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## Construct Validity of a Questionnaire to Measure the Type of Fluid Intake and Type of Urinary Incontinence

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### Abstract

**Objective**—to determine the reproducibility and construct validity of the Questionnaire Based Voiding Diary (QVD) for measuring the type and volume of fluid intake and the type of urinary incontinence.

**Methods**—250 women completed the QVD, a 48-hour bladder diary and underwent complete urogynecologic evaluation to determine a final clinical diagnosis. The questionnaire was re-administered after a 2-week period with no change in treatment, and 2–3 months later following treatment of urinary symptoms.

**Results**—The reproducibility of the fluid intake, output, fluid intake behavior and urinary symptom subscales of the QVD was 0.68–0.92. Correlation of the fluid intake scale of the QVD with the 48-hour voiding diary for determining the type and volume of fluid intake was high ( $r = 0.65$ – $0.83$ ,  $P < 0.01$ ). High correlations were noted between the fluid intake behavior scale and urinary frequency ( $r = 0.82$ ,  $P < .01$ ), urgency ( $r = 0.77$ ,  $P < .01$ ) and urge incontinence ( $r = 0.71$ ,  $P < .01$ ). The median total fluid intake and mean urinary symptom score was significantly lower in responders (2074 mL,  $10.2 \pm 3.3$ ) than non-responders (2347 mL,  $18.5 \pm 4.6$ ). As compared to the final clinical diagnosis, the sensitivity, specificity and positive likelihood ratio of the QVD for the diagnosis of predominant stress urinary incontinence are 86%, 66% and 2.6 and for predominant urge incontinence 82%, 79% and 4.0 respectively.

**Conclusion**—The QVD provides clinically meaningful information on the type and volume of fluid intake and the type of urinary incontinence at the initial office visit.

### Keywords

Fluid intake; urinary incontinence; questionnaire; construct validity

## INTRODUCTION

Guidelines<sup>1–3</sup> for the diagnosis and management of urinary incontinence recommend that clinicians determine the type of urinary incontinence and the type and volume of fluid intake prior to initiating treatment. Several self-administered instruments to measure the type of

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Conflict of interest: Lily A. Arya has served as consultant for Pfizer & Astellas. Both companies make drugs for urge incontinence. The present paper is not related to treatment of urge incontinence.

urinary incontinence exist.<sup>4-7</sup> The type and volume of fluid intake is typically measured using a bladder diary. However, bladder diaries are often omitted due to patient and physician burden<sup>8-9</sup> and more than one-third of physicians fail to utilize bladder diaries in their evaluation of urinary incontinence.<sup>10</sup> Similarly, patient compliance for recording voided volumes in clinical practice is also low and “diary fatigue” can result in incomplete and inaccurate data.<sup>9</sup> Non-compliance with bladder diaries carries the potential for delay in the diagnosis and treatment of urinary incontinence. A self-administered tool that provides rapid and valid information on the type and volume of fluid intake and common types of urinary incontinence would be immensely useful for the initial diagnosis and treatment of urinary incontinence in the ambulatory setting.

The Questionnaire-Based Voiding Diary (QVD) is a self-administered instrument that can be completed at the initial office visit in 5–7 min and is designed to obtain information that is typically collected through a 48-hr voiding diary.<sup>11</sup> The instrument collects data in four subscales, fluid intake, output, fluid intake behavior, and urinary output. In the initial validation study,<sup>11</sup> the instrument was noted to have high internal consistency and test–retest reproducibility. The purpose of the present study is to determine the construct validity and reproducibility of the QVD for measuring the type and volume of fluid intake and the type of urinary incontinence in women.

## MATERIALS AND METHODS

A prospective study was performed following approval by the Institutional Regulatory Board. Women 18 years or older reporting to a urogynecology clinic with the chief complaint of urinary incontinence at their initial visit were recruited. We excluded women with complex conditions that could potentially make incontinence symptoms difficult to classify. Exclusion criteria included greater than three urinary tract infections in the previous year, interstitial cystitis, advanced prolapse (more than 1 cm past the hymen), prior anti-incontinence or urethral surgery or procedures, current or recent (within 3 months) medications for urinary incontinence, treatment for pelvic cancer or pelvic radiation within the previous 6 months, urogenital fistula, and neurologic disease likely to affect the urinary tract.

