

A SIMPLE WELL VALIDATED METHOD FOR MEASURING URINARY URGENCY

Hypothesis / aims of study

In recent years there have been a number of publications describing different methods for measuring urgency, these including electronic diary records and warning time measurement. A primary motivation is that we lack reliable methods for detecting between drug differences in efficacy in the treatment of the overactive bladder (OAB)

In 2005 a paper in the J.Urol presented data that indicated that it should be possible to measure the symptoms of urgency by referencing the circumstances under which patients experienced this symptom. In this study it was found that the least frequency and incontinence tended to be associated with urgency on waking and rising and on getting home to put a key in the door (latchkey urgency). The middle grades of frequency and incontinence were additionally associated with urgency precipitated by the sound of running water and cold weather. The worst frequency and incontinence saw the addition of urgency aggravated by fatigue or worry. The linear qualities of these relationships suggested a simple summed scale which is illustrated in this table, as a means of measuring urgency.

Question	Yes Score	No Score
Do you suffer from urgency?	1	0
Do you suffer from urge incontinence?	1	0
Do you have urgency on rising after waking in the morning?	1	0
Do you have urge incontinence on rising after waking in the morning?	1	0
Do you have urgency on putting a key in the front door when arriving home (latchkey urgency)?	1	0
Do you have urge incontinence on putting a key in the front door when arriving home (latchkey urgency)?	1	0
Do you have urgency aggravated by the sound of running water?	1	0
Do you have urge incontinence aggravated by the sound of running water?	1	0
Are your urge symptoms aggravated by cold?	1	0
Are your urge symptoms aggravated by fatigue or anxiety?	1	0
Possible Maximum and Minimum Scores	10	0

A scale must pass a number of tests in the process of validation : Construct Validity, Internal Consistency, Reliability (Test-retest & Inter-observer), Internal Responsiveness, External Responsiveness.

Study design, materials and methods

215 patients (188 female, 27 male) with a mean age of 56 (sd=20) who had been diagnosed with an overactive bladder, were treated with a bladder retraining regime and antimuscarinic agent. They were followed up and their responses recorded. CR Oxybutynin 10 mg nocte or SL Tolterodine 4 mg nocte were used.

Construct validity is a measure of how the scale performs when compared with an appropriate standard. Average daily frequency and average daily incontinence were chosen as appropriate comparators and Spearman's correlation coefficient measured the association

Internal consistency examines whether the items which compose the scale are related to one another. The assessment is achieved by calculating Cronbach's alpha (α) where $\alpha=1$ indicates identical and perfectly correlated items and $\alpha=0$ indicates independent items. A Cronbach's alpha 0.8 is regarded as satisfactory.

Reliability was measured in two ways. **Test-retest reliability** and **Inter-observer reliability**. For numerical data the reliability can be assessed by calculating Pearson's product moment correlation. The questionnaire was applied to a sample of patients twice by two different clinicians working in the same clinic who each interviewed the patients using a randomised chronology. Another group of patients were asked to complete the questionnaire on two occasions prior to undergoing treatment for their symptoms. The operators were blind to the comparative data. In both cases the datasets were assessed for their correlative properties.

Internal responsiveness was assessed by two different experiments that used a single group repeated measure design. The patients had already been pre-treated with standard antimuscarinic therapy and bladder retraining but were dissatisfied. They were allocated either to receive imipramine in addition to their extant medication or their current antimuscarinic was swapped for solifenacin. The ability of the scale to detect the effects of treatment change were measured by the ANOVA and by calculation of the standardised response mean (SRM). This is the mean change

divided by its standard deviation and is used to measure internal responsiveness. Values of 0.20, 0.50 and 0.80 have been proposed to represent small, moderate and large responsiveness, respectively.

External responsiveness reflects the extent to which changes in a measure relate to corresponding changes in an alternative measure, that would be considered to be an accepted assessment of health status in the domain of interest. The score was compared to the patients' grading of their state, "Worse", "No change", "Better", in response to treatment.

Results

Construct validity: For frequency Spearman's $R = 0.38$ ($p < 0.001$); for incontinence Spearman's $R = 0.15$ ($p < 0.001$)

Internal consistency: Cronbach's alpha (α) calculated from 8247 cases from the ten items $\alpha = 0.83$

Test-retest reliability: Pearson's $R = 0.99$, $p < 0.001$, $N = 30$

Inter-observer reliability: Pearson's $R = 0.99$, $p < 0.001$, $N = 58$

Internal responsiveness: Imipramine add-on study- 130 patients (115 female, 15 male; mean age=58, SD=18) $F = 15$, $df = 2$, $p < 0.001$ $SRM = -0.6$ – Solifenacin swap study - 130 patients (108 female, 22 male; mean age=58, SD=19) - $F = 17$, $df = 2$, $p < 0.001$ $SRM = -0.67$.

External responsiveness: $F = 36.7$, $df = 2$, $p < 0.001$ $SRM = -0.69$

Interpretation of results

This scale succeeded in all of the validation tests and now needs to cut its teeth in a proper double blind randomised controlled trial.

Concluding message

This new scale promises to prove useful in measuring between drug differences in efficacy and in monitoring treatment responses in patients with OAB

References

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2. *BJU.Int.* 2005;95:335-40.
3. *J.Reprod.Med.* 1996;41:801-6.
4. *J.Urol.* 2005;173:1214-8..

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HUMAN SUBJECTS: This study was approved by the Whittington and Moorfields Research Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.