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VALIDATION OF A REAL- TIME URODYNAMIC MEASURE OF URINARY URGENCY

Hypothesis / aims of study
Urinary urgency is a key symptom of overactive bladder syndrome (OAB) and may be more bothersome to a patient than the symptom of urinary frequency, although urinary frequency and incontinence are often the primary focus of study in the field of OAB. Unfortunately, controversy continues to surround the term 'urgency' and there is no good tool to evaluate the severity of urgency. Although we do obtain measures of bladder sensation during filling cystometry, very little formal attention has been paid to the patient experience of urinary urgency. This fact has constrained the performance of clinical research in this field. We have designed a novel device, here referred to as the 'urgeometer', which records urinary urgency on a continuous scale (e.g. from 0='No urgency at all' to 100='The most urgency I can imagine'). The device is a box with a moveable lever and with a 100 mm excursion from left to right, with the left extreme labeled with the anchor 'No urge to void' and the right extreme labeled with the anchor 'Most extreme urgency I can imagine'. The box contains a potentiometer which is linked to the moveable lever, and which has an output in volts that is proportional to the position of the lever. Output from this device is connected to a designated channel on our Laborie Multichannel Urodynamic instrument, creating a continuous display of reported urinary urgency during urodynamic testing.
Our objective was to validate the 'urgeometer' as an objective tool for evaluation of urgency symptoms. This device will be useful for better characterizations of OAB patients and for the evaluation of different treatment modalities on urgency symptoms.

Study design, materials and methods
We analyzed data from consecutive urodynamic tests undertaken at our center from August 2006 to November 2006, which included patients having urodynamic testing as part of their clinical care, and also data from 9 control subjects without lower urinary tract symptoms. During multichannel urodynamic testing, all patients underwent bladder filling while seated at a 45-degree inclination, using a Laborie multichannel urodynamic instrument and 7F microtip catheters. Catheters continuously record bladder, abdominal and urethral pressures during bladder filling at a rate of 80mL/minute with sterile room-temperature water. Before bladder filling begins, patients are asked to continuously indicate their level of urinary urgency using the Urgeometer, and also asked to indicate when they feel a 'First Desire to void' (Please tell me when your bladder is at a fullness that, if you were watching a TV show, you would feel as though you should get up and go to the bathroom at the next commercial break'), 'Strong Desire to void' ('Please tell me when your bladder is at a fullness that, if you were watching a TV show, you would get up and go to the bathroom immediately, and would not wait for a commercial break'), and 'Maximum Cystometric Capacity (MCC)' ('Please tell me when you just can't take any more water in your bladder'). Urodynamic diagnoses are otherwise made according to ICS recommendations. As part of their routine clinical care, patients also complete validated urinary symptom questionnaires including the short form of the Urogenital Distress Inventory (UDI6) and the Medical Epidemiological and Social Aspects of Aging (MESA) urinary incontinence questionnaire. Demographic data, including age, race, parity, prior surgery, medical co-morbidities, stage of prolapse and urodynamic diagnoses were recorded. We used descriptive analyses to display trends in urgency during cystometry according to eventual urodynamic diagnosis. Growth curve models with random intercepts were fit to the data in order to capture the trend of urgency by increasing percentage of MCC. ANOVA was used to compare urgency sensation at 50% of MCC across different diagnoses groups. Correlation analysis was performed to corroborate the association between urge sensation at 50% of MCC and scores on validated questionnaires (MESA, UDI6).

