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COMPARISON OF SF-12 DATA ON QUALITY OF LIFE IN NOCTURIA PATIENTS WITH US NORMS

Hypothesis / aims of study

Poor sleep is associated with multiple negative consequences for daytime functioning, quality of life (QoL), well-being and overall health. Nocturia is the most frequently-reported reason for sleep fragmentation in adults over 55 years (1), and also affects a substantial proportion of younger adults ≤39 years – in this age group, ~40% have ≥1 void/night and ~15% have ≥2 voids/night on average (2). In this study, the QoL of adults (≥18 years) with nocturia who were recruited to a large Phase III clinical trial of nocturia therapy in the USA and Canada, was assessed at baseline using the Short Form-12 (SF-12) of the health-related quality of life (HRQoL) survey instrument. To evaluate the impact of nocturia on QoL, the scores of nocturia patients were compared with normative scores of the US population of similar gender and age group.

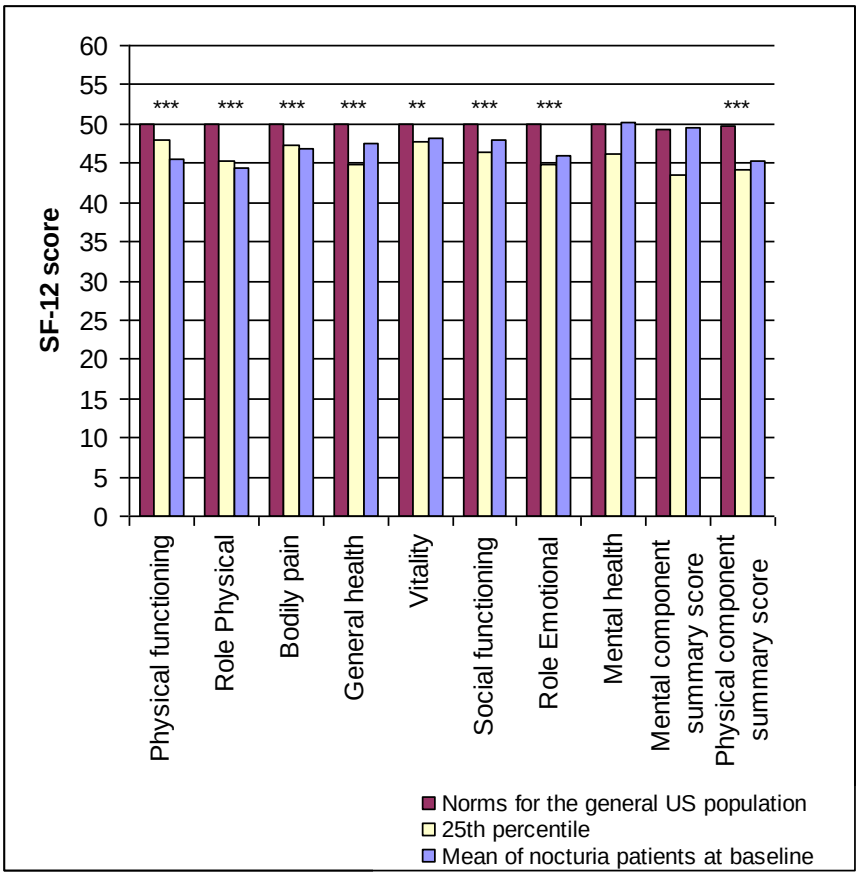
Study design, materials and methods

Subjects were recruited from 83 study centers in the USA and Canada. Patients were considered eligible if they were ≥18 years of age, had an average of ≥2 voids per night (determined using a 3-day frequency-volume chart [FVC]), and provided informed consent. Subjects were excluded if genitourinary tract disorders were suspected. In males, this included suspicion of bladder outlet obstruction (BOO), or surgical treatment for BOO or benign prostatic hyperplasia (BPH) in the past 6 months. In females, this included pregnancy, use of a pessary for pelvic prolapse, or the presence of an unexplained pelvic mass. In both sexes, subjects were excluded if urinary retention was suspected by history, if they had ever experienced urologic malignancies, or if there was a history of neurogenic detrusor overactivity. Other exclusions included heart failure, uncontrolled hypertension, uncontrolled diabetes mellitus, renal insufficiency, hepatic and/or biliary disease, hyponatremia, diabetes insipidus, Syndrome of Inappropriate Anti-Diuretic Hormone (SIADH) secretion, psychogenic or habitual polydipsia and obstructive sleep apnea requiring therapy. Individuals were also excluded if they had known alcohol or substance abuse, if their work/lifestyle potentially interfered with regular night-time sleep (eg shift workers), if they had received previous desmopressin treatment for nocturia, or if they were receiving loop diuretics. Other classes of diuretics were permitted, either as monotherapy or combination therapy. The HRQoL SF-12 (Short Form-12) questionnaire was used to measure the impact of nocturia and lack of sleep on participants' general QoL at baseline. The SF-12 consists of 12 questions spanning 8 domains: physical functioning, role function-physical, role function-emotional, bodily pain, general health, vitality, social functioning, and mental health. These scales are combined to create 2 summary measures: the Physical Health Summary and Mental Health Summary. Higher numbers indicate better QoL. The difference between mean scores of nocturia patients and US norm scores was tested for significance using t-tests. Consistent with the SF-12 instructions and the approach utilized in other studies, subjects were considered particularly impaired if they scored below the 25th percentile of the US general population norms.

Results

The intention to treat (ITT) population included 757 patients. Mean age was 62 years (range 20–89), 55% were male and mean nocturia frequency was 3.3 voids/night. Mean SF-12 scores for the full ITT sample are shown in Figure 1, together with the published normative and 25th percentile scores of the US population.

Figure 1. Mean SF-12 score for nocturia patients in study (in blue), compared with US norms (in red) and 25th percentile scores (in yellow)



*** p<0.0001, ** p<0.0003 for comparison of nocturia patients vs US norms

Interpretation of results

As can be seen in Figure 1, nocturia patients at baseline scored significantly lower than US norms for all domains of QoL in the SF-12 questionnaire, except mental health. For the summary scores, nocturia patients were similar to US norms for the mental component, but significantly below the norm score, and only a little above the 25th percentile, for the physical component. Nocturia patients were particularly impaired in the domains of physical functioning, role physical (comprised of questions regarding whether the patient a) accomplishes less than they would like, and b) is limited in the kind of work or other activities they perform), and bodily pain. For all three of these domains, nocturia patients (≥2 voids/night) scored on average lower than the 25th percentile of the US population. The SF-12 is a very broad, generic questionnaire, often considered to be insensitive in relation to diseases which do not induce pain or impact physical activity directly. However, since we do see clinically meaningful differences in scores for nocturia patients, this only serves to highlight that getting up to void several times a night is not just a trivial problem.

Concluding message

Amongst a broad sample of US and Canadian nocturia patients aged ≥18 years and experiencing ≥2 voids per night, QoL was reduced in comparison with US norms for 7 out of 8 SF-12 domain scores. Particularly, patients reported impaired physical function and inability to reach desired levels of daily activity and work performance. These results confirm that nocturia (≥2 voids/night) can seriously affect the daily function and QoL of patients. Since approximately 15% of all adults in the USA experience nocturia of a similar severity (3), nocturia could represent a significant QoL burden for the US population, warranting a more proactive management of the condition, including treatment strategies targeting the causes of the problem in each patient.

References

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Specify source of funding or grant	**Ferring Pharmaceuticals**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
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Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Approved by Independent Ethics Committee (IEC) and/or Institutional Review Board (IRB) at each participating centre**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**