

## HOW MANY NOCTURIA EPISODES IS CLINICALLY MEANINGFUL? RESULTS OF A POPULATION-BASED STUDY

### Hypothesis / aims of study

Nocturia is common and disrupts sleep. The International Continence Society defines nocturia as waking at night one or more times to void. Historically, having  $\geq 2$  nightly episodes has been regarded as being clinically meaningful, yet the scientific rationale for this remains unclear. We aimed to assess the relation between nocturia episodes and bother, and impact of nocturia on health-related quality of life (HRQoL).

### Study design, materials and methods

Questionnaires were mailed to 6,000 Finns aged 18-79 years, randomly drawn from the Population Register. A nocturia frequency score based upon respondent answers to the American Urological Association Symptom Index (1) and the Danish Prostatic Symptom Score (2) was examined in relation to bother from nocturia and HRQoL. Bother from nocturia was on a scale none-small-moderate-major. HRQoL was measured by the validated, generic 15D instrument (3). The 15D consists of 15 dimensions. Each dimension has a single question with 5 response options. The 15D can be used as a profile measure or to give a single index score (15D Score) by means of population-based preference weights. The index score is between 0 (being dead) and 1 (being totally healthy); 0.03 is regarded as the minimum clinically important difference in the 15D Score (3). The age-standardised prevalence was calculated using the population structure of Finland.

### Results

Of the subjects, 3,727 (62.4%) took part, and of them 130 were excluded due to pregnancy, puerperium, or urinary tract infection. The degree of bother increased as nocturia frequency increased ( $p < 0.001$ ) (**Figure 1**). On average, bother from 1 void/night was "none", 2 voids/night "small", and 3 voids/night and  $\geq 4$  voids/night "moderate" or "major". There was no difference between sexes in the age-standardized prevalence of nocturia by degree of bother (**Figure 1**). Among men, age did not affect perceived bother but among women, increasing age was associated with less bother from nocturia ( $p < 0.001$ ,  $p = 0.001$ ,  $p = 0.016$ , and  $p = 0.080$  for women with 1, 2, 3, or  $\geq 4$  voids/night, respectively). The mean age-adjusted 15D score for men (women) without nocturia was 0.953 (0.950), 0.925 (0.927) with 1 void/night, 0.898 (0.890) with 2 voids/night, and 0.833 (0.840) with  $\geq 3$  voids/night. The differences between the groups (within sex) were statistically significant. Nocturia was associated with statistically significant decrease in all 15 dimensions of HRQoL, except eating (**Figure 2**).

### Interpretation of results

We conducted a questionnaire survey in a representative sample of Finnish people and achieved a high response rate. Having  $\geq 2$  nocturia episodes (compared to zero) and having  $\geq 3$  nocturia episodes (compared to  $\leq 2$ ) is associated with clinically meaningful differences in HRQoL. The majority of respondents report nocturia being at least moderate bother only once there are 3 or more nocturia episodes, though responses varied.

### Concluding message

The majority of respondents report nocturia being a bother once there are 2 nocturia episodes and moderate or major bother only once there are 3 or more nocturia episodes. Having  $\geq 2$  nocturia episodes is associated with meaningful differences in HRQoL.

