## 179

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# THE DEVELOPMENT AND VALIDATION OF A NEW QUESTIONNAIRE (ICIQ) TO MEASURE CARE EFFORTS AND SYMPTOM-RELATED IMPACT OF URINARY INCONTINENCE IN COGNITIVELY IMPAIRED ADULTS

#### Hypothesis / aims of study

For the assessment of urinary incontinence in clinical practice and research several validated ICIQ modules are available for urinary tract symptoms, vaginal and lower bowel symptoms. Additionally sexual matters and quality of life modules will become available for each condition area. Although these modules are feasible for different patient groups, there is still no validated assessment tool for the specific group of cognitively impaired often older adults with incontinence, unable to fill out a questionnaire by themselves.

For this purpose, a new measure ICIQ-tool has been created in accordance with the ICQ- Advisory board to assess diseaserelated bother and nurses' care efforts in the specific group of cognitively impaired adults with incontinence. Existing incontinence questionnaires are not including the special needs of frail elderly and neglect the impact of incontinence care on the caregiver. Given the fact that due limited financial resources work load of the caregivers, especially those of the frail elderly, is increasing, additional methods to evaluate workload on caregivers are warranted.

## Study design, materials and methods

A correlational, test-retest design was applied to assess disease and caregiver outcomes and to analyse the psychometric properties of the new ICIQ assessment tool consisting of two measures: a)The Health-Care-Index (HCI) assessing disease-related bother by observing corresponding behavioral (emotional, motoric, physiological) characteristics of clinical and care giving relevance, and b) the Nurse's-Care-Index (NCI) assessing the level of the care efforts with respect to the special needs of this patient group. The initial item pool was developed by selecting appropriate items from existing ICIQ questionnaires and by creating new items based on patient- and caregiver interviews carrying out to cover the special needs of this clinical sample. The items used in this study have been created after a "blank-paper-meeting" like demanded by the WHO. Experts were instructed to notice relevant aspects of care and behavioral indicators of incontinence combined with cognitive limitations. In this study the inclusion criteria for participation have been controlled by confirming the diagnosis of incontinence and by examining the cognitive function of the participants with two cognitive tests (Mini Mental State Examination and Global Deteriotation Scale). The psychometric properties of the new assessment tool were explored using different methods: a) factor analyses for categorical variables (EFA and CFA), using a weighted least squares estimator and oblique rotation criterion to assess the construct validity, b) computation of internal consistency (Cronbach's alpha) and stability (test-retest reliability) to determine the reliability of the scales, and c) correlation analyses between the new measures and standard measures (SF-12 and a Rasch-based measure to assess activity restrictions) to provide preliminary results on the criterion of validity.

#### Results

A total of 60 adults aged between 62 and 100 years (m=87, sd=7) recruited from two nursing homes in Germany enrolled in the study (ethics vote no. 182/13, University Bonn). All participants suffered from incontinence (41.7% urinary incontinence, 53.3% mixed incontinence) and mild to severe cognitive limitations (MMST< 24, GDW >3). The mean duration of incontinence was 2.65 years (sd = 2.6), the mean length of stay in the nursing homes was 42 months (sd = 36).

<u>ICIQ-Health-Care-Index (HCI)</u>. A short form has been created composed of 8 items that fulfilled the psychometric requirements of unidimensionality ( $\chi 2 = 21.2(20)$ , p>.05, RMSEA=.03, CFI/TLI=.99/.99, SRMR=.08). The confirmatory factor analysis of the re-test also revealed unidimensionality ( $\chi 2 = 27.4(20)$ , p>.05, RMSEA=.07, CFI/TLI=.99/.99, WRMR=.51). The internal consistency for the two measurement times was  $\alpha = .78$  and  $\alpha = .87$ , respectively. The retest-reliability amounted to r= .56.

<u>ICIQ-Nurse's-Care-efforts-Index (NCI)</u>. The Confirmatory Factor Analyses confirmed the unidimensionality of NCE (t1:  $\chi 2 = 4.4(5)$ , p>.05, RMSEA=.0, CFI/TLI=1/1.05, SRMR=.06). The internal consistency for the two measurement times was  $\alpha = .69$  and  $\alpha = .79$ , respectively. The retest reliability was r=.83.

<u>Correlation analyses</u>. The disease-related burden measured with ICIQ-HCI and the nurses' care-effort-index (ICIQ-NCI) correlated with severity of incontinence indicated by the number of nocturnal episodes of incontinence (HCI: r=.66, NCI: r=.62, p<.01) and with outcomes concerning care management like average portion of continence care with respect to the patient being assessed HCI: r=.41, NCI: r=.46, p<.01, the experienced workload by caring the patient (NCI r=.35, p<.01) or the work experience of the nurses (HCI: r= -.40, NCI: r= -.62, p<.01). The ICIQ-NCI correlated with sf12 (r= -.58, p<.01). No other significant correlations between the new assessment tool and the AAPI or sf12 were obtained.

#### Interpretation of results

The ICIQ measures HCI and NCI have been developed and evaluated specifically for cognitively impaired adults with incontinence. The content validity was ensured by a careful item construction process and supported by an expert panel ("blank paper meeting"). Both measures produce reliable scores in terms of internal consistency and stability over time. The construct validity was supported by a unidimensional structure of the items in each scale. Preliminary results on criterion validity showed a low association between the HCI and the generic instrument sf12 indicating that disease-related burden may vary independent of the general status of well-being and functional health; on the other side the association of JH MZto NCI indicates that nurses are likely to make more care efforts by decreasing stage of the patients' well-being. Further, the low association between both new measures and the AAPI also seems to support the disease-specific design of HCI and NCI as they may not cover general activity and participation restrictions assessed by AAPI. This may be due to the broad spectrum of incontinence forms and causes.

Concluding message The new ICIQ rating scales HCI and NCI show promise as valid outcome indicators for assessing and monitoring disease-related symptom-behaviour and care status among cognitively impaired adults with incontinence. Further data on criterion validity should be obtained through an additional study.

### **Disclosures**

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