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THE PSYCHOMETRIC PROPERTIES OF THE PRAFAB QUESTIONNAIRE: A BRIEF ASSESSMENT QUESTIONNAIRE TO EVALUATE SEVERITY OF URINARY INCONTINENCE IN WOMEN

Hypothesis / aims of study
To determine the psychometric properties of the (5-item) PRAFAB-questionnaire (PRAFAB-Q) in a group of patients with predominantly stress or urgency urinary incontinence (UI) to justify its use in clinical practice and research. The second aim was to replicate the results in a new set of data and to determine the factorial validity, internal consistency and minimal important change (MIC). The MIC could be used as a threshold by which practitioners decide to continue, change or end a specific intervention.

Study design, materials and methods
Psychometric properties were assessed in an observational cohort of patients with primary or recurrent stress or urgency UI referred for physiotherapy treatment (N=99). Data from a prognostic cohort study of 279 mainly Caucasian women with a primary or recurrent episode of stress urinary incontinence was used as the replication sample to investigate the factor structure, construct validity and to estimate the MIC (including test-retest reliability). A cross validation study design was used to investigate the factor structure and construct validity in 279 patients who were randomly divided in sample A or B. The MIC was determined in the same cohort by: (1) the 'mean change' method, (2) the 95% limit cut-off point, and (3) the ROC method, visualized by the anchor-based MIC distribution. These MIC values were compared to the smallest detectable change (SDC) accounting for measurement error. The effect of initial baseline scores on the MIC was assessed.

Results
Out of 99 enrolled women in our first study, 87 were classified as stable at 10 days and included for analyses. Factor analysis suggests a single strong underlying factor in both UI groups and the appropriateness of a total score. The PRAFAB-Q scores in both UI groups demonstrated excellent test-retest reproducibility (high ICCs [0.93-0.95] and kappa scores for individual items) and excellent internal consistency (Cronbach's alpha's: 0.82). The PRAFAB-Q was able to discriminate between both patient groups with excellent correlations (0.79-0.89) with patients' perceived benefit on the global rating scale indicating excellent construct validity. Spearman's correlation coefficients between the mean number of UI events per day as measured with the 4-day diary and the 'frequency' item of the PRAFAB-Q was 0.41 (p=0.002) for the stress UI and 0.67 (p=0.000) for the urgency group. Responsiveness to clinical improvement for both groups was shown to be excellent with large effect size statistics.
The second study confirmed the high test-retest reliability (ICC non-severe group =0.91; ICC severe group =0.70), the responsiveness (with large effect sizes) and estimates of the MIC. The results of all methods used to define the MIC were finally based on our larger cohort study and ranged from -1.9 to -2.7 points (SDC = -1.6) for the non-severe and -3.6 to -4.1 (SDC = -2.3) for the severe classified patients. These estimates were very close to those estimated in our first study. All MIC estimates were larger than the measurement error as determined by the SDC in both studies.

The data of the second study was also used to investigate the factorial validity, internal consistency and construct validity. In our previous psychometric study we were not able to demonstrate a two-factor solution as was theoretically expected: the more objective UI 'leakage severity' items and the more subjectively 'perceived symptom impact' items. The most likely explanation was that our study was underpowered for appropriate factor analyses but, on the other hand, the PRAFAB-Q may also have only one strong underlying factor. The data in our larger prospective cohort study (N=279) allowed us to investigate the multi dimensionality and expected two-factor structure of the PRAFAB-Q score more appropriately by using a cross validation study design. Confirmatory factor analyses resulted in a two-factor structure or subscales: items related to 'leakage severity' (protection, amount and frequency) and items related to its 'perceived symptom impact' or consequences of stress UI on the patient's life (adjustment and body (or self) image). The patterns of the factor loadings were fairly identical for both study samples. The two constructed subscales demonstrated adequate internal consistency with Cronbach's alphas in a range of 0.78 and 0.84 respectively. Scale scores differed by demographic characteristics according to the expectations and supported the construct validity of the scales as demonstrated in our first study.

Interpretation of results
The 5-item PRAFAB-Q is a brief outcome measure with demonstrated psychometric properties that easily can be used to document the severity and impact of UI in individuals, to support clinical-decision making and to interpret meaningful improvement or change in individual women with stress UI in every day's clinical practice. Summary indices of the two subscales 'leakage severity' and its 'perceived symptom impact' may be used as separate outcomes in future research, thereby emphasising that the questionnaire contains two different concepts.

Concluding message
The quick and easy to administer PRAFAB-Q demonstrated good psychometric properties to justify its use in clinical practice and research to evaluate treatment effects for (stress) UI in women. However generalization of the two-factor solution for different types of UI or male population is unclear. Future validation with other health status or quality of life measurements and replication of these findings is still necessary for different clinical settings, types of UI, gender and the (institutionalised) elderly.

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Institutional Review Board of the Deventer Ziekenhuizen (The Netherlands), gave medical ethical approval.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**