**Figure 1.** Age-standardized prevalence of bother by frequency of nocturia.

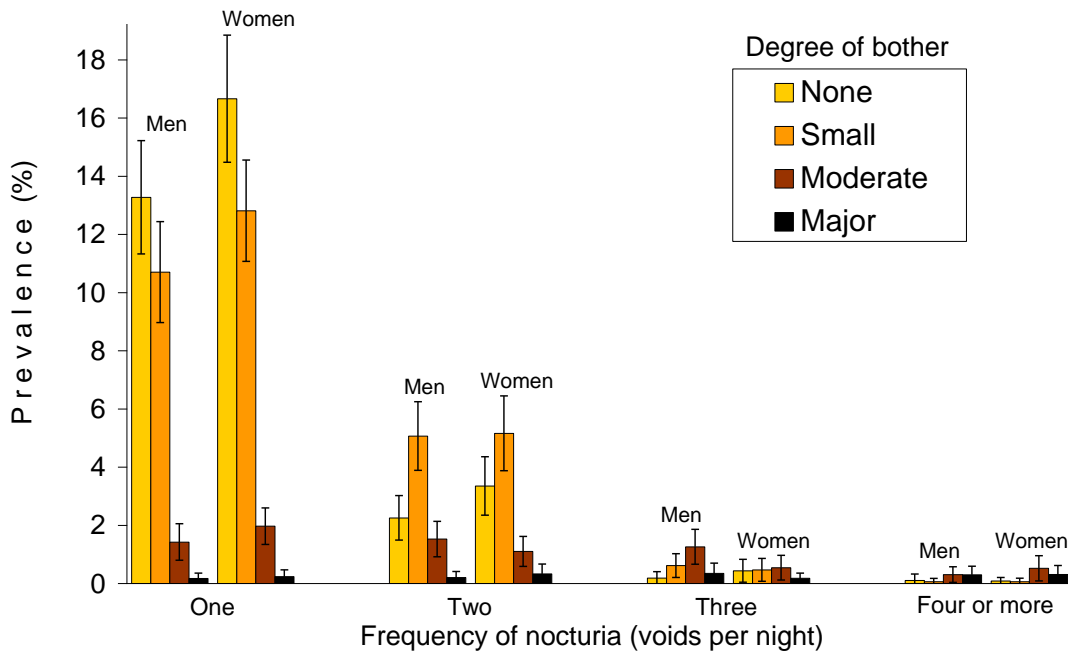
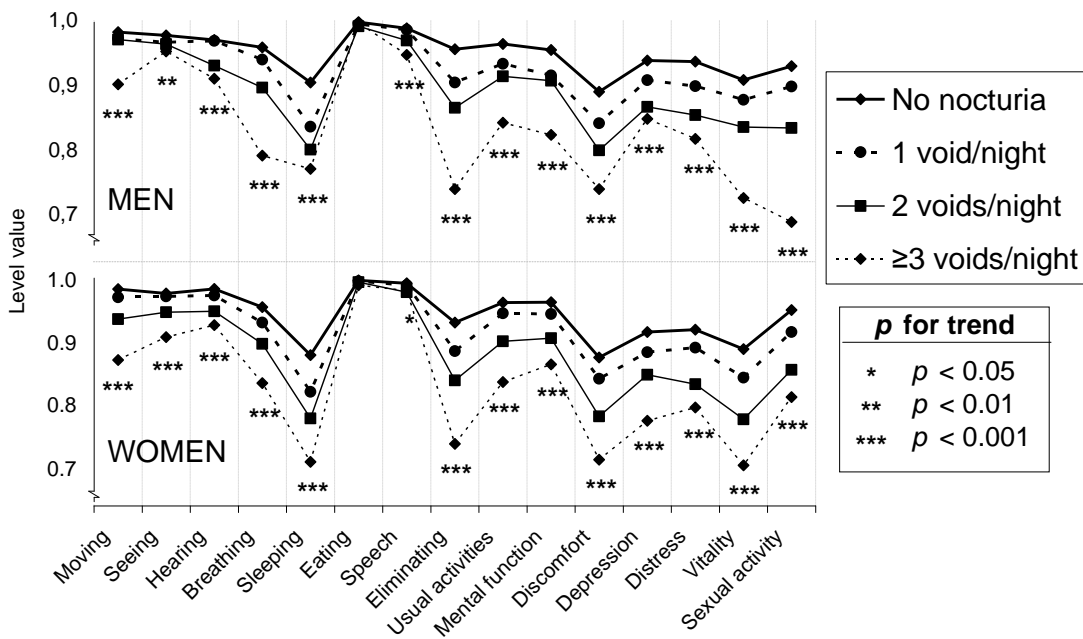


Figure 2. The age-adjusted means for dimension level values (profiles) of 15D instrument by frequency of nocturia.



References

1. J Urol (1992) 148;1549-57; discussion 1564.
2. Scand J Urol Nephrol (1993) 27; 489-92.
3. Ann Med (2001) 33; 328-36.

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Is this a clinical trial?

No

What were the subjects in the study?

HUMAN

Was this study approved by an ethics committee?

No

This study did not require ethics committee approval because

In accordance with the Finnish regulations on questionnaire surveys, an exemption from ethical review was granted by the ethics committee of the Pirkanmaa Hospital District (Tampere, Finland).

Was the Declaration of Helsinki followed?

Yes

Was informed consent obtained from the patients?

Yes