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## PSYCHOMETRIC VALIDATION OF A 3-DAY BLADDER DIARY FOR THE EVALUATION OF LOWER URINARY TRACT SYMPTOMS.

### Hypothesis / aims of study

A bladder diary is recommended for accurate assessment of lower urinary tract symptoms (LUTS) and to confirm a clinical pattern in daily practice. Despite being a recommended tool, its use is not so extensive and there is not a validated model. It is necessary to standardise the measurement of symptom frequency and severity. The objective of this study was to evaluate the psychometric characteristics (feasibility, reliability and validity) of a 3-day Bladder Diary (3dBD) model in adult women with LUTS.

### Study design, materials and methods

An epidemiological, descriptive, cross-sectional study was conducted. 14 Functional Urology and Urodynamic Units from a Group of Investigation in Spain participated. Women  $\geq 18$  years old with LUTS referred to a Functional Urology and Urodynamic Unit for Urodynamic Investigation (UDS), who were able to fill in the bladder diary, were recruited. Patients with intermittent or indwelling bladder catheterisation were excluded. Patients were instructed to complete the 3dBD, the International Consultation on Incontinence - Short Form (ICIQ-SF) questionnaire and the Bladder Control Self Assessment Questionnaire (BSAQ). Women also filled in the 3dBD 15 days after they first filled it in to assess the test-retest reliability (stability over time). The diary model for validation captures the time of each void and the degree of urgency associated with each void using PPIUS (Patient Perception of Intensity of Urgency Scale). The bladder diary yields the variables: frequency, urgency, nocturia, incontinence episodes and pads, intake amount and voided volume. These variables were assessed by the researcher of each Urodynamic Unit and also centralized by the two principal investigators of the study. Each 3dBD includes 42 variables. Mean scores were calculated for each of these variables.

Table I. Description of statistical analysis.

<b>Feasibility</b>	Defined as the number of patients who complete all the 3dBD variables
<b>Test-retest Reliability</b>	-McNemar test for qualitative variables. -Intraclass correlation coefficient (ICC) for quantitative variables.
<b>Interobserver Reliability</b>	Estimated from comparisons of all pairs of responses from principal investigators -Kappa (qualitative variables) -ICC (quantitative variables)
<b>Convergent Validity</b>	- Rho de Spearman: correlation between 3dBD and ICIQ-SF for incontinence and 3dBD and BSAQ for urgency, incontinence and frequency -Kappa (3dBD and UDS)

A value of ICC>0.7 indicates satisfactory reliability.

### Results

136 women were included. Mean age (SD) 55,2 (13,8) years old. 110 women completed 3dBD for test-retest reliability.

**Feasibility:** 77,2% women completed 80% of the 3dBD variables.

Table II. Test- Retest & Interobserver Reliability and Convergent Validity

Variable	RELIABILITY			VALIDITY			
	TEST-RETEST	INTEROBSERVER		BSAQ & ICIQ-SF (Spearman)		UDS (Kappa)	
		TEST	RETEST	TEST	RETEST	TEST	RETEST
Daytime Frequency	0,74	0,95	0,93	0,551*	0,427*		
Nocturia	0,79	0,84	0,93				
24-hour Frequency	0,84	0,98	0,94				
VVmax (day time)	0,92	0,29	0,3				
VVmax (night time)	0,54	0,73	0,84				

<b>VV Average</b>	0,7	1	0,84				
<b>Urgency (Nº)</b>	0,67	0,45	0,44				
<b>Degree of Urgency</b>				0,424*	0,399*	0,299§	0,174#
<b>UUI</b>	0,87	0,95	0,86	0,585*	0,517*	0,214§	0,168#
<b>SUI</b>	0,72	0,78	0,96				
<b>MUI</b>	0,88	0,64	0,57				
<b>Pads</b>	0,91	0,86	0,98				
<b>Intake 24hour</b>	0,86	0,99	0,94				
<b>24-hour production</b>	0,83	0,99	0,98				
<b>Night production time</b>	0,75	0,95	0,97				

\*p<0,0001 §<0.01 #p=0,02

VVmax: Maximum voided volume

UUI: urge urinary incontinence

SUI: stress urinary incontinence

MUI: mixed urinary incontinence

#### Interpretation of results

Data demonstrated 3dBD to be feasible, reliable, as substantial test-retest reliability and interobserver agreement was observed, and valid as convergent validity was demonstrated in the evaluation of LUTS in women.

#### Concluding message

This study thus confirms the psychometric properties of the 3dBD.

#### Disclosures

**Funding:** Research grant Astellas Pharma Spain **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committee of Hospital Ramón y Cajal, Madrid, Spain **Helsinki:** Yes **Informed Consent:** Yes