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Low Dose Oral Desmopressin for Nocturnal Polyuria in Patients With Benign Prostatic Hyperplasia: A Double-Blind, Placebo Controlled, Randomized Study

Hypothesis / aims of study
We evaluated the long-term efficacy and safety of low dose oral desmopressin in elderly patients with benign prostatic hyperplasia with more than nocturnal voids and nocturnal polyuria more than 30% of total daily urine volume.

Study design, materials and methods
Eligible patients with benign prostatic hyperplasia older than 65 years with nocturia, nocturnal polyuria and International Prostate Symptom Score 14 or greater were included in the study. All patients received placebo or 0.1 mg desmopressin orally at bedtime. Patients were required to visit the outpatient clinic from the first visit, and after 1, 3, 6 and 12 months of treatment. Patients maintained flow volume charts and used diaries to record voiding data throughout the study. During followup urinalysis, urine sodium, urine osmolality, serum electrolytes, prostate specific antigen, International Prostate Symptom Score, quality of life, transrectal ultrasonography of prostate, uroflowmetry and post-void residual urine volume were performed at each visit.

Results
A total of 115 patients were enrolled in the study and randomized as 58 in the placebo group and 57 in the desmopressin group. Desmopressin significantly decreased nocturnal urine output and the number of nocturia episodes, and prolonged the first sleep period (p _0.01). Compared to before treatment desmopressin gradually decreased serum sodium and induced statistically but not clinically significant hyponatremia after 12 months of treatment. No serious systemic complications were found during edication.

Interpretation of results
Low dose oral desmopressin is an effective and well tolerated treatment for nocturnal polyuria in the lower urinary tract symptoms of patients with benign prostatic hyperplasia. Long-term desmopressin therapy gradually decreases serum sodium and it might induce hyponatremia even in patients without initial hyponatremia.

Concluding message
For long-term desmopressin administration serum sodium should be assessed carefully, at least at 1 week after treatment.

Specify source of funding or grant	**No**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**St. Martin De Porres Hospital Ethics committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**