Following informed consent, all women were assessed at baseline (visit 1). At this visit, all women underwent structured interview of their pelvic floor symptoms, complete pelvic examination with pelvic organ prolapse quantification, measurement of postvoid residual volume (by catheter or ultrasound) and urinalysis. All methodology and terminology adhere to existing International Continence Society guidelines unless specified otherwise.<sup>1</sup> A research assistant collected demographic data, administered the QVD, and provided detailed instruction on completing the 48-hr bladder diary using a log and a urinary collection container.

All women reported for a second visit after a 2-week period with no change in treatment (visit 2). At the second visit, the QVD was re-administered for test–retest reliability and the bladder diary was reviewed. Multi-channel urodynamic assessment was performed in women who desired definitive surgical therapy or in whom symptoms did not advocate a clear diagnosis. Urodynamics consisted of uroflowmetry and complex cystometrogram in the sitting up right position using air-charged (T-Doc) catheter and Duet<sup>®</sup> Logic G/2 (Medtronic, Inc., Minneapolis, MN). All terminology and methods are in accordance with International Continence Society nomenclature.<sup>1</sup> A final clinical diagnosis of the type of urinary incontinence (stress predominant, urge predominant, or balanced mixed urinary incontinence) was determined by the treating physician on a structured form using data from the interview, examination, bladder diary, and urodynamic evaluation using standard

guidelines.<sup>1</sup> Types of urinary incontinence are as defined by Digesu et al.<sup>12</sup> All clinical examinations were performed by one specialist (first author). A second specialist (last author) reviewed all clinical data (history, pelvic examination, urinalysis, and urodynamics if performed) to make a second independent diagnosis of the type of urinary incontinence. If disagreement about the type of incontinence occurred, the two specialists discussed the case and arrived at a consensus diagnosis. Overall 13 disagreements in diagnosis required discussion for a consensus diagnosis. The clinicians did not have access to the patient responses recorded on the QVD. At visit 2, all women also received a one-page information sheet on healthy fluid intake<sup>13</sup> and treatment for urinary symptoms as recommended by the clinician.

All women reported for a third visit 2–3 months later following treatment of their urinary symptoms (visit 3). At this visit, the QVD was administered for a third time and women were administered a 7-point global scale of improvement.<sup>14</sup> Based on the response, women were divided into two groups, responders (women who reported themselves to be “much better” or “very much better”) and non-responders (women who reported themselves to be “worse,” “much worse,” or “very much worse”).

The type and volume of fluid intake was calculated by multiplying the “number of drinks per day” for each fluid type by the “size of each drink” as reported on the QVD at visit 1. The type of urinary incontinence was based on responses to two questions of the QVD at visit 1, one each on urge and stress incontinence. Responses to each question are recorded in five levels from 0 to 4 (never, occasionally, sometimes, most of time, and all of the time). The type of urinary incontinence was classified in three categories, stress predominant (stress score > urge score), urge predominant (urge score > stress score), or balanced (stress score = urge score) urinary incontinence. The treating clinician was not aware of the QVD diagnosis of the type of incontinence.

For fluid intake behavior, urinary symptoms, and urinary output subscales, respondents indicated on a scale of 0 (never) to 4 (all of the time) the degree to which they experienced the symptom or behavior. Higher scores on urinary symptom subscale (range 0–20) and urinary output subscale (range 0–16) indicate more severe urinary symptoms and larger urinary output, respectively. Higher score on the fluid behavior subscale (range 0–20) indicate presence of a fluid intake pattern known to be associated with lower urinary tract symptoms.<sup>15–16</sup>

