

QUALITY OF LIFE AND WORK IMPAIRMENT IN NOCTURIA PATIENTS BEFORE AND AFTER ANTIDIURETIC TREATMENT.

Hypothesis / aims of study

To compare productivity and quality of life before and after three month of oral desmopressin (Minirin[®]) treatment in 72 professionally active people suffering from nocturia.

Study design, materials and methods

Occupational health clinics in 7 major companies/organisations in Sweden participated in this open, longitudinal, multi-centre study. Women and men between 18 and 65 years of age were included based upon verified nocturnal polyuria (nocturnal proportion of $\geq 33\%$ of 24-hr urine production and a mean frequency of at least one voiding per night). The dose titration period following the 72 hr screening period was of 1 – 3 weeks' duration.

Patients were dose titrated on the basis of a stepwise evaluation. The lowest effective dose was identified and used for a treatment period of 3 months. Efficacy defined as prolongation of first period of sleep and as reduction in number of nocturnal voidings is reported elsewhere. Quality of life and work impairment were assessed as secondary endpoints comparing baseline with results from evaluations after 1 and 3 months treatment. All QoL and productivity data were recorded electronically. To explore productivity the WPAI-SHP measure was chosen. This is an instrument developed for use in clinical trials and validated in several diseases. It includes seven questions focusing on a quantitative assessment of different types of impairment of work productivity. SF36 was chosen for the QoL assessment due to its universal use. In addition the choice of SF36 made it possible to compare our results with a study investigating the effect of nocturia on 203 working nocturics and 80 age-matching non-nocturics conducted by Kobelt et al (Kobelt et al, 2003).

Results

139 patients were screened of whom 72 entered the titration period. 11 patients were withdrawn during titration. Withdrawals were due to adverse event (8), lack of efficacy (2) and other (1) leaving 61 patients for the intent-to-treat (ITT) analysis. Data was received from approximately 90% of the study population. Due to a higher level of received data after 1 month treatment (n=57) these results were considered more reliable than 3 month results (n=51). The 1 month results were however confirmed in the 3 month follow up evaluation.

Significant impact was detected in 2 of 8 SF36 domains and in 1 of 7 WPAI-SHP domains. Both QoL and productivity results are based on the Wilcoxon test.

	Baseline	Value after 1 month treatment	Comparative group (Kobelt et al, 2003)
	Mean (Std)	Mean (Std), p value of reduction.	Mean (Std) p value of reduction.
N	58	57 (impairment of activity =56)	80
SF-36 vitality domain (0-100).	54.14 (26.89)	64.21 (21.29) p<0.001	71.8 (19.7) p<0.001
SF-36 mental health (0-100)	73.38 (21.61)	80.00 (15.93) p<0.001	81 (12.2) p<0.001
WPAI Impairment of activity (%)	13.22 (19.78)	5.54 (10.71) p<0.001	5.2 (12.23) p<0.001

Interpretation of results

The vitality of the nocturia patients was significantly improved by antidiuretic treatment of nocturia, thus as a direct effect of treatment the patients came close to the vitality of a comparative group of non-nocturia. Also mental health

and impairment of activity changed significantly due to the antidiuretic treatment and the results show an improvement comparable to levels reported on non-nocturics.

Concluding message

Nocturia has a strong impact on vitality, mental health and activity in working nocturics. Antidiuretic treatment (Minirin[®]) improves QoL and work productivity of working nocturics to levels earlier reported for individuals not suffering from nocturia.

References:

(1) Kobelt G, Borgström F and Mattiasson A. Productivity, vitality and utility in a group of healthy professionally active individuals with nocturia. BJU International 2003, 91, 190-195.

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HUMAN SUBJECTS: This study was approved by the etisk kommite - Lund and followed the Declaration of Helsinki Informed consent was obtained from the patients.