

CLINICAL AND URINARY FLOW EFFICACY OF ALFUZOSIN ONCE DAY FORMULATION: A 24 HOURS HOME-UROFLOMETRY EVALUATION

Aims of Study

Medical therapy is considered the first line treatment for the majority of patients with lower urinary tract symptoms (LUTS) related to enlarged prostatic glands (EPG). Alpha 1 blockers are considered a good option to provide symptomatic relief for patients with LUTS. Alfuzosin 10 mg once a day (OD) formulation is an alpha blocker that uses an innovative oral delivery technology which should ensure a 24 hours coverage (1). A home uroflowmetry analysis should assess the grade of treatment success better than the conventional free flowmetry (2). Aim of our study was to analyse the clinical and 24 hours urinary flow efficacy of alfuzosin 10 mg OD by means of I-PSS and home uroflowmetry in patients affected by EPG.

Methods

We evaluated men with LUTS who were referred at our University Hospital by means of the International prostatic symptom Score (I-PSS) and conventional free flow. 12 male patients (median age 67, range 63-76) with IPSS more than 15 (median 16, range 16 – 18) and maximum urinary flow (Qmax) less than 15 ml/sec (median 8, range 3-10) were the object of our study. The home flowmetry (P-Flow) registers both time and volume at each time during voiding and calculate Qmax, voiding time, flow time and urinary volume. Patients underwent two days of Home uroflowmetry (P-Flow) evaluation (median 12,5 urinary flows, range 9-17). From day 3 to day 9 they received alfuzosin 10 mg OD formulation at 9 o'clock p.m.. On day 7 and 8 they underwent a second home flowmetry evaluation (median 14 urinary flows, range 11-16). A second I-PSS was recorded on day 9. Instructions for handling P-Flow were explained to the patients. They were asked to void as they would normally, produce consecutive flows and not be restricted in their daily activities. The symptoms score and value obtained on the first and second P-Flow evaluation were compared with the Wilcoxon matched-pairs signed ranks test. Data are presented as mean +/- standard deviation.

Results

A statistically significant ($p < 0.01$) difference between the two evaluation were noted for IPSS (15.7 +/-0.8; 9.5 +/-2; $p = 0.02$). Overall 328 flows were recorded by Home flowmetry and evaluated. A statistically significant improvement of maximum flow (10.8 +/-2.8; 12.4 +/-3 ml/sec; $p = 0.02$); urinary voiding volume (219 +/-70; 233 +/-55 ml; $p = 0.04$) investigated by P-flow were observed after treatment. No differences in the number of urinary flows were observed between the two evaluation (13 +/-2.9; 14 +/-1.8 flows; $p = 0.199$). No differences were noted between maximum flow recorded 22 hours after the drug was taken and mean maximum flow during treatment (12.4 +/-3; 13 +/-4 ml/sec).

Conclusions

Our study demonstrated a significant improvement in symptoms and flow parameters after few days of treatment with alfuzosin 10 mg OD formulation. In particular P-Flow evaluation showed that the urinary flow efficacy of this new drug formulation was maintained for up to 22 hours a day.

References

- 1) PhEV van Kerrebroek. The efficacy and safety of a new once a day formulation of an alpha blocker. Eur. Urol. 2001, 39, suppl 6, 19-26
- 2) R Boci, M Fall, M Walden et al. Home uroflowmetry: improved accuracy in outflow assessment. Neurol Urodyn, 1999, 18, 25-32

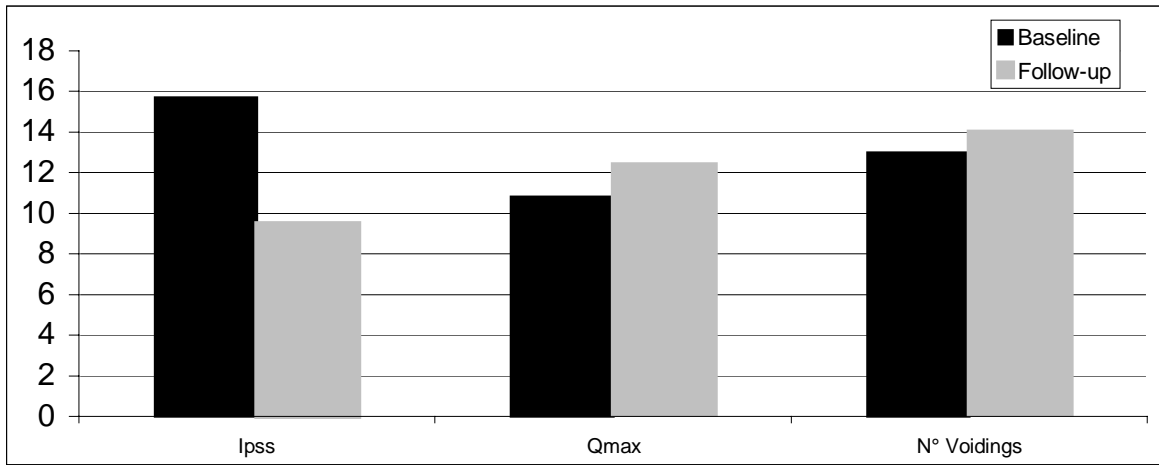


Fig 1: Clinical and P-Flow parameters changes in patients treated with alfuzosin 10 mg once a day formulation