All data were analyzed using SAS for Windows version 9.1 (SAS Institute, Cary, NC). All fluid data are daily values and described using median and interquartile range. *Internal consistency reliability*, was determined from the Cronbach’s alpha coefficient. A level of 0.80 or higher was considered reliable. The test–retest reproducibility of the QVD for measuring the volume of the different types of fluid intake was measured using the intraclass correlation coefficient. The test–retest reproducibility of the QVD for the type of urinary incontinence was measured using the  $\kappa$  statistic. A intraclass correlation coefficient or  $\kappa$  statistic of 0.75 or greater indicates excellent agreement, and values between 0.40 and 0.75 indicates fair to good agreement.<sup>17–18</sup>

*Construct validity* of the QVD for measuring the type and volume of fluid intake was evaluated by correlating QVD fluid intake data to bladder diary data using the Spearman correlation coefficient. Observed significant correlations below 0.3 were considered low, between 0.3 and 0.5 moderate, and 0.5 or above high.<sup>19</sup> *Discriminant validity*, the ability to distinguish between distinct populations, was determined on the basis of detection of mean differences in QVD subscale scores between responders and non-responders using the Wilcoxon rank sum test. For construct validity of the QVD for measuring the type of urinary

incontinence (stress or urge predominant), we compared bladder diary parameters between women with stress or urge predominant incontinence using the Wilcoxon rank sum test. We also calculated the sensitivity, specificity, and likelihood ratios of the QVD for the diagnosis of the type of incontinence as compared to the final clinical diagnosis using appropriate sample proportions and computed the 95% confidence intervals for each proportion using the efficient-score method.<sup>20</sup> A 0.05 significance level was used for all statistical tests.

Sample size calculation was based on the ability of the QVD to detect a significant change in the volume of total fluid intake and the type of urinary incontinence between responders and non-responders. The mean total fluid intake using the QVD in a prior study<sup>11</sup> of women with urinary incontinence was  $2,190 \pm 1,032$  ml and the mean urinary symptom score was  $9.2 \pm 3.6$ . We fixed alpha at 0.05 and power at 90%. A sample size of 117 subjects in each group is required to detect a difference of 20% in the total fluid intake between responders and non-responders. This sample size is also sufficient to detect a clinically meaningful change in severity of two levels on a single question in the urinary symptom domain score between responders and non-responders. Based on a conservative response rate of 50% for women with mixed incontinence in clinical practice,<sup>21</sup> and an estimated loss to follow-up rate of 20%, we planned to enroll 300 women with urinary incontinence.

## RESULTS

Of 362 women screened between June 2008 to March 2009, 48 women (13%) with complex incontinence were excluded and 6 refused participation. We enrolled 308 consecutive eligible women. Thirty women (10%) did not report for visit 2 and an additional 28 women (9%) did not report for visit 3. Results presented here are of 250 women who completed all three visits. Despite detailed instructions, 23% of bladder diaries were noted to have missing data. Seven patients had missing data on the QVD at any visit.

Mean age, body mass index of the women was  $54 \pm 17$  years and  $27.9 \pm 6$  kg/m<sup>2</sup>, respectively. Median parity was 2 (range 1–5). Seventy percent women were white and 23% were African-American. Sixty-nine percent women had received at least 2 years of college education. In addition to urinary incontinence, 48% women also had pelvic organ prolapse (of these 37% had stage 2 prolapse) and 12 reported fecal incontinence. The rate of prior hysterectomy in this cohort was 17%. Urodynamic testing was performed in 62% women, with the majority being performed for women who desired definitive surgical therapy (43%) and in 19% for women whose symptoms did not indicate a clear diagnosis. Elevated postvoid residual volume (>150 ml) was noted in 15 women (6%). The median length of time taken to complete the QVD was 7 min (range 5–20 min).

The internal consistency (Cronbach's alpha) of the fluid intake, fluid intake behavior, urinary symptom, and urinary output subscales of the QVD in this population was 0.88, 0.84, 0.9, and 0.81, respectively. The mean fluid intake behavior, urinary output, and urinary symptom scores on the QVD were  $12.4 \pm 6.1$ ,  $13.6 \pm 3.6$ ,  $17.5 \pm 3.2$ , respectively. The test-retest reproducibility of the fluid intake behavior, urinary symptom, and urinary output subscales in this population was 0.92, 0.9, and 0.68, respectively.

