontinence group (0.73-0.76), followed by the prolapse + urgency urinary incontinence group (0.77-0.85) and utility scores were the highest (best) for the prolapse only group (0.80-0.86). Utility scores from all generic instruments except the visual analog scale were significantly correlated with the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire total scores (r values −0.26 to −0.57), and prolapse, bladder, and bowel subscales (r values −0.16 to −0.50). Utility scores from all instruments except the visual analog scale were highly correlated with each other ($r = 0.53$-0.69, $P < .0001$).

CONCLUSION: The Health Utilities Index Mark 3, EuroQol, and Short Form 6D, but not the visual analog scale, provide valid measurements for utility scores in women with pelvic organ prolapse and associated pelvic floor disorders and could potentially be used for cost-effectiveness research.

Key words: EuroQol, fecal incontinence, health-related quality of life, Health Utilities Index Mark 3, pelvic floor disorders, pelvic organ prolapse, Short Form 6D, urinary incontinence, utility score

Introduction

Pelvic organ prolapse (POP) is a prevalent condition,[1] although its impact on women's quality of life markedly varies.[2] While approximately 200,000 operations for POP are performed annually,[3] >50% of women seen for routine gynecologic care have asymptomatic POP.[4] Many women with POP also experience comorbid pelvic floor conditions such as urinary and/or fecal incontinence.[5,6] Women who present with multiple pelvic floor disorders report lower quality of life as compared to women with isolated POP.[7,8]

Understanding the impact of POP and associated comorbid pelvic floor disorders on quality of life is important both clinically and for cost-effectiveness research. Utility preference scores are metrics that quantify disease severity, burden, and the impact of treatment and can be applied to women with pelvic floor disorders.[9] These scores are a standardized generic health-related quality of life (HRQOL) measure that summarizes morbidity on a scale from 0 (death) to 1 (optimum health). Utility preference scores allow comparison across a wide range of disease states, populations, and treatment modalities and serve as an integral component to the quality-adjusted life-years measure, commonly utilized when quantifying the benefits of a medical intervention and used as a basis of cost-utility analysis, the most common type of health economic evaluation.[10] Validating utility scores in women with POP and other pelvic floor disorders will also allow researchers and health care planners to measure HRQOL, assess the effect of treatment, perform health economic evaluation, and compare the cost-effectiveness of pelvic floor disorders to that of other conditions.

Several condition-specific instruments exist to measure quality of life in women with pelvic floor disorders including the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ).[11,12] However, these condition-specific instruments do not allow calculation of utility scores or comparison of the

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benefit of treatment across other disease states such as heart disease or stroke. Several general scales have been developed to measure utility preference scores for a wide variety of disease conditions and populations. These include the single-item generic visual analog scales (VAS) and the widely used multiitem multiattribute health-status classification system instruments: Health Utilities Index Mark (HUI)-3, EuroQol 5 dimensions (EQ-5D), and Short Form (SF)-6D.[13-15] For the HUI-3, EQ-5D, and SF-6D, population norm data are available and widespread use facilitates the interpretation of results and comparison of disease and treatment outcomes at the local, national, and international levels. Although the HUI-3, EQ-5D, and SF-6D have been validated and used in women with urinary incontinence and fecal incontinence,[16-21] the validity of these instruments for measuring utilities in women with POP has not been established. In addition, multiple pelvic floor disorders frequently coexist. The effect of coexisting pelvic floor disorders on utility preference scores is also not known.

The aim of this study is to evaluate the construct validity of the HUI-3, EQ-5D, SF-6D, and VAS for measuring utility preference scores in women with POP within a population of women with pelvic floor disorders and to explore the effect of coexisting pelvic floor disorders. Our hypothesis was that worsening stage of prolapse will be associated with worse utility scores. Additionally, women with multiple coexisting pelvic floor disorders (POP, urinary incontinence, and/or fecal incontinence) will have worse utility scores than women with only POP and that women with all 3 pelvic floor disorders will have the worst utility scores.

Materials and Methods

This is a prospective observational study of 286 consecutive new women presenting to the University of Pennsylvania urogynecology practice in the 24-month period from March 2008 through December 2010 with the chief symptom of urinary incontinence or POP. Institutional review board approval was obtained from the University of Pennsylvania.

All women presenting for new visits were evaluated for eligibility. Women with POP stage $\geq$2 were invited to participate in the study. Additional inclusion criteria included ability to give consent and complete questionnaires in English. Exclusion criteria included age $<$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 general HRQOL questionnaires: HUI-3, EQ-5D, and SF-6D, and the VAS. They also completed 2 condition-specific symptom and HRQOL questionnaires: the PFDI short form (PFDI-20) and the PFIQ short form (PFIQ-7) along with the Questionnaire for Urinary Incontinence Diagnosis, a questionnaire validated for the diagnosis of urinary incontinence (details given below). Elements of their physical exam and medical history were obtained from the medical chart. Prolapse was staged using the POP quantification system.[22]

Three common preference-based 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 is scored on a 0-1.00 scale and 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 is scored on a $-$0.59 to 1.00 scale and 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 SF-12, is scored on a 0.29-1.00 scale 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 comparable to the utility score 0-1 scale. Higher scores on the health-status instruments and VAS indicate better quality of life.

Condition-specific symptom and HRQOL questionnaires were used to assess the impact of POP and urinary and fecal incontinence. Symptoms were assessed by 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 POP symptoms. Items on the PFDI first ask whether each symptom is experienced (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).[11,12] Pelvic floor—related quality of life was measured by the PFIQ-7, a validated condition-specific HRQOL questionnaire also with bladder, bowel, and POP 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).[11,12] Scores on the PFDI Q2 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.[23] Comorbid medical conditions were measured by the Charlson Comorbidity Index.[24] All questionnaires were self-administered on the same day during Q3 the baseline evaluation. Order of questionnaire administration was varied each day to minimize order effect.

POP was defined as stage $\geq$2 based on the POP quantification system.[22] Based on the validated Questionnaire for Urinary Incontinence Diagnosis, 3 groups of urinary incontinence were defined: predominant urgency urinary incontinence (urge score $\geq$6 and urge score $>$ stress score), predominant stress urinary incontinence (stress score $\geq$4 and stress

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