

THE HEALTH-RELATED QUALITY OF LIFE (HRQOL) IMPACT OF THE SYMPTOMS OF NOCTURIA IN PATIENTS WITH OVERACTIVE BLADDER

Aims of Study

Prior to the ICS standardisation paper(1) there was no firm consensus regarding a definition for nocturia. Nocturia is rarely considered as a stand-alone symptom but nocturia symptoms deemed problematic were consistently reported by subjects with overactive bladder (OAB) participating in a large multinational clinical trial. The objectives of this study are to:

1. Describe the relationship between the symptoms of nocturia and various physical and psychological domains of health related quality of life (HRQoL).
2. Evaluate how a change in patients' perception of nocturia as a problem impacts upon HRQoL.

Methods

Subjects enrolled in a 12-week double-blind safety and efficacy trial and a 12-month open-label extension provided data for these analyses. Efficacy endpoints and HRQoL were assessed at baseline, 12 weeks and then at 3 and 12 months after rollover.

HRQoL was measured using the King's Health Questionnaire (KHQ), a multidimensional disease-specific measure for patients with OAB(2). The KHQ is scored on a 0(best) to 100(worst) scale. The impact of urinary symptoms including nocturia ("getting up at night to pass urine") was based on the self-reported symptom severity checklist of the KHQ. Patients rated the degree of effect on their life of certain bladder symptoms ("a little", "moderately" or "a lot"). The absence of a rating was interpreted as "no problem". Nocturia improvement was defined as a positive change from baseline at 12 months post-rollover or a change from a response category to a "no problem" status. No improvement in nocturia symptoms was defined as no change in response, or moves from less to more problematic ratings.

The patient population used for these analyses was the intent to treat (ITT) open-label population for whom a translated KHQ was available and who reported nocturia as a symptom at baseline (n = 838). Multiple regression was used to assess the impact of symptoms on KHQ domains. Differences in mean KHQ change scores (split plot repeated measures ANCOVA with visit and improvement in bladder condition as factors, with age, gender and country as covariates) were tested. Significance levels were adjusted for multiple comparisons by the Hochberg method.

Results

In the regression analysis, nocturia was a significant predictor of sleep/energy domain scores. Frequency and bladder pain were also significant, albeit with smaller beta coefficients. Table 1 shows sleep/energy score improvement from baseline was better (negative numbers reflect improvement in domain score) in improvers than non-improvers at each time period. Patients reporting improvement in nocturia symptoms at 12 months also had significantly more improvement in physical (Table 2) and psychological domain scores (Table 3) at 12 weeks with the exception of personal relationships and general health domains.

Table 1 -Change Scores: KHQ Sleep/Energy Scores for Nocturia Patients With/Without Improvement

Timeline	No Improvement Mean (SD) [95% CI]	Improvement Mean (SD) [95% CI]
Baseline to 12 weeks	-5.7 (1.1) [-7.9, -3.5]	-14.7 (1.2) [-17.1, -12.3]
Baseline to months	-8.3 (1.1) [-10.5, -6.0]	-19.9 (1.2) [-22.3, -17.5]
Baseline to 12 months	-4.6 (1.1) [-6.9, -2.4]	-21.4 (1.2) [-23.8, -19.0]

Table 2 -Change Scores: KHQ "Physical" Domains for Nocturia Patients With/Without Improvement (baseline to 12 weeks)

KHQ Domain	No Improvement – Mean (SD) [95% CI]	Improvement Mean (SD) [95% CI]
Incontinence Impact	-11.1 (1.5) [-13.9, -8.2]	-20.5 (1.6) [-35.2, -29.0]
Role Limitations	-13.0 (1.5) [-15.9, -10.1]	-22.7 (1.6) [-25.7, -19.6]
Physical Limitations	-10.5 (1.5) [-13.3, -7.6]	-20.0 (1.6) [-23.0, -16.9]
Severity (coping) Measures	-8.5 (1.1) [-10.7, -6.3]	-14.5 (1.2) [-16.8, -12.2]
General Health Perceptions	-1.0 (0.9) [-2.7, 0.7]	-1.7 (0.9) [-3.5, 0.2]
Symptom Severity	-6.1 (0.7) [-7.5, -4.7]	-13.6 (0.8) [-15.1, -12.1]

Table 3 –Change Scores: KHQ "Psychological" Domains for Nocturia Patients With/Without Improvement (baseline to 12 weeks)

KHQ Domain	No Improvement Mean (SD) [95% CI]	Improvement Mean (SD) [95% CI]
Social Limitations	-6.9 (1.1) [-9.1, -4.7]	-13.4 (1.2) [-15.7, -11.0]
Personal Relationships	-4.6 (1.5) [-7.6, -1.6]	-8.6 (1.6) [-11.8, -5.4]
Emotions	-8.0 (1.2) [-10.4, -5.6]	-13.7 (1.3) [-16.3, -11.2]

Conclusions

The degree to which OAB patients experience nocturia symptoms impacts on their self-reported HRQoL. Nocturia symptoms are particularly important in explaining sleep/energy domain scores, although frequency and bladder pain are also associated with sleep/energy domain scores.

Changes in perception of the effect of nocturia symptoms are related to changes in HRQoL. Patients reporting an improvement in nocturia also report improvements in a number of domains of HRQoL most notably sleep/energy.

The results suggest that nocturia is frequently perceived as a problem by OAB patients and effective treatments that reduce nocturia symptoms will likely improve patient quality of life.

References

- (1) Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, vanKerrebroeck P, Victor A, Wein A, *Neurology and Urodynamics*, 2002 21:167-178
- (2) *British J. Obstet. Gynaecol.* 1997;104:1374-1379