

URODYNAMIC EFFECTS OF 1A-BLOCKER TAMSULOSIN 0,4 MG ON VOIDING DYSFUNCTION IN PATIENTS WITH DETRUSOR UNDERACTIVITY

Hypothesis / aims of study

Detrusor underactivity (DU) is defined as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span.¹ Some of the established causes of detrusor underactivity include neurogenic, myogenic, aging, and medication side effects. Voiding difficulty may impair quality of life and lead to recurrent urinary tract infections and upper urinary tract damage. The management of individuals with DU remains unsatisfactory, in fact the catheters play a role in managing DU in older adults, yet clinical indications are circumscribed, but offers a poor quality of life². The aim of this study is to investigate the effectiveness of Tamsulosin 0.4 mg in treating men and women with DU. The medical treatment for detrusor underactivity aims to enhance detrusor contractility and to reduce urethral outlet resistance thereby improving voiding. Because α 1-ARs appear to play roles in lower urinary tract function at multiple sites and levels, including the bladder neck and external urethral sphincter, and because these non-prostate effects should be gender-independent, it seems logical that α 1-AR antagonists could be used in women with voiding dysfunction³

Study design, materials and methods

Between December 2008 and January 2010 a total of 42 patients (30 women and 12 men) with a mean age of 52 years, presenting LUTS symptoms were enrolled in the study. Patients with possible neurogenic voiding dysfunction or anatomical bladder outlet obstruction (e.g., urethral stricture, bladder neck contracture, bladder calculi, bladder tumour, prostate tumour, severe pelvic organ prolapse, previous incontinence surgery, urethral diverticulum, BPH (BOOI > 40), etc.) were excluded from the study. Patients with active urinary tract infection (UTI), history of recurrent UTIs (symptomatic UTIs ≥ 4 times in the last year), suspected interstitial cystitis, previous surgical procedures related to incontinence or cystocele, medications of α -1 blockers and/or anticholinergics within 7 days before the enrollment, estrogen replacement started within 2 months, and the electrostimulation and/or bladder training within the 14 days preceding the enrollment, men with chronic prostatitis and acute prostatitis were excluded from this study. Inclusion criteria were: Maximum Flow Rate (Q_{max}) < 10 ml/sec; PVR > 50 ml; Bladder Outlet Obstruction Index (BOOI) < 20; Bladder Contractility Index (BCI) < 100. All patients were informed about the study purpose and protocol and provided consents. Baseline patients evaluation included: medical and pharmacological history, physical examination, uroflowmetry, urinary system ultrasonography and post-void residual (PVR) urine measurement, lumbosacral MRI, and voiding cystourethrography. Patients completed a self-administered IQoL (International quality of life questionnaire) questionnaire and an IPSS (International Prostate Symptom Score) was determined for male patients. A urodynamic exam was also performed (Menfis, Pro-2000). It was performed according to the recommendations of the International Continence Society (ICS). After baseline evaluation, a majority of patients were treated with 0,4mg tamsulosin daily for 6 months. Patients were requested to return at months 1 and 3 for an evaluation of adverse events, free urinary flow, urinary system ultrasonography with PVR urine measurement, once a week voiding diary and completed self-administered PGI-I (Patient Global impression of improvement) questionnaire. Finally, patients were requested to return at month 6 for evaluation of a second urodynamic exam, physical examination, uroflowmetry, urinary system ultrasonography with PVR measurement and complete the self-administered IQoL, PGI-I and IPSS (for male patients) questionnaires. Once data was collected and recorded, we evaluated the following parameters at baseline and after 6 months treatment with Tamsulosin 0.4 mg: Q_{max} , Detrusor Pressure (P_{det}) at Q_{max} , PVR, IPSS for male patients. Data were expressed as mean \pm standard deviation or percentages and were analyzed using commercial statistical software. The Student's *t*-test was used to compare the differences of values between baseline and end-point. For all tests, a *P*-value of less than 0.05 was regarded as significant

Results

Results outcome show that α 1-blocker tamsulosin improved urodynamic voiding parameters in patients with underactivity bladder. An improvement in symptom score, storage symptom score, Q_{max} , PVR, voiding efficiency, IPSS (for men) IQoL and PGI questionnaire was observed in all patients, and a concrete therapeutic response with improved voiding symptoms was observed in 62,7% of the patients. The maximal flow rate increase was better in men (Q_{max} baseline 10,1 \pm 4,3; Q_{max} endpoint 12,63 \pm 6,4), than in women (Q_{max} baseline 7,80 \pm 3; Q_{max} endpoint 9,59 \pm 4,6).

Interpretation of results

Our study suggests that tamsulosin 0,4 mg improves voiding symptoms, Q_{max} (with better effectiveness in men than women), PVR, and all 3 questionnaire scores. These results are linked to the drug interaction with receptors α 1a α 1D bladder neck, trigone, urethra more expressed in men. No increase of P_{det} at maximum flow rate after 6 months of treatment was observed in either sex.

However an increase in P_{det} at maximum flow rate after 6 months treatments was not observed.

Concluding message

Our study suggests that tamsulosin improves voiding symptoms and urodynamic parameters in patients with voiding difficulty and comparable good therapeutic response rates were observed between men and women. This study also shows that the patient quality of life was improved by treatment and that the majority of patients felt a treatment benefit

References

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	this is an observational study that involves the use of drugs already on the market, approved by the AIFA.
<i>Was the Declaration of Helsinki followed?</i>	No
<i>This study did not follow the Declaration of Helsinki in the sense that</i>	this is an observational study that involves the use of drugs already on the market, approved by the AIFA.
<i>Was informed consent obtained from the patients?</i>	Yes