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PATIENT-REPORTED OUTCOME MEASURES FOR NOCTURIA

Hypothesis /Aims of Study:
It is commonly assumed that the number of times an individual reports waking at night needing to pass urine is the appropriate marker of treatment efficacy for nocturia. However, not all patients with nocturia report the same frequency night to night or level of bother. Given the multifactorial causal pathway, the high prevalence of clinically relevant comorbidities and the potential floor effect of nocturia frequency, this may be an insufficient measure.

The primary aim of this study was to investigate predictors of nocturia bother and episode frequency in order to identify variables that can be individualized as additional outcome measures of treatment efficacy. A secondary aim was to identify variables that either amplify or modify the bother associated with nocturia.

Study Design, Materials & Methods:
Prospective data from tertiary hospital Urology and Continence cohorts was matched for identical variables and merged to generate a sample of 204 datasets. Factors associated with atypical nocturia constituted exclusion criteria: end-stage renal failure, bladder cancer, previous pelvic radiotherapy and terminal malignancies, and any form of urinary catheterisation.

Items in the datasets were derived from commonly used validated questionnaires available in both English and Flemish. Source metrics for items included the Pittsburgh Sleep Quality Index (PSQI), ICIQ-Overactive Bladder (ICIQ-OAB), ICIQ-Female Lower Urinary Tract Symptoms Long Form (ICIQ-FLUTS), ICIQ-Male Lower Urinary Tract Symptoms Long Form (ICIQ-MLUTS) and Nocturia Quality of Life (NQoL) patient-completed metrics. Approval was obtained from the Human Research Ethics Committee at each institution.

Descriptive analysis, univariate and multivariate logistic regression were performed. Variables independently predictive of i) nocturia frequency ≥2 times/night and ii) moderate to extreme nocturia-related bother (regardless of nocturia frequency) were identified and formatted into patient-reported outcome measures (PRO).

Results:
Sample characteristics: median age 67 years (IQR 56-75 years); 55% female; average BMI 26.3; diagnosis of hypertension 43%; nocturia frequency 1-11 episodes per night, median 2.0 night voids.

Variables predictive of nocturia ≥2 per night were: moderate to extreme bother (OR 7.34); daily urgency (OR 5.29); short time to first waking to void or FUST (OR 0.26); low sleep efficiency (OR 2.37); sleep disturbed by uncomfortable breathing (OR 5.94) and bad sleep quality (OR 2.37). Independent predictors that explained 44-61% of the variance of high frequency nocturia were FUST, bother and daily urgency. This model correctly classified 89% of affected patients.

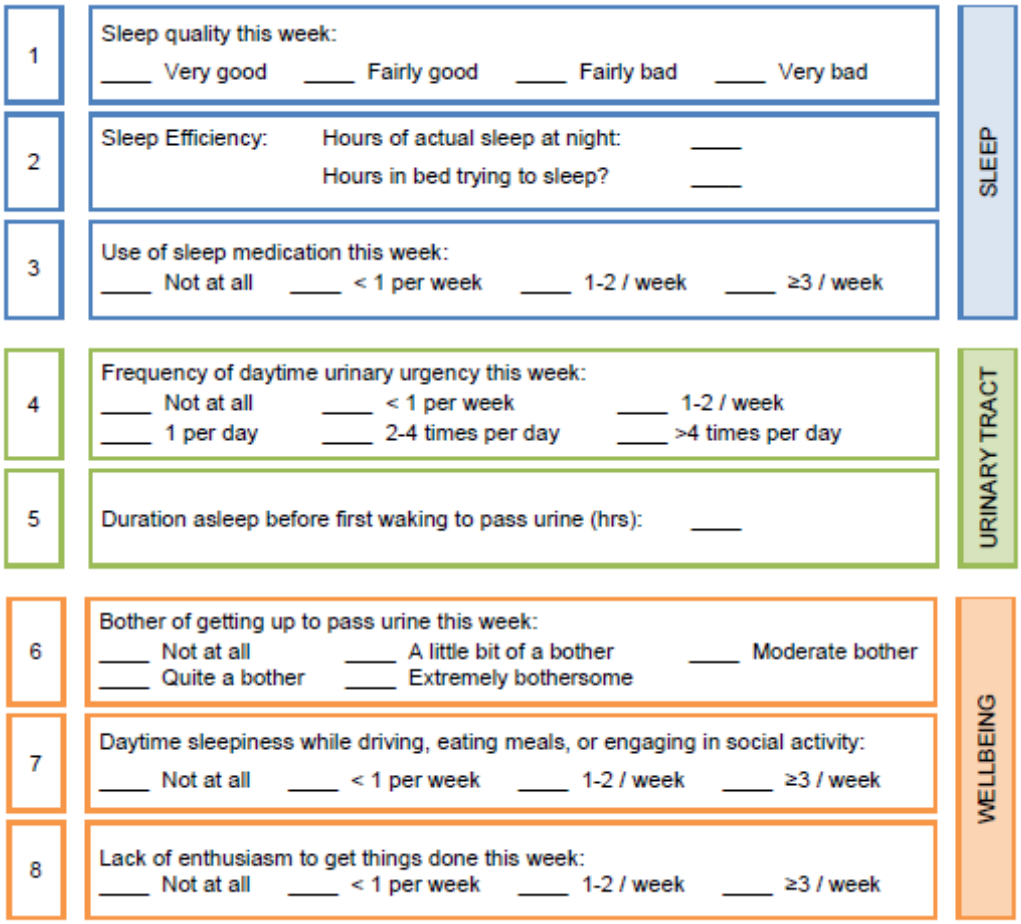
Predictors of moderate to severe nocturia-related bother were: fair to very bad sleep quality (OR 4.13), short FUST (OR 0.60), daily urgency (OR 2.78), high nocturia frequency (OR 1.70) and weekly use of sleep medication (OR 2.24). This model explained 21-29% of the variance in nocturia bother and correctly classified 84% of individuals.

High bother related to a single episode of nocturia was associated with impaired sleep (quality and total hours of sleep), use of sleep medication and daytime fatigue. Older age, male gender and urgency were protective against high bother in patients with multiple episodes of nocturia.

Interpretation of Results:
Data was used to develop a suite of individualised outcome measures for nocturia that address domains of importance to individual patients (Figure 1). Items were drawn from validated and reliable metrics.

Concluding Message:
This is the first study to translate individual multifactorial aetiological data into a clinically useful framework that allows patients to prioritise aspects of nocturia impact. Treatment efficacy can then be evaluated based on change in patient-selected variables of importance. These measures sit alongside self-report of nocturia frequency.

Figure 1: Patient-Reported Outcome Measures for Nocturia



Disclosures
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