

## UROGYNECOLOGY

# Validity of utility measures for women with urge, stress, and mixed urinary incontinence

Heidi S. Harvie, MD, MSCE, MBA; Judy A. Shea, PhD; Uduak U. Andy, MD; Kate Probert, PhD; J. Sanford Schwartz, MD; Lily A. Arya, MD, MS

**OBJECTIVE:** We sought to evaluate the construct validity of 3 health status classification system instruments—Health Utilities Index Mark 3 (HUI-3), EuroQol (EQ-5D), and Short Form 6D (SF-6D)—and a visual analog scale (VAS) for measuring utility scores in women with urge, stress, and mixed urinary incontinence.

**STUDY DESIGN:** Utility scores were measured in 202 women with urinary incontinence. Pelvic floor symptom severity and quality of life were measured using the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire, respectively. Construct, discriminant, and concurrent validity were evaluated.

**RESULTS:** Significant correlations were noted between utility scores and the Pelvic Floor Distress Inventory ( $r = -0.22$  to  $-0.42$ ,  $P < .05$ ) and the Pelvic Floor Impact Questionnaire ( $r = -0.32$  to  $-0.50$ ,  $P < .05$ ). Mean utility scores were significantly lower for women with urge or mixed incontinence compared to

stress incontinence for the EQ-5D ( $0.71 \pm 0.23$ ,  $0.73 \pm 0.26$ , and  $0.81 \pm 0.16$ , respectively,  $P = .02$ ) and the SF-6D ( $0.76 \pm 0.12$ ,  $0.74 \pm 0.12$ , and  $0.81 \pm 0.11$ , respectively,  $P = .02$ ) but not the HUI-3 or the VAS. There was a clinically important difference in utility scores ( $>0.03$ ) between women with urge or mixed incontinence as compared to stress incontinence for the HUI-3, EQ-5D, and SF-6D but not the VAS. Utility preference scores were significantly lower for women with combined urinary and fecal incontinence ( $0.69$ - $0.73$ ) than urinary incontinence alone ( $0.77$ - $0.84$ ,  $P < .01$ ).

**CONCLUSION:** The HUI-3, EQ-5D, and SF-6D, but not the VAS, provide valid measurements for utility scores in women with stress, urge, and mixed urinary incontinence.

**Key words:** EuroQol, health-related quality of life, Health Utilities Index Mark 3, Short Form 6D, urinary incontinence, utility score

Cite this article as: Harvie HS, Shea JA, Andy UU, et al. Validity of utility measures for women with urge, stress, and mixed urinary incontinence. *Am J Obstet Gynecol* 2014;210:85.e1-6.

Urinary incontinence is a common and costly condition. Over 10 million women in the United States suffer from urinary incontinence.<sup>1</sup> Urinary incontinence severely affects health-related

quality of life (HRQOL) and contributes to social isolation, depression, decreased activity, falls, fractures, and nursing home admission.<sup>1-7</sup> The direct medical cost of urinary incontinence in the United States has been estimated at  $>\$16$  billion each year.<sup>1</sup>

Utility preference scores are key elements in cost-effectiveness research. A utility preference score (or utility score) is a measure of patient preference for a given health state, a standardized generic HRQOL measure that summarizes morbidity on a scale from 0 (death) to 1 (optimum health).<sup>8</sup> 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 scores are also combined with life expectancy estimates to calculate quality adjusted life-years, a unit of measure for quantifying the benefits of an intervention.

Several condition-specific instruments to measure quality of life in women with

urinary incontinence exist such as the Pelvic Floor Distress Inventory (PFDI)<sup>9,10</sup> and the Pelvic Floor Impact Questionnaire (PFIQ).<sup>9,10</sup> 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)<sup>10</sup> and the widely used multiitem multiattribute health status classification system instruments, Health Utilities Index Mark 3 (HUI-3)<sup>11</sup> (<http://www.healthutilities.com>); Health Utilities Inc, Hamilton, Ontario, Canada), EuroQol (EQ-5D)<sup>12</sup> (<http://www.euroqol.org>); EuroQol Group, Rotterdam, the Netherlands), and Short Form 6D (SF-6D)<sup>13</sup> (<http://www.qualitymetric.com>); QualityMetric Inc, Lincoln, RI). For the HUI-3, EQ-5D, and SF-6D, population norm data are available and widespread use facilitates the interpretation of results and permits comparisons of disease and

From the Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics and Gynecology (Drs Harvie, Andy, and Arya); Department of Medicine (Drs Shea and Schwartz); and Department of Biostatistics and Epidemiology, Center for Clinical Epidemiology and Biostatistics (Dr Probert), University of Pennsylvania School of Medicine, Philadelphia, PA.

