

## EFFICACY AND TOLERABILITY OF DESMOPRESSIN IN THE TREATMENT OF REFRACTORY NOCTURIA IN ELDERLY MEN WITH BLADDER OUTLET OBSTRUCTION ASSOCIATED WITH BENIGN PROSTATIC HYPERPLASIA

### Hypothesis / aims of study

Nocturia is a well recognized and bothersome symptom of benign prostatic hyperplasia (BPH), which is commonly treated by  $\alpha$ 1 blockers, anticholinergics or/and 5 $\alpha$ -reductase inhibitors. However, the effectiveness of these drugs for nocturia is reported to be only 25-70% [1]. The aim of this study was to assess the efficacy and safety of nasal desmopressin for the management of refractory nocturia on a specific subgroup of elderly patients with bladder outlet obstruction (BOO) associated with BPH, as well as its interaction with  $\alpha$ -blockers and anticholinergics by evaluating the patients' subjective response, urodynamic parameters and possible side-effects

### Study design, materials and methods

Between March 2006 and December 2007, 27 BPH patients aged 67-77 (mean 69.8) years who had severe nocturia ( $\geq 3$  voids per night) that was refractory to a standard 12-week treatment with  $\alpha$ 1 blockers and anticholinergics, were successfully recruited into the study. Patients with nocturnal polyuria, history of congestive heart failure or diabetes were excluded from the study. In addition, patients excluded from the study if they were currently using other drugs that were potentially harmful in combination with desmopressin such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRI), chlorpromazine, carbamazepine and diuretics. Data from urodynamic studies, voiding diaries, nocturnal urine volume, quality of life index and serum sodium were evaluated at baseline prior to treatment, 1 week, 4 weeks and 12 weeks later. Statistical analysis was performed using Fisher's exact test.

### Results

The combination of antidiuretic hormone, anticholinergics and  $\alpha$ -blockers resulted in a significant reduction of the mean number of nocturnal voids (5.8 vs. 3.2,  $p < 0.001$ ) and an increase of the mean duration of the first sleep period (2.2hrs vs. 3.9hrs,  $p < 0.001$ ). A significant improvement of the Quality of Life index was also noted. These beneficiary effects were noted within 7 days of treatment initiation and persisted at 6 months of follow-up. No significant adverse effects were reported.

### Interpretation of results

Our study suggests that the administration of desmopressin may be considered for elderly men with nocturia refractory to anticholinergics or/and  $\alpha$ 1-blockers, even in the absence of nocturnal polyuria [2]. Its beneficial and relatively safe effect might be attributed to the restoration of equilibrium between urine production during the night and nocturnal functional bladder capacity.

### Concluding message

This study shows that nasal desmopressin is an effective and well-tolerated treatment in BPH patients with refractory nocturia and without nocturnal polyuria.

### References

1. J Urol 2003, 170: 145-148.
2. BJU Int 2005, 96(9): 1310-1313.

<b><i>Specify source of funding or grant</i></b>	<b>None</b>
<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>The drug administration was under indication. Desmopressin administration has already been described in the treatment of nocturia</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>