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Angela Marinilli Pinto
CUNY Bernard M Baruch College

Miriam Kupperman
University of California, San Francisco

Sanae Nakagawa
University of California, San Francisco

Eric Vittinghoff
University of California, San Francisco

Rena R. Wing
Brown Medical School, Providence RI

See next page for additional authors

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Comparison and correlates of three preference-based health-related quality-of-life measures among overweight and obese women with urinary incontinence

Angela Marinilli Pinto,
Department of Psychology, Baruch College, CUNY, 55 Lexington Avenue, B8-215, New York, NY 10010, USA

Miriam Kuppermann,
Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco (UCSF), San Francisco, CA, USA; Department of Epidemiology & Biostatistics, UCSF, San Francisco, CA, USA

Sanae Nakagawa,
Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco (UCSF), San Francisco, CA, USA

Eric Vittinghoff,
Department of Epidemiology & Biostatistics, UCSF, San Francisco, CA, USA

Rena R. Wing,
Department of Psychiatry and Human Behavior, Brown Medical School, Providence, RI, USA

John W. Kusek,
National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, USA

William H. Herman, and
Department of Internal Medicine and Epidemiology, University of Michigan, Ann Arbor, MI, USA

Leslee L. Subak
Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco (UCSF), San Francisco, CA, USA; Department of Epidemiology & Biostatistics, UCSF, San Francisco, CA, USA; Department of Urology, UCSF, San Francisco, CA, USA

Abstract

Purpose—To compare three preference-based health-related quality-of-life (HRQL) measures and examine independent correlates of HRQL among overweight and obese women with urinary incontinence (UI) enrolled in a weight loss intervention trial.

Methods—Participants completed baseline questionnaires, which included the Health Utilities Index 3 (HUI3) and Medical Outcomes Study Short Form-36 (SF-36). The SF-36 was used to derive SF-6D and estimated Quality of Well-Being (eQWB) scores. Height, weight, medical history, incontinence measures, and level of physical activity also were assessed. The intraclass correlation coefficient (ICC) was computed, and differences in mean scores across HRQL

Angela.Pinto@baruch.cuny.edu .

For the Program to Reduce Incontinence by Diet and Exercise (PRIDE). Clinical Trial Registration for “PRIDE” is NCT00091988 in www.clinicaltrials.gov

measures were examined. Potential correlates of HUI3, SF-6D, and eQWB scores were evaluated using multivariable generalized linear models.

Results—Mean ± SD scores for the HUI3, SF-6D, and eQWB were 0.81 ± 0.18, 0.75 ± 0.10, and 0.71 ± 0.06, respectively. Significant differences were observed across measures ($P < 0.0001$), and the overall ICC was 0.36. In multivariable analyses, BMI was negatively associated with HUI3 ($P = 0.003$) and eQWB ($P < 0.001$), and UI episode frequency was negatively associated with eQWB ($P = 0.015$) and SF-6D ($P < 0.001$).

Conclusions—Significant differences in mean utilities across the HUI3, SF-6D, and eQWB indicate that these measures do not assess identical dimensions of HRQL. Both BMI and UI episode frequency were related to HRQL in this cohort; however, the magnitude of the relationship depended on the preference-based measure used. These findings highlight the need to consider the method used to generate HRQL values for calculating quality-adjusted life-years in cost-utility analyses, since choice of method may have a substantial impact on the outcome of the analysis.

Keywords

Quality of life; Obesity; Urinary incontinence; HUI; eQWB; SF-6D

Introduction

Both urinary incontinence (UI) and obesity are common conditions that have a significant impact on health [1-4], and observational studies suggest that obesity is a strong risk factor for UI [5, 6]. While numerous studies have shown that obesity and UI have negative effects on health-related quality of life (HRQL) [2, 7-22], fewer studies [2,9, 13, 15, 18-20, 22] have assessed HRQL with preference-based methods that can be used to incorporate the quality-of-life effects of these conditions into economic analyses of interventions aimed at reducing UI and obesity.

