

## DOES THE USE OF SLEEP QUESTIONNAIRES ADD TO OUR KNOWLEDGE ABOUT THE IMPACT OF NOCTURIA?

### Hypothesis / aims of study

Nocturia is a highly prevalent condition in adults. It is the leading cause of sleep disturbance in people of 55 years and over (1) and, due to the interruption of normal sleep patterns, it is reported to be one of the most bothersome lower urinary tract symptoms. Studies investigating the quality of life (QoL) of nocturia patients generally use generic or specific quality of life questionnaires, such as the Short-Form 12 health survey (SF-12) or the Nocturia Quality of Life (N-QoL), and detect increasing impairments with increased severity of the condition (2). Few studies have looked directly at the effects of nocturia on sleep and daytime functioning using sleep questionnaires. This study is one of the first to investigate the ability of the frequently-used sleep questionnaire, the Pittsburgh Sleep Quality Index (PSQI), to detect impairments in nocturia patients, whilst also using QoL questionnaires to verify whether an impact on QoL is seen in this study cohort.

### Study design, materials and methods

Participants screened for a large Phase III trial of nocturia therapy conducted in the USA and Canada were included. For subjects with 1–9 voids per night, mean scores were calculated for the N-QoL, International Consultation on Incontinence Modular Questionnaire-Nocturia (ICIQ-N) question 4, (How much does the number of times you have to get up in the night to urinate bother you?) and PSQI total score and subscale scores. Nocturia frequency was rounded to the nearest whole number.

### Results

A total of 1412 people were screened. There was only one subject with 1 void/night and one with 9 voids/night; these categories of voiding frequency were therefore excluded due to lack of sufficient data. Minimum numbers of patients providing data in each of the other categories of nocturia frequency are shown in Table 1. Mean QoL and sleep questionnaire scores are shown in Figures 1–4.

### Interpretation of results

As expected, and consistent with other studies, the N-QoL and the ICIQ-N detected clinically significant decreases in QoL with increasing numbers of voids. There was some inconsistency in this trend for those with the most severe nocturia using the N-QoL, but this is likely to be affected by the small numbers of subjects in these categories. The global PSQI score showed a clear tendency for patients to experience greater difficulties with increasing nocturia (Figure 3). In addition, when looking at the specific subscales within the PSQI as shown in Figure 4, subjective sleep quality, sleep duration, habitual sleep efficiency (a measure of the ratio of time asleep vs time in bed) and sleep medication had higher scores (ie indicating more difficulty) with more nocturnal voids. However, sleep latency, sleep disturbance and daytime dysfunction showed no consistent pattern. While we would not expect sleep latency to be affected by nocturia, the latter two dimensions are of particular interest. The sleep disturbance questions ask about many causes of sleep disruption (eg feel too cold, feel too hot, have bad dreams). No matter what the burden of nocturia, it can therefore only have very little influence on the overall score for the domain. The lack of relationship between nocturia frequency and daytime dysfunction in the PSQI is intriguing, given the results of QoL questionnaires in this and other studies, and nocturia's effect on sleep detected in other domains of the PSQI in this study. It is possible that the lack of manifestation of poor sleep as impaired daytime functioning within the PSQI is affected by the wording of the two questions in this domain (they refer, for example, to having trouble 'keeping up enthusiasm' and staying awake while eating meals), and that these may not tap into the domains of functioning which are relevant for nocturia.

### Concluding message

Bother of nocturia, as measured by generic and disease-specific QoL questionnaires, increases with nocturia frequency. We found that a sleep questionnaire (PSQI) was able to detect increasing impairments overall with the global score, and in several domains of sleep. However, despite the well-known impact of poor sleep on QoL and functioning, the PSQI was unable to detect effects of increased nocturia frequency on the daytime dysfunction subscale. The PSQI may be a useful tool for the assessment of the impact of nocturia - and its treatment - on sleep, but its limitations and lack of specificity for the condition in some domains should be kept in mind. There may be a need for a new tool which is able to identify both the impact of nocturia on sleep, and the link between poor sleep and

the effects on daytime functioning experienced by nocturia patients, as demonstrated by the results of QoL questionnaires used in this and other studies.

