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# THE EYE OF THE BEHOLDER: THE ACCURACY OF THE PATIENT ASSESSMENT OF INCONTINENCE SEVERITY

Hypothesis / aims of study

Quality of life (QOL) decreases with increasing severity of urinary incontinence (UI). Objective assessments of severity may not adequately reflect QOL impact from UI, and patient-reported assessments may be more relevant when treating QOL disorders. Our aims were to determine if (1) patient assessments are more strongly related to QOL than traditional objective measures; (2) the correlation between patient UI assessments and objective assessments of UI severity; (3) the correlation between patient assessments of their UI severity and QOL impact from UI.

Study design, materials and methods

This is an analysis of preliminary baseline data from a multi-center, randomized clinical trial comparing the efficacy of two urethral bulking agents, Zuidex®, a dextranomer in a hyaluronic acid base, and Contigen®, bovine collagen. Following ethical committee approval at all institutions, women with urodynamic stress incontinence were enrolled in 23 centers across the North America, in compliance with the Declaration of Helsinki. Women with urethral hypermobility (Q-tip angle $\geq$ 30°) or abdominal leak point pressures (ALPP) $\geq$ 100cm$H_2O$ were excluded.

All subjects completed short forms of the Urinary Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ) to determine UI bother and QOL impact. Objective quantification of UI included a 4-day diary, standardized office pad test and urodynamics with ALPP. The mean number of incontinence episodes per day (IEF) was calculated from the diary. The patient perspective was derived from Patient's Global Assessment of Incontinence (PGA) which asks "How would you describe your incontinence problems today?" with four response options (None, Mild, Moderate, Severe). In addition, patients indicated their perceived Incontinence Grade (UI Grade): "How would you grade your incontinence on a scale from with 0=continence and 3=total incontinence?"

Patients' assessments of their UI severity were compared to objective and QOL measures using Kruskal Wallis test. IIQ and UDI scores were compared to objective measures using Pearson correlations. All QOL and objective measures were entered in two backwards-stepwise linear regression models to determine which factors influenced patients' assessments of their UI measured by PGA and UI Grade.

Results

Baseline data was available for 329 women with a mean age of 56$\pm$12 years. Forty percent reported UI symptoms for 1-5 years, and 60% had symptoms for > 5 years. The table below shows median values for objective measures of UI severity and QOL measures.

| **Measures of UI Severity** | **Median (Range)** |
|---|---|
| ALPP (cm$H_2O$) | 68 (0-211) |
| IEF | 4 (0-24) |
| Pad Test (grams) | 51 (10-338) |
| UDI | 39 (6-100) |
| IIQ | 43 (0-100) |

Subject's assessed their UI severity as follows: 21% as severe, 52% as moderate, 25% as mild, and 3% as none. The distribution of UI grade was similar. Four percent reported grade 3 defined as "total incontinence" or "urine loss without any relation to physical activity or position"; 51% reported grade 2 defined as "leaking with lesser degrees of physical stress such as walking, standing erect from sitting position or sitting up in bed"; 45% reported grade 1 defined as "loss of urine with sudden increased in abdominal pressure (coughing, sneezing, laughing), but never in bed a night"; and only one reported grade 0 defined as "continent".

In univariate analysis, IIQ and UDI scores did not correlate with ALPP and only weakly correlated with IEF ($\rho$=.35 and $\rho$=.26, p<.0001) and pad test ($\rho$=.14, p=.01 and $\rho$=.12, p=.03). Higher IIQ and UDI scores were significantly associated with worse patient assessments of their UI using the PGA and UI Grade (p<.0001) and with duration of symptoms > 5 years (p=.02). Worse PGA and worse UI Grades were significantly associated with IEFand pad test (p<.0001), but not ALPP (p=.69 and p=.11). In the linear regression models, worse PGA scores were associated with higher IIQ scores, IEF, and pad test results (p<.0001) and worse UI Grades were associated with higher IIQ scores (p=.0005), UDI scores (p=.05), IEF (p<.0001), and pad test result (p=.02).

Interpretation of results

Patients' assessments of their own UI severity better reflect bother and QOL impact from UI than traditional objective measures. Objective measures of UI severity poorly indicate the impact of UI on women's QOL. While patients' assessments of UI severity are associated with some objective measures, the lack of association between objective measures and QOL suggests that more global patient-centered measures of disease impact may be better to assess UI severity. When making clinical recommendations, we do so based on patient's goals for treatment, which are

typically broader than simply reducing the amount or number of UI episodes. Yet, clinicians and investigators continue to rely heavily on objective measures when planning and assessing treatment outcomes.

Concluding message

Patients' assessments of their UI severity may be better predictors when planning and assessing treatment outcomes than objective measures of UI severity. The lack of association of ALPP with QOL and patients' UI assessments questions the relevance of this test for determining UI severity.

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