Unlike non-preference-based measures of HRQL that assign scores based on the level of functioning in various domains of health assessed, preference-based measures incorporate how patients (or members of the general public) value experiencing a given health state (or a hypothetical health state) that is defined by levels of functioning and well-being in these domains. These scores can be combined with life expectancy estimates to calculate quality-adjusted life-years (QALYs) for use in cost-utility analyses (CUAs) [23]. Several preference-based HRQL measures have been developed, including the Health Utilities Index (HUI) [24, 25], Quality of Well-Being scale (QWB) [26-28], Short Form 6D (SF-6D) [29, 30], and EuroQol 5D (EQ5D) [31, 32]. Each is based on different dimensions, items, and preference weights, which typically yield diverging utility scores for currently experienced health states. Variability in the estimates obtained from different measures may complicate comparisons of the cost effectiveness of interventions. To better understand potential differences in preference-based HRQL estimates and further inform the selection of measures to be used in economic analyses, comparative studies of these measures have been recommended [33].

The purpose of the current study was to compare three preference-based HRQL measures and examine independent correlates of HRQL among overweight and obese women with urinary incontinence (UI) enrolled in a weight loss intervention trial. We used HUI3 and Medical Outcomes Study Short Form-36 (SF-36) data collected in this cohort to generate the following preference-based HRQL scores: HUI3, SF-6D, and estimated QWB (eQWB). Correlates of these scores were also examined.

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Methods

Participants

Participants (*N* = 338) were recruited between July 2004 and April 2006 in Providence, Rhode Island and Birmingham, Alabama and enrolled in the Program to Reduce Incontinence by Diet and Exercise (PRIDE) randomized clinical trial. Characteristics of the study sample and inclusion and exclusion criteria have been previously reported [34]. Women who were at least 30 years of age and had a BMI of 25–50 kg/m^2 and reported 10 or more urinary incontinence episodes on a 7-day voiding diary at baseline were eligible for the study. Exclusion criteria included the use of medical therapy for incontinence or weight loss within the prior month, current urinary tract infection, major medical or genitourinary tract conditions, pregnancy or having given birth in the previous 6 months, type 1 or type 2 diabetes requiring medical therapy that increases the risk of hypoglycemia, and uncontrolled hypertension. The study was approved by the institutional review board at each site, and written informed consent was obtained from all participants before enrollment.

Study design

The PRIDE study was an 18-month two-site clinical trial to determine whether a behavioral weight reduction intervention for overweight and obese women with incontinence results in greater reductions in frequency of incontinence episodes at 6- and 18-months compared with a control group. Eligible participants were randomly allocated to a 6-month intensive behavioral weight loss program (intervention; *n* = 226) followed by a 12-month weight maintenance program or to a structured education program (control; *n* = 112). The current investigation is a cross-sectional analysis of the preference-based measures of HRQL collected at baseline (prior to randomization) including all participants.

Measures

Demographic characteristics and medical, behavioral, and incontinence histories were ascertained using self-report questionnaires. Body weight was measured in street clothes with shoes removed, using a calibrated digital scale (Tanita BWB 800) and recorded to the nearest 0.5 kg. Height was measured at baseline to the nearest centimeter using a calibrated wall-mounted stadiometer and a horizontal measuring block. Body mass index (BMI) was calculated as weight in kg/height in meters squared (kg/m^2).

Participants completed a 7-day voiding diary in which they recorded each incontinence episode, identified by the participant as stress (involuntary loss of urine with coughing, sneezing, straining, or exercise), urge (loss of urine associated with a strong need or urge to void), or other, based on the instructions provided. Incontinence type was then classified as stress only; stress predominant (stress episodes comprised at least 2/3 of the total); urge only; urge predominant (urge episodes comprised at least2/3 of the total); or mixed incontinence (at least two types were reported but no type comprised at least 2/3 of the total). The quantity of urine lost involuntarily was measured using a standardized pad test [34]. Participants collected and returned in sealed plastic bags pre-weighed urinary incontinence pads used during a 24-h period, and the post-test weight of each pad was recorded.