The median intake and interquartile range of the different types of beverages consumed is shown in Table I. The test-retest reproducibility of the QVD for measuring the different types of beverages at the first and second visit was high (Table I). High correlation was noted between the amount of fluid intake (total and different beverages) as measured by the QVD and fluid intake amounts as reported on the bladder diary (Table I). Correlations were higher for caffeinated beverages, decaffeinated beverages, and total fluid intake than for water and "other fluids." Only 37% women reported intake of carbonated beverages.

We also examined the relationship between the fluid intake subscale and the urinary symptoms recorded on the bladder diary. The correlation between increasing quartiles of total fluid intake and increasing urinary frequency on the bladder diary was 0.82 ( $P < 0.001$ ). Increasing quartiles of total fluid intake was significantly correlated to increasing number of urgency ( $r = 0.77$ ,  $P < 0.01$ ), urge incontinence ( $r = 0.71$ ,  $P < 0.001$ ), and stress urinary incontinence episodes on the bladder diary ( $r = 0.66$ ,  $P < 0.01$ ). The correlation between increasing quartiles of caffeinated tea and coffee intake and increasing number of urge incontinence episodes was 0.51 ( $P = 0.03$ ). A similar pattern was noted between increasing quartiles of total and caffeinated fluid intake and urinary symptom scale of the QVD.

High correlations were noted between fluid intake behavior as measured by the QVD and fluid intake as reported on the bladder diary. Self-reported behavior of drinking large amounts of caffeinated tea or coffee and carbonated beverages was correlated with increasing caffeinated beverage ( $r = 0.89$ ,  $P < 0.01$ ) and carbonated fluid ( $r = 0.87$ ,  $P < 0.01$ ) intake on the bladder diary, respectively. Responses to the fluid behavior question “Do you drink extra fluids to lose or maintain weight?” was correlated with increasing total fluid intake ( $r = 0.82$ ,  $P < 0.01$ ). The behavior of restricting fluid intake was significantly negatively correlated to total volume of fluid intake ( $r = -0.68$ ,  $P < 0.01$ ) and positively correlated to urinary output (0.51,  $P < 0.05$ ).

The correlation between the urinary output subscale of the QVD and urinary output as recorded on the bladder diary was 0.55 ( $P < 0.05$ ). All 12 women who recorded low daily urinary output (800 ml or less) on the bladder diary reported scores of 6 on the urinary output subscale while only 3 women with urinary output  $>800$  ml reported this score.

The prevalence of the different types of urinary incontinence as measured by the QVD at the first visit and the final clinical diagnosis at the first visit is shown in Table II. On the basis of final clinical diagnosis, 110 (44%) women had stress predominant, 73 (29%) had urge predominant, and 67 (27%) had balanced mixed urinary incontinence. As compared to the final clinical diagnosis, the QVD correctly classified 86% women with stress predominant incontinence and 89% women with urge predominant incontinence.

Test–retest reproducibility for different types of incontinence as classified by the QVD at the first and second visits was 0.87 (95% CI 0.81–0.91) for stress predominant, 0.81 (95% CI 0.75–0.86) for urge predominant, and 0.75 (0.62–0.83) for balanced mixed urinary incontinence. Lowest reproducibility was noted in the balanced mixed urinary incontinence category, but was still high with 75% women classified in the same category at the second visit.

The construct validity of the QVD for measuring the type of urinary incontinence was determined by evaluating the relationship between the type of urinary incontinence as diagnosed by the QVD, urinary symptoms on the bladder diary, and urodynamic findings (Table III). Women with stress predominant urinary incontinence had significantly greater number of stress incontinence episodes on the bladder diary and urodynamic stress incontinence than women with urge predominant incontinence. In women with urge predominant incontinence, the number of voids, urgency episodes and urge incontinence episodes, and urodynamic detrusor overactivity were significantly greater than in women with stress predominant incontinence. In the 12 women with balanced mixed urinary incontinence, urodynamic stress incontinence, and detrusor overactivity each were noted in 5 (42%) women and there was no significant difference in the mean number of stress ( $2.5 \pm 3.1$ ) and urge incontinent episodes ( $3 \pm 2.8$ ,  $P = 0.3$ ) on the bladder diary.

