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PILOT ASSESSMENT OF THE PSYCHOMETRIC PROPERTIES OF THE ICIQ-UAB PATIENT REPORTED OUTCOME INSTRUMENT IN PATIENTS WITH DETRUSOR UNDERACTIVITY

Hypothesis / aims of study

The ICIQ-UAB is the first patient reported outcome (PRO) measure for the assessment of the symptoms and impact associated with underactive bladder (UAB), developed in-line with the Food and Drug Administration (FDA) PRO guidance (2009, 2014). UAB is the proposed symptom complex associated with urodynamically diagnosed detrusor underactivity (DU). This study describes the pilot testing of the psychometric properties of the draft ICIQ-UAB in patients with known DU. Based on the initial qualitative interview phase, a draft of the ICIQ-UAB was developed consisting of the following domains:

- Medical history and related bother (3 items)
- Symptoms, signs and related bother (20 items)
- Impact and related bother (8 items)

To assess the measurement properties, the reliability (test-retest reliability, internal consistency), validity (known group validity, convergent and divergent validity) and item distribution of the draft ICIQ-UAB were investigated. For symptom and sign items, different versions with a 24 hour and 1 week recall period were tested.

Study design, materials and methods

Patients recruited for the study met eligibility criteria based on pressure flow study (PFS) parameters for DU. Patients completed paper versions of the ICIQ-UAB and seven validated concurrent PRO measures relating to general health, urinary symptoms, and severity, over a period of 10 days. ICIQ-UAB (1 week) was completed on days 1 and 8, and ICIQ-UAB (24 hr) on days 1, 2, 3 and days 8, 9, 10.

Results

A total of 54 patients with a primary diagnosis of DU on PFS were recruited from 8 sites in the United Kingdom, Netherlands and Germany. The mean age was 61.2 years, 80% were male (n=43) and all patients were Caucasian. Overall, the level of missing data on items was less than 7%. Items were considered to have a floor effect if >20% of the patients answered the lowest response option (1st of 5). A total of 9 of 20 of the symptom and sign items and all of the impact items in the ICIQ-UAB (1 week), and 12 of 20 symptom and sign items in the ICIQ-UAB (24 hr) had floor effects. Following sub-group analysis using subjects with moderate to severe symptoms as determined by the Patient Global Impression of Severity (PGI-S), the floor effects found were reduced to 4 symptom and sign items in the ICIQ-UAB (1 week) and 3 symptom and sign items in the ICIQ-UAB (24 hr). Internal consistency for the ICIQ-UAB (1 week) was high (Cronbach's $\alpha = 0.85$), and similar for the ICIQ-UAB (24 hr) ($\alpha = 0.86$). Table 1 shows the intra-class correlation coefficient (ICC) for the ICIQ-UAB (1 week) and ICIQ-UAB (24 hr) when calculated between consecutive administrations in 'stable' patients (n=42) as determined by the Patient Global Impression of Change (PGI-C).

Table 1. Test-retest reliability of the ICIQ-UAB (1 week) and ICIQ-UAB (24 hr) scores (between consecutive administrations).

ICIQ-UAB 1 week (Day 1 and day 8)	**ICC**	**95% CI**
All items	0.91	0.84-0.95
Symptom and sign items	0.90	0.82-0.94
Impact items	0.90	0.83-0.95
ICIQ-UAB 24 hr		
Day 1 and day 2	0.88	0.78-0.93
Day 2 and day 3	0.92	0.86-0.96
Day 8 and day 9	0.93	0.88-0.96
Day 9 and day 10	0.94	0.88-0.97

Evidence for scale construct validity for both versions based on correlations with concurrent PRO measures was acceptable. The symptom subscales of both versions were able to differentiate between groups of known severity: participants with moderate to severe symptoms (based on the PGI-S) had higher scores (analysis of covariance $p<0.005$).

Interpretation of results

Overall, the ICIQ-UAB, both 1 week and 24 hour versions, showed acceptable reliability and validity. The internal consistency and test-retest reliability were above the standard threshold of 0.7 to indicate acceptable reliability in both versions. Convergent and discriminant validity was demonstrated by the correlations with concurrent PRO measures. The analysis of groups of known severity supports the validity of the symptom subscales. The high floor effects found on some items may indicate further revisions (revised response options, deletion of items, or removal of items from the scoring) are required.

Concluding message

These results provide initial evidence to support the reliability and validity of both versions of the draft ICIQ-UAB in a pilot setting. Following minor revisions, further assessment of the measurement properties will be conducted in larger studies, to confirm the suitability of the ICIQ-UAB for use as a research and clinical outcome measure.

Disclosures

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