Table 1: Minimum number of patients with 2–8 voids per night and providing data

Mean voids/night	2	3	4	5	6	7	8
n	215	291	176	55	26	8	5

Figure 1: N-QoL scores (lower score indicates reduced QoL)

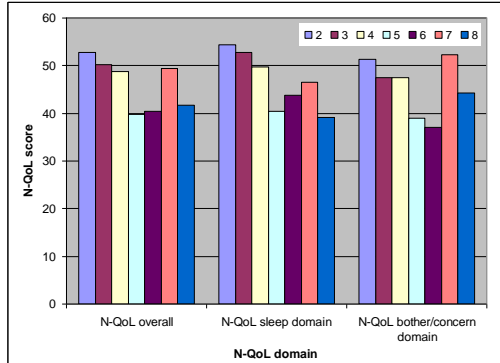


Figure 2: ICIQ-N Q4 scores (higher score indicates reduced QoL)

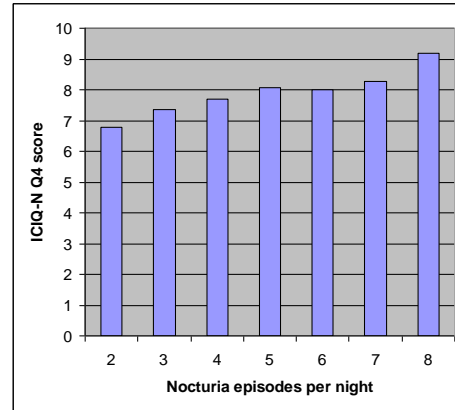


Figure 3: PSQI global score; ≥5 indicates 'poor' sleeper

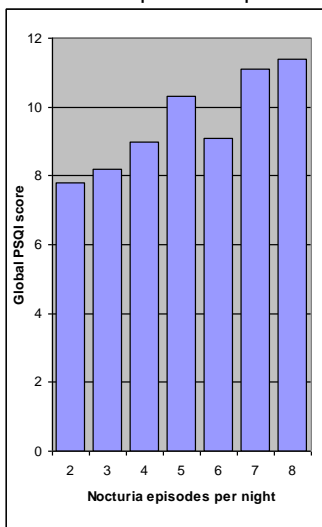
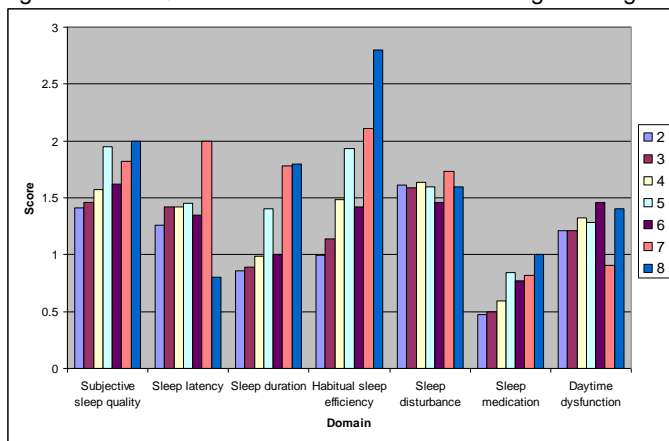


Figure 4: PSQI domain scores with increasing voiding frequency. Score range: 0 (no difficulty) to 3 (severe difficulty)



References

1. Bliwise et al. Sleep Med 2008 Aug 12 Epub ahead of print
2. Yu et al. Urology 2006;67:713–718

<b>Specify source of funding or grant</b>	Ferring Pharmaceuticals
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	Yes
<b>Specify Name of Public Registry, Registration Number</b>	Clinicaltrials.gov NCT00477490
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Approved by Independent Ethics Committee (IEC) and/or Institutional Review Board (IRB) at each participating centre
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes