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A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY BETWEEN THE EFFECT OF TAMSULOSIN 0.4 MG AND 0.2 MG ON LUTS DUE TO BENIGN PROSTATIC HYPERPLASIA

Hypothesis / aims of study
This study aimed to compare between the efficacy and safety of Tamsulosin 0.2 mg and 0.4 mg in the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Study design, materials and methods
This is a prospective randomized comparative study that was conducted on patients with LUTS related to BPH who were treated at our department in the period between January 2012 and October 2013. All the patients with prostate up to 60 gm, International Prostatic Symptom Score (IPSS) up to 19, Qmax between 5 and 15 ml/s, Post-Voiding Residual (PVR) volume of less than 200 ml and serum Prostatic Specific Antigen (PSA) concentration of less than 4 ng/ml were included in our study. Patients were evaluated before the start of medical treatment by detailed history taking, IPSS and Quality of life (QoL) score, physical examination including digital rectal examination and complete neurological examination, laboratory investigations including urine analysis, fasting blood sugar level, renal function test and serum PSA. Also radiological investigations were done including KUB, Abdominopelvic U/S with measurement of the PVR, Qmax and transrectal U/S to estimate the prostate size. The patients were randomized into two groups by using block randomization technique. Group A including patients taking Tamsulsoin 0.4 mg once daily and group B including patients taking Tamsulosin 0.2 mg once daily. All patients were followed up at 1 month and 6 month from the start of medical treatment by measuring the IPSS and QoL score, Qmax, PVR and the vital signs including blood pressure and heart rate to report any adverse events.

Results
Eighty-three patients were included in the present study and randomized into two groups (A and B), 1 patient was lost during the follow up and 2 patients didn't improve on the medical treatment and was shifted to TURP. At baseline evaluation mean age in group A and B was 62.70 ± 6.48 and 63 ± 5.48, respectively (P>0.05). Mean prostate size in group A and group B was 47.65 ± 8.87 and 48.85 ± 7.23, respectively (P>0.05). Both groups were comparable regarding other parameters at baseline evaluation with no statistically significant difference between mean serum PSA (2.72 ± 0.99 and 2.38 ± 0.79), mean IPSS (14.50 ± 2.70 and 15.75 ± 1.86), mean QoL score (3.65 ± 0.74 and 3.85 ± 0.87), mean Qmax (11.80 ± 1.10 and 11.01 ± 1.75), mean PVR (76.7 ± 39.85 and 94 ± 11), with (P>0.05).
At 1 month of follow-up after start of the medical treatment there was a significant improvement in both groups (A and B) in comparison to the pre-treatment values of all parameters "IPSS, Qmax, QoL and PVR" (P<0.05). On the other hand in comparing between both groups at 1 and 6 months there was no statistically significant difference found between both groups (P>0.05).
The analysis of safety revealed that tamsulosin was well tolerated in both groups during the whole treatment period with no significant difference (P>0.05). Seven adverse events were found throughout the whole duration of the study and they included (Dizziness, Abnormal ejaculation in the form of anejaculation or low volume ejaculate, headache, gastrointestinal disorders, Nausea, hypotension and postural hypotension), these adverse events occurred in a total number of 35 patients (22%) of the whole study population.

Interpretation of results:
It seems that there was no significance difference between the Tamsulosin 0.4 mg and 0.2 mg in the management of LUTS resulting from BPH and also there is no significant difference between the two groups regarding their effect on blood pressure. Our results regarding the adverse events were comparable between both groups.

Concluding message
The present study revealed that both Tamsulosin 0.4 mg and 0.2 mg have equal efficacy and safety in treating LUTS secondary to BPH. We recommend using Tamsulosin 0.2 mg from the economical point of view as the starting dose. Further larger studies are required to confirm our results.

Disclosures
Funding: Non **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Tanta University, Faculty of Medicine ethical committee **Helsinki:** Yes **Informed Consent:** Yes