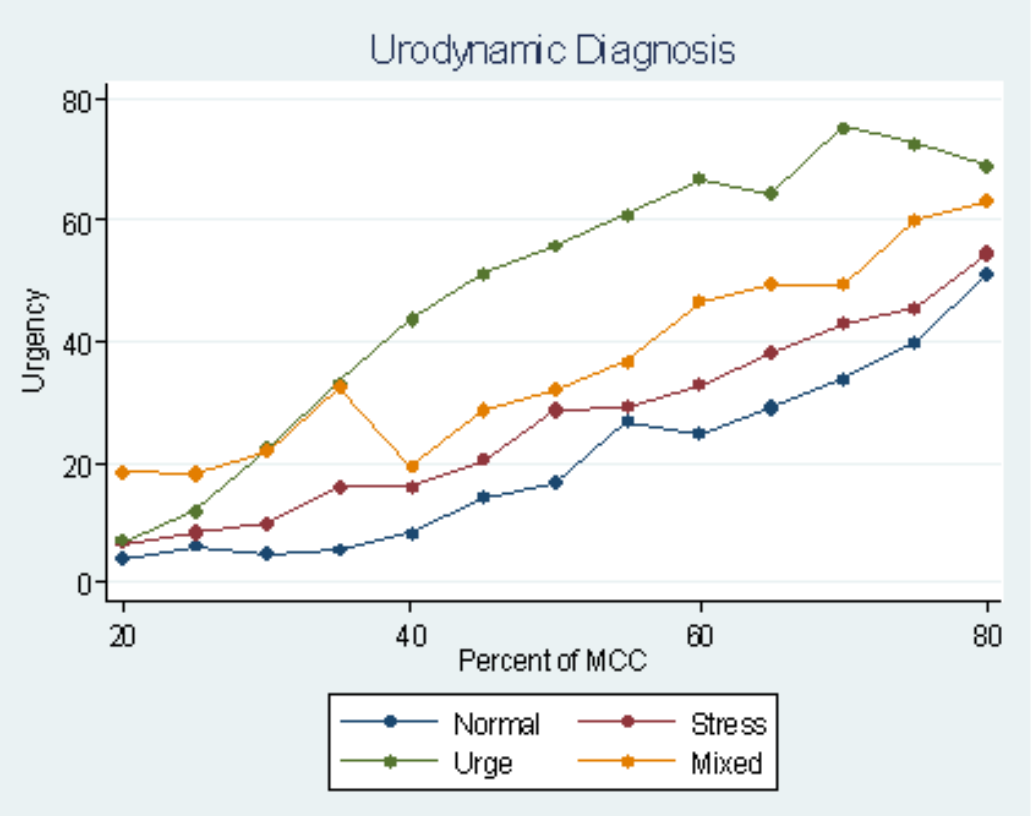
Results:
Fifty-one subjects with mean age of 58 years (range 26-86) old were included in the study. Urodynamic diagnoses included 9(18%) patients with mixed incontinence, 18(34%) patients with pure urgency incontinence, 15(30%) patients with pure urodynamic stress incontinence and 9(18%) patients with no abnormalities demonstrated. Figure 1 depicts the increase in urge sensation as the percent MCC increases, according to urodynamic diagnosis. Growth curve models estimate the change in urge sensation per 1% increase in %MCC for each of the four groups categorized by urodynamic diagnosis. The incremental growth varies between 0.69 and 0.72 for normal and stress incontinent groups respectively compared to 0.82 and 0.92 for the mixed and the urge incontinent groups respectively. In the volume range between 35% and 75% of MCC, urgency values differed significantly between the four groups ($p<.04$). A moderate correlation was found between the urge sensation at 50% of MCC and the UDI6 and total MESA urge subscale scores ($\rho=0.34$, $p<0.03$ and $\rho=0.39$, $p<0.02$ respectively). The mean urgency level as recorded by the 'urgeometer' at first desire (21±18), strong desire(68±27) and MCC (85±21) was significantly different ($p <0.001$). Among the three indicators, strong desire was the only measure that discriminated between the three urodynamic diagnosis groups (urge, stress, and mixed) ($p<0.04$).

Interpretation of results
We provide preliminary evidence of the validity of a continuously recorded measure of urinary urgency that can be used during urodynamic testing.

Concluding message
Evaluation of bladder sensation offers a potentially valuable new tool for assessing disordered lower urinary tract function.The urgeometer provides a continuous record of urgency level during bladder filling and correlates reasonably well with questionnaire measures of lower urinary tract symptoms. Further studies are needed to investigate the clinical implications of this novel tool.

Figure1.

Increase in urge sensation as the percent MCC increases in four different urodynamic diagnostic groups



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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the IRB-Loyola Medical Center, Chicago and followed the Declaration of Helsinki Informed consent was not obtained from the patients.