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COMPARISON STUDY OF TAMSULOSIN AND PRAZOSIN EFFECTS ON VOIDING DIFFICULTIES IN WOMEN

Hypothesis / aims of study

Women who have bladder outlet obstruction (BOO) or voiding difficulty are at increased risk for developing many problems including: urinary retention, urinary tract infection, renal insufficiency and impacts on quality of life. Alpha sympathetic blockers are the first line treatment in men with BOO, due to prostate enlargement. Some recent studies show distribution of alpha sympathetic receptors in bladder neck and different parts of pelvic floor of females.
In this study we conducted a randomized control trial of some patients with non-neurogenic voiding difficulty. We compared Prazosin and Tamsulosin effects on urodynamic findings, BOO symptoms and patient satisfaction. Also complications of such treatment were evaluated in this research

Study design, materials and methods
Between September 2005 and June 2006, 63 females aged 20-65 years enrolled to this study within female urology clinic of Tabriz University of medical sciences. Initial screening included a comprehensive medical history and lower urinary tract symptom assessment via American urologic association symptom score (AUASS), a physical and urogyneclogical examination.
Voiding difficulty defined as symptoms such hesitancy, low urination flow, post void dribbling, frequency, nocturia and AUASS>8, maximal flow rate (Qmax) < 10 ml/s and post void residual volume (PUR)>50 cc.
13 patients were excluded because of spinal cord injury history, severe cardiovascular disease, cerebrovascular disease, urinary retention, indwelling catheterization, anatomic outlet obstruction, renal diseases or orthostatic hypotension. 40 females with AUASS >8 were elegable to this randomized control trial.
Urinalysis was performed and if indicated, urine culture was undertaken. Full urodynamic study (Laborie Delphic B) included urethral pressure profile (UPP), filling and voiding cystometry was performed on all participants.
40 patients randomly assigned to 3 months treatment with Tamsulosin 0.4mg daily (20) or Prazosin 1-2 mg daily (20) in this parallel design double-blind, control trial with sealed, opaque envelop.
Every month up to three months patients visited for symptoms and adverse effects of medications. If any important adverse effects were reported, medication stopped. Questionnaire accomplishment, physical exam and urodynamic study were duplicated after treatment course. Patient satisfaction also was evaluated (no satisfaction, relative, or complete). Adverse effects of drugs were recorded as reported with patients. Expected outcomes were: decrease of AUAAS, high level of satisfaction, improvent of urodynamic parameters. Ethic committee of Tabriz University of medical sciences approved this study.
Results

A total of 40 participants aged 20-65 years within urogynecology clinic participitated in this study. There was no significant difference between two group in term of age, family, AUASS & pelvic organ prolapse (P>0.05).
Twenty women in each group were followed for 3 months just for symptom improvement and patient satisfaction. But one of Tamsulosin (T) group and 2 of Prazosin (P) group ignored doing control urodynamic study. Intention to treat analysis was done to data evaluation.
AUASS improved in group P from 13.90 ± 6.61 to 10.58± 7.64 (PV≤0.008,). Also in group T a dramatic decrease from 14.65 ± 6.02 to 8.41± 4.23 (P≤ 0.001).
Nine of group P and 16 patients of group T were completely satisfied with treatment (PV < 0.017, 95% CI: 1.31-11.79). Patients with relative satisfaction in T and P groups were 1 and 4 respectively. With regard to complete patient satisfaction absolute risk reduction (ARR) of T group relative to P was 35%, so number needed to treat (NNT) was greater than 2.8. PVR decrement after treatment was 45 ± 25.26 ml and 44±18.16ml in T and P group respectively (P=0.6).
PVR and detrusor pressure at peak flow (PPF) were decreased and average flow rate (AFR) and peak flow rate (PFR) were increased significantly in both groups.
Adverse effects, which was seen in group P were 13 cases with dizziness, two mild orthostatic hypotension, drowsiness in 2 patient, headache in 5 and blurred vision in one patient. In group T there was only one case with drowsiness and no other side effect was seen else.

Interpretation of results

The purpose of this study was to access effects of Tamsulosin and Prazosin on female voiding difficulty and we found symptom improvement in both groups. But the response rate of Tamsulosin group is significantly better than Prazosin group. Also adverse effects of Tamsulosin was less than Prazosin.There is no evidence based guideline for treatment of voiding difficulty or functional bladder outlet obstruction (BOO).
Concluding message

Tamsulosin and Prazosin both are effective in palliating symptoms of women with voiding dysfunction and improvement of their urodynamic parameters (but not normalizations).

References

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the Tabriz University of Medical Science ,Regional Ethics Commitee and followed the Declaration of Helsinki Informed consent was obtained from the patients.