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UTILITY PREFERENCE SCORES FOR URGE AND STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Our hypothesis is that utility scores are valid measures of health related quality of life (HRQOL) for women with urinary incontinence. A 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). 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. The aim of this study is to evaluate the construct validity of three multi-attribute health-status classification system instruments, Health Utilities Index Mark 3 (HUI-3), EuroQol (EQ-5D), and Short Form 6D (SF-6D) and a visual analogue scale (VAS) for measuring utility preference scores for women with urinary incontinence within a population of women with pelvic floor disorders.

Study design, materials and methods

This is a prospective observational study of 260 consecutive new women presenting to a urogynecology practice with symptoms of pelvic organ prolapse or urinary incontinence. Institutional Review Board approval and subject written informed consent were obtained. Utility scores were measured with three health-status classification system instruments (HUI-3, EQ-5D, SF-6D) and a VAS. Pelvic floor symptom severity was measured using the Pelvic Floor Distress Inventory (PFDI-20) and the Incontinence Severity Index (ISI); condition-specific quality of life was assessed with the Pelvic Floor Impact Questionnaire (PFIQ-7). Based on the validated Questionnaire for Urinary Incontinence Diagnosis, women were divided into 3 groups: urge-predominant, stress-predominant and the no incontinence group. Comorbid medical conditions were measured by the Charlson Comorbidity Index. Prolapse was staged using the pelvic organ prolapse quantification system. Categorical data were compared using Pearson Chi-square. Continuous variables were compared between the groups using ANOVA and parametric and non-parametric t-tests as appropriate. For the utility instruments, groups were first compared with ANOVA and non-parametric t-tests. Then linear regression was used to adjust for confounding risk factors such as age, co-morbidities and presence of co-existent pelvic organ prolapse. Spearman correlations were used to assess relationships among instrument scores. For sample size, literature suggests 5-10 patients per item for within instrument analysis. This results in a sample size of 60-120 based on the longest utility instrument. All reported p-values were two-sided and p-values < 0.05 were considered statistically significant. All statistical analysis was done using Stata version 10.0 (StatCorp, College Station, TX).

Results

Of the 260 women enrolled in this study, 187 (72%) had urinary incontinence while 73 (28%) did not. Among women with urinary incontinence, 77 (41%) had stress or stress-predominant incontinence (SUI) and 85 (46%) had urge or urge-predominant incontinence (UUI). Mean age, BMI, and comorbidity index were 56.2 ± 13.5 years, 28.3 ± 6.7 kg/m2, and 0.27 ± 0.64, respectively. Median parity was 2 (range 0-9). Race was 75% white, 20% black, and 5% other. There were no differences in these demographic factors between the three groups. The rate of stage ≥2 pelvic organ prolapse was lower in the SUI group compared to the UUI group (49% vs 71%, p=0.006), and the no incontinence group had a higher rate of prolapse than either of the incontinence groups (85%, p <0.0001). Mean utility preference scores for women with UUI, SUI and no incontinence are summarized in table 1. The pattern of increasing (better) utility scores from UUI < SUI< no incontinence persisted for all the health-status classification system instruments, but not the VAS.

Table 1: Mean utility preference scores

	UUI	**SUI**	**p-value[a]**	**No Incontinence**	**p-value [b]**
	N=77	N=85		N=73	
HUI-3	0.77 ± 0.24	0.84 ± 0.19	**0.041**	0.86 ± 0.17	**0.025**
EQ-5D	0.71 ± 0.26	0.78 ± 0.19	0.066	0.80 ± 0.17	**0.031**
SF-6D	0.74 ± 0.12	0.79 ± 0.12	**0.046**	0.80 ± 0.13	**0.047**
VAS[c]	0.80 ± 0.14	0.78 ± 0.18	0.819	0.83 ± 0.17	0.240

UUI = urge and urge-predominant incontinence
SUI = stress and stress-predominant incontinence
[a] Non-parametric t-test comparing UUI and SUI groups
[b] ANOVA comparing UUI, SUI and No Incontinence groups
[c] VAS scores were divided by 100 to enhance comparability

Women with UUI had lower (worse) utility scores than women with SUI with the HUI-3 and SF-6D and this remained significant after adjusting for age, comorbidity index, and pelvic organ prolapse. Women with UUI had lower (worse) utility scores than women with no incontinence for the three health-status classification system instruments but not the VAS. This remained significant for the HUI-3 and SF-6D after adjusting for age, comorbidity index, and pelvic organ prolapse. The difference between utility scores for women with SUI and those with no incontinence did not reach significance.

Measurement of construct validity showed that utility scores from all four instruments were significantly correlated with the PFDI and PFIQ and their bladder subscales. All correlations were negative (r-values -0.20 to -0.44), indicating that worsening utility scores correlated with worse symptom severity and HRQOL scores as measured by condition-specific instruments. Correlations were lowest for the VAS. Utility scores were correlated with measures of incontinence severity: individual items on the PFDI pertaining to stress and urge incontinence symptoms and the ISI. All utility scores were significantly correlated with the PFDI stress incontinence item (r-values -0.16 to -0.18). However, for the PFDI urge incontinence item, only the health-

status classification system instruments were significantly correlated (r-values -0.16 to -0.30); this relationship was not seen with the VAS. For the ISI, only the HUI-3 was significantly correlated (r-value -0.17, p=0.009). Measurement of concurrent validity showed that utility scores from all instruments were highly correlated with each other (r = 0.42 to 0.69, p <0.0001); correlation was lowest with the VAS.

Interpretation of results

Utility scores as measured by generic HRQOL instruments are widely used to compare the effect of different disease states on overall functional status and quality of life. However, it is unknown if generic questionnaires with non-specific items and scoring functions applicable to widely varying health states and populations have adequate sensitivity in urinary incontinence. This study demonstrates that utility preference scores are valid quantitative measures of the negative impact of urinary incontinence on general HRQOL. Utility scores also correlate with condition-specific measures of incontinence severity and HRQOL. All three health-status instruments, HUI-3, EQ-5D and SF-6D, were able to discriminate between the UUI and no incontinence groups and the HUI-3 and SF-6D were able to discriminate between UUI and SUI. The VAS provides poor discrimination for women with urinary incontinence.

Concluding message

The multi-attribute health-status classification system instruments provide valid utility preference scores in women with urinary incontinence and would be useful in clinical trials and cost-effectiveness research. The HUI-3 and SF-6D appear to be the most useful generic instruments for measuring utility scores in women with urinary incontinence.

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