

The Impact of Nocturia on Patient-Reported Sleep Quality

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Background and Objective

- Nocturia, defined by The International Continence Society as “the complaint that the individual has to wake at night one or more times to void,” has been shown to be a frequent cause of sleep disturbance.
- There is a continued and growing interest in evaluating and capturing the patient experience of disease to provide a more robust understanding of the value of intervention and treatment benefit.
- While the relationship between nocturia and sleep disturbance is well described, assessment and interpretation of the direct impact of nocturia on overall sleep quality is somewhat limited, and evaluative qualitative studies to evaluate this impact are even more so.
- The aim of this research was to fully characterize the most proximal impacts of nocturia on sleep quality from the patient perspective in order to inform clinical development programs and guide development and selection of best-fit patient-reported outcome (PRO) measures.

Results

- After review of the citations and abstracts from the targeted literature review, 34 articles were selected for in-depth review.
- The most proximal concepts of patient-reported, sleep-related symptoms or impacts of nocturia are described in Table 1.
- A total of 18 subjects participated in the interview study.
 - Of these, 50% were female, and 83.3% had at least some college.
 - Ten participants (55.6%) were employed either part- or full-time.
 - Eleven participants (61.1%) reported being “quite a bit disturbed” by nocturia-related sleep disturbance, and seven (38.9%) reported being “moderately disturbed.”
- The primary impacts of nocturia were identified as awakening frequently during the night to urinate in combination with the impact on overall sleep quantity and quality caused by these awakenings. For most participants, good sleep quality was defined as achieving a deep sleep and was related to having uninterrupted, restful, restorative sleep without awakening.
 - Two concepts were included in the hypothesized domain of sleep quantity: total sleep and early awakening.
 - Three concepts were included in the hypothesized domain of sleep quality: overall sleep, restful sleep, and refreshing sleep.
- Importantly, participants separated the concept of the number of voids during the night from awakenings, noting these concepts as distinct (e.g., more awakenings could occur than voids alone).
- Participants described the impact of frequent awakenings from sleep and the lack of any significant blocks of deep, uninterrupted sleep and the downstream effect this appeared to have on overall sleep quality.

Table 1. Proximal Concepts of Patient-Reported Sleep-Related Symptoms or Impacts

Identified Key Concept
Frequency of waking to void (even if not getting up to void)
Waking to void within 2-3 hours of sleep onset, which interrupts restorative sleep
Bother related to needing to void at night with incremental increases in bother associated with additional nocturia episodes
Difficulty falling asleep after waking to void
Impaired sleep quality, sleep duration, and sleep efficiency
Increased risks of falls and injury
Impact on partner and/or caregiver sleep

Methods

Figure 1. Targeted Literature Review

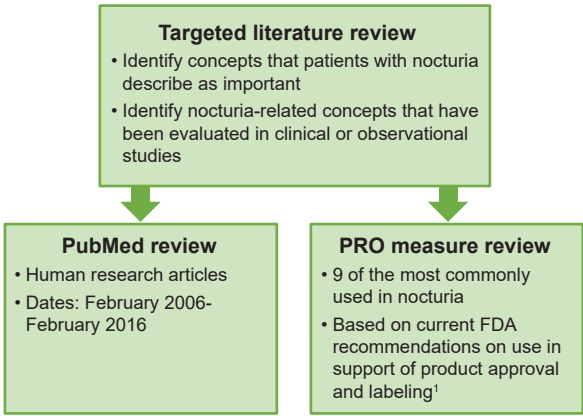
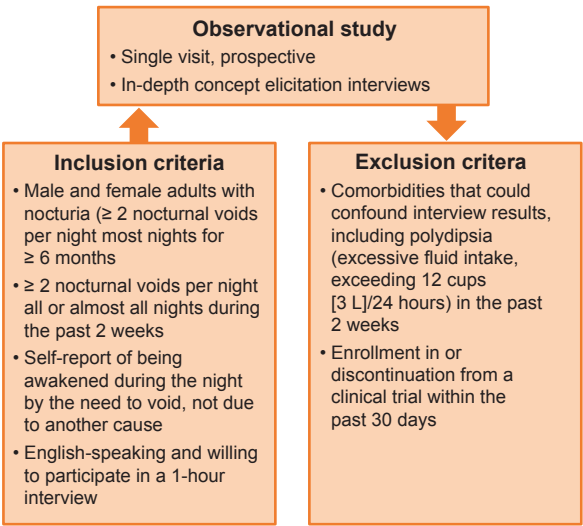


Figure 2. Observational Study



Conclusions

- Results gained from a targeted literature review of concepts, instruments, and 18 concept elicitation interviews provided a comprehensive list of important concepts to assess the impact of nocturia on sleep from the patient perspective.
- The experience of nocturia has a deep impact on sleep quantity and quality. This was supported through a review of the literature, expert input, and patient direct report.
- Awakenings due to nocturia were described as independent of the number of actual voids per evening and could more accurately explain the impact of nocturia on sleep quality.
- Proximal impacts focused on sleep quality and may be more easily and accurately captured via self-report, compared with other impacts more distal to the patient experience, and therefore are potentially influenced by factors other than nocturia.
- Improved sleep quality may be an important treatment target and benefit.
- Best-fit, content-valid measures are necessary.

References

- Food and Drug Administration (FDA). <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>. Accessed July 31, 2018.

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