Physical activity was assessed by self-report using the Paffenbarger Activity Questionnaire [35], which estimates calorie expenditure in overall leisure activity (e.g., number of stairs climbed, number of blocks walked) and in light (5 kcal/min), medium (7.5 kcal/min), and high (10 kcal/min) intensity physical activity.

Health-related quality of life was measured using the HUI3 and the SF-36. The HUI3 [24, 25] is a 15-item generic, participant-completed measure of health status, and HRQL that has been used in both clinical and population health studies. The HUI3 includes items assessing eight attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain. Each attribute has 5–6 levels of functioning, describing 972,000 unique health states. These data are converted into a multiattribute utility score using community-based preference weights that reflects global HRQL on a scale of −0.36 to 1.0, where −0.36 is the worst possible state, 0 is equal to dead, and 1.0 is equal to perfect or ideal health. A difference of 0.03 or greater on the overall HUI3 score is clinically important [19, 36-38]. The SF-36 [39, 40] is a 36-item generic self-report survey that assesses health across eight dimensions (physical functioning, role limitations-physical, bodily pain, general health, vitality, social functioning, role limitations-emotional, and mental health). It has been widely used to assess general health status in population studies, estimate disease burden, and examine health outcomes in clinical research trials of numerous conditions [40].

The SF-36 was used to generate two scores: an SF-6D score [29] and an estimated QWB score, referred to as the eQWB [41, 42]. The SF-6D score was derived from 11 questions on the SF-36 that include six health dimensions (physical functioning, role limitations, social functioning, pain, mental health, and vitality) and defines 18,000 health states. Developed in the UK general population, SF-6D scores range from 0.30 to 1.00 (where 1.00 indicates “full health”). For the SF-6D, the mean minimal important difference has been reported as 0.03–0.04 [43, 44]. The eQWB score was derived using the regression equation from Fryback and colleagues [42] based on data from a community-based population study (Beaver Dam Health Outcomes Study) and includes five health dimensions (physical functioning, mental health, bodily pain, general health perceptions, and role limitations-physical). This derivation has been used in prior studies [41, 45]. The bounds of the eQWB based on this equation are 0.45–0.84. We did not find published reports of the minimal important difference for the eQWB; however, the minimal important difference for the QWB has been reported as 0.03 [46].

Statistical analyses

Multivariable generalized linear models were developed to identify potential correlates of HUI3, SF-6D, and eQWB scores. To meet normality assumptions, the HUI3 was log-transformed; UI frequency, an independent variable in the models, was likewise log-transformed to meet linearity assumptions. Variables with P values <0.20 in univariable (i.e., single-predictor) analyses were considered for inclusion in the multivariable (i.e., multi-predictor) models. These variables included educational level, annual household income (<$40,000, $40,000–$99,999, ≥$100,000), BMI, menopausal status, prior hysterectomy, prior pelvic organ prolapse surgery, number of live births, current smoking, ever smoked 100 cigarettes, UI episode frequency, monthly or greater fecal incontinence, and kilocalories expended per day through physical activity (quartiles: 0–112, 140–364, 392–1,078, 1,092–7,841). Relationship status (married/partnered, single/widowed/divorced), alcohol use, UI type (stress, urge, mixed), and 24-h involuntary urine loss on pad test had P values > 0.20 in univariable analyses and thus were not included in multivariable models. Age, race (white/non-white), and clinical site (Providence/Birmingham) were included in all models. The final model for each endpoint was chosen by backward elimination of variables with P values > 0.20. Effect size [47] was assessed using the η^2 statistic, which indicates the proportion of variance explained by each variable independently in a multivariable model. To examine degree of agreement among HRQL measures, the intraclass correlation coefficient (ICC) was computed using the between-subject and error mean squares from a two-way analysis of variance with random participant and fixed instrument effects; this is case 3,1 in Shrout and Fleiss’s framework [48]. In addition, we assessed differences in mean response levels on the three instruments using a repeated measures model with unstructured residual covariance matrix. In this analysis, untransformed HUI-3 scores were used. Finally, we used a repeated measures model with appropriate interactions to determine whether covariates were differentially associated with the three instruments. In this analysis, we standardized each instrument score to have unit variance.

Multiple imputation was used for missing data, in particular for household income (21% not reported or missing) and post-menopausal status (6% missing). Twenty imputed data sets were made, with results combined using standard techniques for multiply-imputed data, as implemented in SAS Proc MI and Proc MIAnalyze. A *P* value of<0.05 was considered statistically significant. All analyses were implemented in SAS Version 9.2 (SAS Institute, Cary, NC).

Results

Mean ± standard deviation (SD) age for participants was 53 ± 11 years. Nineteen percent of these women were African American and 45% reported their health to be "excellent" or "very good". They had a mean BMI of 36 ± 6 kg/m^2 and a mean weight of 97 ± 17 kg (Table 1). The average number of total weekly incontinence episodes was 24 ± 18; 22% of the participants were classified as having stress only or stress predominant UI, 44% urge only or urge predominant UI, and 34% mixed UI.

Means ± SD on the HUI3, SF-6D, and eQWB were 0.81 ± 0.18 (range = 0.08–1.00), 0.75 ± 0.10 (range = 0.47–0.97), and 0.71 ± 0.06 (range = 0.55–0.83), respectively. Mean scores differed significantly in the repeated measures analysis ($P < 0.0001$), and the overall ICC was 0.36. We also found evidence that BMI was differentially associated with the three measures ($P = 0.009$), with differences in BMI having a greater effect on HUI3 than on eQWB, and no effect on SF-6D. While the distributions of the SF-6D and eQWB were approximately normal, the HUI3 was negatively skewed with some evidence of a ceiling effect (3% of participants scored the maximum compared with 0% scoring the maximum for the SF-6D and eQWB).

In multivariable analyses (Table 2), lower HUI3 scores were associated with higher BMI ($P = 0.003$) and having undergone a hysterectomy ($P = 0.018$), but not with frequency of UI. Scores on the SF-6D were lower among women reporting greater frequency of UI episodes ($P < 0.001$) and monthly or greater fecal incontinence ($P = 0.012$) and higher among women with greater physical activity (*P* for trend = 0.002). Lower eQWB scores were associated with white race ($P = 0.042$), higher BMI ($P < 0.001$), and greater UI episode frequency ($P = 0.015$); higher eQWB scores were associated with greater physical activity (*P* for trend = 0.010). BMI accounted for a greater proportion of variance in eQWB score ($\eta^2 = 0.031$) compared with UI frequency ($\eta^2 = 0.016$).

Discussion

In this study of overweight and obese women with urinary incontinence enrolled in a clinical trial of a lifestyle weight loss intervention, mean HUI3, SF-6D, and SF-36-derived eQWB scores were 0.81, 0.75, and 0.71, respectively. With an overall ICC of only 0.36, significant differences in mean utility scores, and differential effects of BMI on the three measures, our results indicate that these instruments do not assess identical dimensions of HRQL. Our findings are consistent with previous reports documenting differences in mean values and score distributions across preference-based HRQL measures [41, 49-55]. We found that the eQWB produced the narrowest range of scores and the HUI3 produced the widest range, although this may be related in part to differences in the upper and lower bounds of the scales. The eQWB and SF-6D yielded higher minimum scores (0.55 and 0.47, respectively) compared with the HUI3 (lowest score = 0.08), which may suggest that these measures overestimate poor health relative to the HUI3. Prior studies [29, 52] have noted that the SF-6D may overpredict poor health states. Conversely, the HUI3 may underestimate poor health relative to the SF-6D and eQWB. In addition to differences in scoring/valuation methods across measures, variability in utilities obtained may also reflect differences in how health is characterized using the HUI3 and SF-36 and how sensitive certain domains are to the health effects associated with UI and obesity. As has been reported by others [49-51, 53, 54], significant variability in utility estimates across preference-based HRQL measures can have a substantial impact on the outcome of CUAs. Thus, when choosing a measure to obtain values to generate QALYs, researchers should consider whether the health domains assessed by the instrument are reflective of and responsive to the specific health condition being studied.

In multivariable models, higher BMI was the strongest independent correlate of lower HRQL as reflected in both HUI3 and eQWB scores. In particular, among women with HUI3 scores near the sample mean of 0.81, decreases of just 1.3 kg/m^2 in BMI predict increases of .03 units in HUI3 score, which is a clinically important difference. In contrast, only a very large decrease of 14 kg/m^2 in BMI would predict a clinically meaningful increase of .03 units in average eQWB score. This reflects the statistically significant heterogeneity of the BMI effects we found across the three outcome measures and illustrates the degree to which choice of HRQL instrument can influence results. We also found that higher UI episode frequency was independently associated with lower SF-6D and eQWB scores. However, only very large decreases of 68 and 91% in UI episode frequency predict clinically meaningful increases of 0.03 units in SF-6D and eQWB scores, respectively. Other independent correlates of lower HRQL scores on at least one of the three measures in this study included white race, hysterectomy, lower physical activity, and fecal incontinence.

The inverse relationships found between BMI and HUI3 and eQWB scores are consistent with previous reports showing that increased BMI is associated with poorer HRQL [9, 22]. Lack of an association between BMI and SF-6D is in contrast to results of other studies that report a significant relationship between BMI and SF-6D after controlling for demographic variables and comorbid conditions. For example, a population study in Australia [56] showed a significant negative association between BMI and SF-6D score among women aged 18–79 years, and a large clinic-based study in the United Kingdom [18] reported lower SF-6D scores among obese men and women compared with their normal-weight counterparts. There are relatively few published studies of SF-6D scores in overweight and obese samples or among women with incontinence, thus additional research is needed to examine the sensitivity of this measure to decrements in HRQL associated with these conditions.

The association between BMI and HUI3 in the current study suggests that the HUI3 is sensitive to health effects of obesity and thus may be a useful tool to measure HRQL in studies of obesity or weight loss. Certain HUI3 items such as those that address physical pain and discomfort and walking ability may be more relevant to individuals who are obese. On the other hand, our findings of a relationship between UI and SF-6D suggest that the SF-6D may be more useful in studies of UI. This may be related to SF-36 items that address social functioning, which perhaps is more relevant to individuals affected by UI. Since the eQWB was the only score related to UI and obesity, investigations that include both outcomes may benefit from computing this preference score from the SF-36. Further, it may be informative for future studies to examine the usefulness of the self-administered version of the QWB (QWB-SA) in this population given its broader range of values.

Strengths of the current study include the observed measures of height and weight and inclusion of three approaches to estimating preference-based HRQL. Limitations of this study are that it is cross-sectional and thus no causal associations can be made and that it includes only overweight and obese women with UI and therefore does not provide information regarding the relation between BMI and HRQL for other populations. In addition, since this study was a secondary analysis of baseline data from a randomized controlled trial, it may not have been adequately powered to detect statistically significant effects for all correlates of HRQL tested.

In this cohort of overweight and obese women with urinary incontinence, we found significant differences in scores obtained from three preference-based measures of HRQL. Both BMI and UI episode frequency were found to be related to HRQL; however, the magnitude of the relationship depended on the measure used.

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Table 1

Characteristics of the participants[a]

	Total (*N* = 338)
Age (years)	53 ± 11
Race—no. (%)	
White	262 (77.5)
Black	64 (18.9)
Other	12 (3.6)
Education beyond high school—no. (%)	293 (86.7)
Relationship status—no. (%)	
Married or living with partner	256 (75.7)
Single, widowed, or divorced	82 (24.3)
Annual household income—no./total no. (%)	
<$40,000	72/268 (26.9)
$40,000–$99,9,999	142/268 (53.0)
$100,000 or more	54/268 (20.1)
Body mass index (BMI; kg/m^2)	36 ± 6
Diabetes—no. (%)	10 (3.0)
Current smoker—no. (%)	18 (5.3)
Current alcohol use—no. (%)	228 (67.5)
Post-menopausal—no./total no. (%)	177/316 (56.0)
Self-reported health status—no. (%)	
Excellent or very good	151 (44.7)
Good	150 (44.4)
Fair or poor	37 (10.9)
Hysterectomy—no./total no. (%)	99/337 (29.4)
Parity	2 ± 1
Type of urinary incontinence—no. (%)[b]	
Stress only/stress predominant	75 (22.2)
Urge only/urge predominant	149 (44.1)
Mixed	114 (33.7)
Urinary incontinence episodes per week	24 ± 18
24-h involuntary urine loss (g)[c]	33 ± 55
Monthly or greater fecal incontinence—no. (%)	35 (10.4)

[a]Data are presented as mean ± standard deviation or number (percent)

[b]Type of urinary incontinence was classified according to the participant's designation of each incontinence episode in a 7-day voiding diary

[c]Involuntary urine loss was measured by the 24-h increase in pad weight

Table 2

Factors associated with health-related quality-of-life scores in multivariable linear regression analyses

	HUI3[a]			SF-6D			eQWB		
	Effect estimate (95% CI)	***P* value**	η^2	**Effect estimate (95% CI)**	***P* value**	η^2	**Effect estimate (95% CI)**	***P* value**	η^2
Age per 10 years	0.041 (−0.061, 0.153)	0.449	0.002	0.007 (−0.007, 0.020)	0.342	0.002	−0.004 (−0.011, 0.002)	0.218	0.004
Race (Non-White)	0.112 (−0.138, 0.435)	0.414	0.002	0.010 (−0.017, 0.036)	0.468	0.001	0.017 (0.001, 0.034)	0.042	0.011
Household income	NA			NA				0.173	0.011
<$40,000							Reference		
$40,000–$99,999							0.014 (−0.002, 0.030)		
$100,000 or more							0.003 (−0.018, 0.025)		
Body mass index (kg/m^2)	−0.028 (−0.046, −0.010)	0.003	0.025	NA			−0.002 (−0.003, −0.001)	<0.001	0.031
Weekly UI episode frequency[b]	−0.010 (−0.025, 0.004)	0.155	0.006	−0.003 (−0.004, −0.001)	<0.001	0.030	−0.001 (−0.002, −0.0002)	0.015	0.016
Current smoking	−0.346 (−0.576, 0.011)	0.057	0.010	NA			NA		
Hysterectomy	−0.243 (−0.398, −0.048)	0.018	0.016	NA			NA		
Fecal incontinence	−0.230 (−0.442, 0.064)	0.114	0.007	−0.044 (−0.078, −0.010)	0.012	0.017	−0.017 (−0.038, 0.005)	0.124	0.006
Physical activity (kcals expended per day	NA				0.002*	0.028		0.010*	0.017
1st quartile (range 0,112)				Reference			Reference		
2nd quartile (range 140, 364)				0.016 (−0.014, 0.045)			0.007 (−0.011, 0.025)		
3rd quartile (range 392, 1,078)				0.020 (−0.009, 0.049)			0.018 (0.0001, 0.036)		
4th quartile (range 1,092, 7,841)				0.047 (0.018, 0.077)			0.022 (0.003, 0.040)		
Pelvic organ prolapse surgery	NA			NA			−0.026 (−0.059, 0.007)	0.123	0.006
Post-menopausal	NA			0.021 (−0.007, 0.049)	0.136	0.006	NA		

Analyses controlled for clinic site, NA indicates that variable was not included in the final multivariable model, *HUI3* Health Utilities Index Mark 3, *eQWB* estimated Quality of Well-Being score

[a] Log transformation applied; effect on the outcome is expressed as proportional change in HUI3

[b] Log transformation applied; estimate coefficient is per 10% increase in weekly UI episode frequency

* *P* value is for the trend

η^2 statistic indicates the proportion of variance explained by each variable independently in the multivariable model