Table IV shows the discriminant validity of the QVD. Responders had significantly lower urinary symptom scale scores, median total, and caffeinated beverages intake than non-



responders. The fluid intake behavior score was significantly lower and urinary output score was slightly lower in responders than non-responders. The sensitivity, specificity, positive and negative likelihood ratios of the QVD for the diagnosis of the type of urinary incontinence as compared to the final clinical diagnosis is shown in Table V.

## DISCUSSION

Though bladder diaries provide clinically useful information, non-compliance with diary keeping is common.<sup>9-10</sup> The most important finding of this study is that a questionnaire administered in the office can provide reproducible and valid data on the type and volume of fluid intake in women with uncomplicated urinary incontinence. The structure of the fluid intake portion of the QVD is based on the existing food frequency questionnaires<sup>22</sup> and the instrument has excellent reproducibility and construct validity for measuring the type and volume of total fluid intake and different beverages as compared to the bladder diary. The fluid intake behavior scale determines if the observed pattern of fluid intake is repetitive and is highly correlated with bladder diary data. The fluid intake data of the QVD also correlate with urinary symptoms. Though the correlation of the urinary output scale of the QVD with urinary output measurements of the bladder diary is modest, a score of 6 or less on the urinary output scale reliably identifies women with low urinary output.

The QVD also has high test-retest reproducibility and good construct validity for measuring the type of urinary incontinence as compared to the bladder diary and urodynamic data. Our urodynamic findings for women with urge and stress predominant mixed incontinence are similar to previously reported findings.<sup>12</sup> As compared to the final clinical diagnosis, the sensitivity and the specificity of the QVD for measuring common types of incontinence seen in the ambulatory setting, stress, and urge predominant incontinence, are similar to other published instruments.<sup>5-6</sup> The positive predictive value of a questionnaire for determining the type of incontinence depends on the prevalence of the condition and cannot be generalized beyond the study sample. We measured the accuracy of the QVD for diagnosing the type of urinary incontinence using the positive likelihood ratio, the odds in the increase of the disease when a test is positive.<sup>23</sup> The accuracy of the QVD for measuring the type of urinary incontinence as compared to the final clinical diagnosis is modest but is acceptable for initiating behavioral therapies for urinary incontinence. A clinician could use the QVD to first determine the type of urinary incontinence and then initiate fluid management based on information collected through the fluid intake, behavior, and urinary output subscales.

Limitations of our study should also be considered. Our findings are limited to women with relatively uncomplicated urinary incontinence since we excluded 13% of screened women with complex incontinence. We also did not have a true “gold standard” test for the diagnosis of the type of urinary incontinence. Similar to prior studies<sup>5-6</sup> and as recommended by the Fourth International Consultation on Incontinence,<sup>1</sup> we used to the final clinical diagnosis, that integrates information from history, examination, and urodynamics, as the “gold standard.” Significant associations of the QVD with the final clinical diagnosis as well as the bladder diary suggest that the QVD provides valid data on the type and volume of fluid intake and common types of urinary incontinence in women.

## CONCLUSION

The QVD is a useful alternative to the bladder diary for physicians and patients unwilling or unable to complete a bladder diary. Advantages of the QVD over the bladder diary are that the instrument can provide the clinician with fluid intake and output data within a few minutes and data can be used to initiate treatment at the first visit. Disadvantages of the QVD are that it does not provide exact measurements of fluid intake or urinary output and

may also potentially lack the “learning effect” of diary keeping on urinary symptoms. Further studies that determine the accuracy, responsiveness, and the potential learning effect of the QVD in women with more complex forms of incontinence will improve the utility of the QVD in diverse population groups.

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## APPENDIX 1: THE QUESTIONNAIRE-BASED VOIDING DIARY

We would like to find out about your fluid intake, urinary output, and urinary symptoms. Please answer each question, thinking about your fluid consumption and the symptoms you have experienced in *the last month*.

For the fluid intake, circle the correct response. Please be sure to circle the number of drinks *AND* the amount for each beverage. If you do not drink a certain type of beverage *daily*, please circle 0.

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### Fluid intake amount

#### Water

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Caffeinated coffee

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Decaffeinated coffee

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Caffeinated tea

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Decaffeinated tea

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Caffeinated soda

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Decaffeinated soda

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Milk

Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

#### Fruit juice/fruit drinks (Hi-C, kool aid, cranberry cocktail)



Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		
Alcoholic drinks												
Number of drinks per day	0	1	2	3	4	5	6	7	8	9	10	More than 10
Size of each drink	Less than 8 oz			8–16 oz			17–24 oz			More than 24 oz		

### Fluid intake behavior

- Do you drink large amounts of caffeinated tea or coffee?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you drink large amounts of carbonated drinks?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you drink extra fluids to lose or maintain your weight?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you “make yourself” drink fluid even if you are not thirsty?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you restrict or cut down on your fluid intake to control your urinary symptoms?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time

### Urinary output

- Do you urinate large amounts of urine when you first wake up in the morning?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you urinate large amounts of urine in the afternoon (12 noon to 5 pm)?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you urinate large amounts of urine in the evening (5 pm to bedtime)?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- Do you urinate large amounts of urine in the night after you have fallen asleep?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time

### Urinary symptoms

- How often do you urinate in the daytime?  
 1–5,  6–10,  11–15,  16–20,  More than 20 times
- How often do you have to get up in the night to urinate after you have fallen asleep?  
 Never,  1,  2,  3,  4 or more
- Do you have to rush to the toilet to urinate?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time

- 4** Do you leak urine (even small drops) as you are rushing to the toilet?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- 5** Do you leak urine when you cough or sneeze or are physically active?  
 Never,  Occasionally,  Sometimes,  Most of the time,  All of the time
- 6a** How often do you experience urinary leakage?  
 Less than once a month,  
 A few times a month,  
 A few times a week,  
 Every Day and/or night
- 6b** How much urine do you lose each time?  
 Drops  
 Small splashes  
 More

Severity Index. This will be completed by your doctor or nurse.

Slight,  Moderate,  Severe,  Very Severe

TABLE I

Test-Retest Reproducibility and Construct Validity of the Type and Volume of Fluid Intake as Measured by the Questionnaire Based Voiding Diary (QVD)

Type of fluid intake	Median (IQR) daily intake by QVD (visit 1)	Median (IQR) daily intake by QVD (visit 2)	Test-retest reliability (ICC) <sup>a</sup>	Median (IQR) daily intake by bladder diary	Correlation with the bladder diary (r) <sup>b</sup>
Total fluid (ml)	2,371 (820–2,867)	2,406 (823–2,901)	0.77	2,265 (836–2,796)	0.75
Caffeinated tea or coffee (ml)	710 (237–1,248)	730 (240–1,303)	0.86	746 (255–1,368)	0.83
Decaffeinated tea or coffee (ml)	360 (240–720)	341 (240–689)	0.81	354 (200–750)	0.79
Carbonated drinks (ml)	390 (240–1,080)	366 (240–1,145)	0.87	343 (229–1,285)	0.81
Water (ml)	1,275 (720–1,920)	1,301 (685–1,746)	0.76	1,184 (450–1,699)	0.71
Other fluids (milk, fruit juice, alcohol) (ml)	347 (200–459)	401 (157–549)	0.71	466 (134–623)	0.65

IQR, interquartile range.

<sup>a</sup>ICC, intraclass correlation coefficient,  $P < 0.01$  for each.

<sup>b</sup>Spearman correlation coefficient,  $P < 0.01$  for each.