Received July 8, 2013; revised Aug. 28, 2013; accepted Sept. 16, 2013.

Financial support for this project was provided by the Leonard Davis Institute of Health Economics and the International Urogynecological Association.

The authors report no conflict of interest.

Reprints not available from the authors.

0002-9378/\$36.00

© 2014 Mosby, Inc. All rights reserved.

<http://dx.doi.org/10.1016/j.ajog.2013.09.025>

treatment outcomes at the local, national, and international levels. Although the HUI-3,<sup>14,15</sup> EQ-5D,<sup>16,17</sup> and SF-6D<sup>15</sup> have been used in women with urinary incontinence, the validity of scores on these instruments for measuring utilities in women with urinary incontinence has not been established. For example, a 2013 review of the psychometric performance of EQ-5D in urinary incontinence stated that the EQ-5D generally performed well on tests of construct validity, however, studies specifically designed to assess the psychometric properties of the EQ-5D are lacking.<sup>18</sup> Additionally, the difference in utility scores for women with stress or urge or mixed urinary incontinence is not known.

The aim of the present study is to evaluate the construct validity of 3 multiattribute health status classification system instruments and the VAS for measuring utility preference scores in women with urge, stress, and mixed urinary incontinence within a population of women with pelvic floor disorders.

## 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 chief complaint of urinary incontinence or pelvic organ prolapse. 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 or pelvic organ prolapse 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: (1) 4 general HRQOL questionnaires: the 3 multiattribute health status classification system instruments as well as a VAS; and (2) 2 condition-specific symptom and HRQOL questionnaires:

the PFDI short form (PFDI-20) and the PFIQ 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.<sup>19</sup>

Three common preference-based multiattribute health status classification system instruments were used to estimate utility preference scores: HUI-3, EQ-5D, and SF-6D. 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, 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.

All women also completed 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-20 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).<sup>9,10</sup> 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-7 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).<sup>9,10</sup> Scores on the PFDI-20 and PFIQ-7 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.<sup>20</sup> Comorbid medical conditions were measured by the Charlson Comorbidity Index.<sup>21</sup> All questionnaires were self-administered on the same day during the baseline evaluation. Order of questionnaire administration was varied each day to minimize order effect.

Based on the validated Questionnaire for Urinary Incontinence Diagnosis, women were divided into 3 groups: predominant urge incontinence (urge score  $\geq 6$  and stress score  $< 4$ ), predominant stress incontinence (urge score  $< 6$  and stress score  $\geq 4$ ), and mixed incontinence (urge score  $\geq 6$  and stress score  $\geq 4$ ). Fecal incontinence was defined as leakage of solid or liquid stool with at least "somewhat" bother on the PFDI-20.

For construct validity, we compared the utility scores among women with urge incontinence, stress incontinence, and mixed incontinence. Our hypothesis was that women with mixed incontinence would have worse (lower) utility scores than women with urge or stress incontinence and women with urge incontinence would have worse (lower) utility scores than women with stress incontinence, similar to the relationship of clinical symptoms and the impact on quality of life previously reported in other studies.<sup>22-24</sup> Utility scores between groups were compared using Kruskal-Wallis test and linear regression was used to adjust for confounding risk factors such as age, comorbidities, presence of coexistent pelvic organ prolapse, and fecal incontinence. For discriminant validity, we examined the relationship of individual subscales of the utility instruments expected to be related to the severity of urinary incontinence (eg, depression, mobility) and also the relationship of individual subscales of the utility instruments not expected to be related to the severity of urinary

Download English Version:

<https://daneshyari.com/en/article/3433539>

Download Persian Version:

<https://daneshyari.com/article/3433539>

[Daneshyari.com](https://daneshyari.com)