119

Bowden A[1], Colman S[2], Sabounjian L [3], Sandage B [3], Schwiderski U [3], Zayed H[2]
1. The Lewin Group, Quintiles UK, 2. Quintiles Late Phase, 3. Indevus Pharmaceuticals

PSYCHOMETRIC VALIDATION OF AN URGENCY SEVERITY SCALE (IUSS) FOR PATIENTS WITH OVERACTIVE BLADDER.

Aims of Study

This U.S. study sought to validate the psychometric properties of an Urgency Severity Scale (IUSS), a new patient-reported outcome assessment instrument for patients with overactive bladder (OAB). The IUSS required a 'quality assessment' to ensure it is a valid, reliable and responsive patient-reported outcome assessment tool.

Methods

This study was based on data collected as a result of administering the IUSS during a 12-week multi-center, parallel, randomized, double-blind, placebo-controlled clinical trial of trospium chloride in patients with OAB associated with predominant urge incontinence. The IUSS was contained within a 'patient urinary diary' that was completed by patients during four 1-week periods in the course of the trial. The IUSS asks patients about their 'degree of urgency' of their toilet voids, and requires that they rate the degree of urgency on a scale as follows:

0: NONE - no urgency
1: MILD - awareness of urgency, but *easily tolerated*
2: MODERATE - enough urgency discomfort that it *interferes with* usual activity/ tasks
3: SEVERE - extreme urgency discomfort that abruptly *stops all* activity/tasks

The patient urinary diary also collected information on the number of toilet voids, urge incontinence (UI), and stress incontinence episodes; and the volume voided (mL). In addition, patients completed the Incontinence Impact Questionnaire (IIQ). Patients were randomized to receive either trospium chloride or placebo, however for the psychometric assessment all patients were pooled into one cohort (n=523). Sensitivity analysis was conducted to ensure that the inclusion of the trospium group into the patient cohort at week 12 was a valid approach. There were two distinct study periods for the psychometric assessment referred to as the baseline and week 12 data collection periods.
Psychometric methods used to evaluate new and adapted patient-reported outcome instruments include standard procedures for the assessment of reliability, validity and responsiveness. Construct validity of the IUSS was assessed by correlating IUSS scores with urinary frequency, frequency of UI episodes, average volume voided per toilet void, and scores on the IIQ. The Mann-Whitney U and CMH tests were used to determine if the IUSS could distinguish between patient's frequency of toilet voids and UI episodes. The effect size statistic was used to assess the responsiveness of the IUSS using toiled void and UI frequency as external criteria to categorize the patients as responders or not. Correlating IUSS scores between day 1 and day 7 at baseline, and day 2 and day 5 at baseline assessed the test-retest reliability of the IUSS. Content validity and respondent burden were examined through a literature review. P-values ≤ 0.05 were considered significant; p-values >0.05 and ≤ 0.10 were thought to represent a trend towards significance.

Results

This study demonstrated the IUSS to be psychometrically sound in terms of construct, content and known groups validity, test-retest reliability and to be responsive to change. The IUSS distinguished between those who scored above and below the median number of toilet voids per 24 hours as well as the median number of UI episodes per 24 hours at baseline and week 12 periods ($p<0.01$). The IUSS was highly responsive to change in the average number of toilet voids per 24 hours (effect size 1.17) and the average number of toilet voids and UI episodes per 24 hours combined (effect size 1.39). It was moderately responsive to change in the average number of UI episodes per 24 hours (effect size 0.49). The IUSS has low-to-moderate correlation with frequency of toilet voids, frequency of UI episodes and scores on

the IIQ. IUSS scores did not correlate with the average volume voided (mL) per toilet void. The test-retest reliability of the IUSS for day 1 vs. day 7 during the baseline period was moderate (0.66) and high (0.80) for day 2 vs. day 5 during the baseline period. The content validity of the IUSS determined that it is a measure of the magnitude (or severity) of urgency associated with OAB and can also be used to determine the frequency of urgency associated with toilet voids. The IUSS is a single-item scale with four possible responses and therefore the respondent burden is minimal.

Conclusions

The IUSS is a single-item scale that has been developed as a self-report instrument for use in clinical trials. It is a measure of the magnitude (severity) of urgency associated with OAB and can also be used to determine the frequency of urgency associated with toilet voids. The psychometric assessment of the IUSS performed retrospectively on data collected during a 12-week clinical trial for trospium chloride demonstrated the IUSS to be a psychometrically valid scale in terms of construct, content and known groups validity, test-retest reliability, and to be responsive to change.