**TABLE II**

Type of Urinary Incontinence by the Questionnaire Based Voiding Diary at Visit 1 and Final Clinical Diagnosis

QVD classification	Final clinical diagnosis			Total
	SP MUI (n, %) <sup>a</sup>	Balanced MUI (n, %) <sup>a</sup>	Urge MUI (n, %) <sup>a</sup>	
SP MUI	95 (86.4)	43 (64.2)	4 (5.5)	142
Balanced MUI	5 (4.5)	3 (4.5)	4 (5.5)	12
UP MUI	10 (9)	21 (31.3)	65 (89)	96
	110	67	73	250

SP MUI, stress predominant mixed urinary incontinence; UP MUI, urge predominant mixed urinary incontinence; balanced MUI, balanced mixed urinary incontinence.

<sup>a</sup>Percentages represent column percentages.

**TABLE III**

Construct Validity: Relationship of the Type of Urinary Incontinence as Diagnosed by the QVD at the First Visit, Urinary Symptoms on the Bladder Diary, and Urodynamic Findings

Urinary symptom on the bladder diary	QVD diagnosis at visit 1		P-value
	Urge predominant incontinence, N = 142	Stress predominant incontinence, N = %	
Voiding frequency (median, IQR)	11 (8.2–15.9)	7.3 (5.2–12.5)	<0.01 <sup>a</sup>
Number of urgency episodes (median, IQR)	5.5 (2–8.7)	1.7 (1–3.3)	<0.01 <sup>a</sup>
Number of urge urinary incontinence episodes (median, IQR)	3.2 (1.8–5)	1.2 (0.2–1.2)	<0.05 <sup>a</sup>
Number of stress urinary incontinence episodes (median, IQR)	0.9 (0.4–2)	2.5 (1.2–5)	<0.01 <sup>a</sup>
Nocturia (median, IQR)	3 (1–5)	1 (0.5–2)	<0.05 <sup>a</sup>
Urodynamic detrusor overactivity	50 (52%)	18 (13%)	<0.001 <sup>b</sup>
Urodynamic stress urinary incontinence	19 (20%)	95 (67%)	<0.001 <sup>b</sup>

<sup>a</sup>Wilcoxon rank sum test.

<sup>b</sup>Chi-square test.

**TABLE IV**

Discriminant Validity: the Questionnaire-Based Voiding Diary Fluid Intake Amount and Urinary Symptom Subscale Scores for Responded and Non-Responders, Visit 3 (n = 254)

<b>QVD data</b>	<b>Responders<sup>a</sup> (N = 167)</b>	<b>Non-responders<sup>a</sup> (N = 83)</b>	<b>P-value<sup>b</sup></b>
Mean urinary symptom score (SD)	10.2 (3.3)	18.5 (4.6)	<0.001
Median total fluid intake amount (IQR) (ml)	2,074 (1,006–2,267)	2,347 (800–2,912)	<0.01
Median caffeinated beverages (IQR) (ml)	545 (240–842)	780 (355–1,242)	0.03
Mean fluid behavior score (SD)	5.3 (2.3)	11.4 (3.2)	<0.01
Mean urinary output score (SD)	9.4 (2.8)	11.8 (4.7)	<0.05

<sup>a</sup>Response to global scale of improvement.

<sup>b</sup>Wilcoxon rank sum test.



**TABLE V**

Sensitivity and Specificity of the QVD for Diagnosing the Type of Urinary Incontinence as Compared to Final Clinical Diagnosis

	<b>Stress predominant urinary incontinence</b>	<b>Urge predominant urinary incontinence</b>
Sensitivity (95% CI)	0.86 (0.78–0.90)	0.82 (0.72–0.85)
Specificity (95% CI)	0.66 (0.57–0.74)	0.79 (0.72–0.85)
Positive likelihood ratio (95% CI)	2.6 (2.0–3.3)	4.0 (2.9–5.5)
Negative likelihood ratio (95% CI)	0.2 (0.12–0.33)	0.22 (0.13–0.37)

CI, confidence interval.