

# EFFICACY OF TAMSULOSIN THERAPY IN FEMALES WITH NON-NEUROGENIC LOWER URINARY TRACT SYMPTOMS

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## ABSTRACT

**Objective:** To determine the efficacy of tamsulosin therapy for the treatment of lower urinary tract symptoms (LUTS) in women.

**Methodology:** This study was conducted in Institute of kidney diseases, Hayatabad medical complex Peshawar from April 2011 to September 2012. All female patients aged 13 and above with LUTS were included. After taking history, physical examination and baseline investigations, specific investigations such as urine culture, urodynamics and ultrasound with postvoid residual volume were performed. Base line international prostate symptom score (IPSS), maximal flow rate ( $Q_{max}$ ) and post-void residual volume (PVR) were recorded for each patient before starting treatment. Tamsulosin therapy was initiated at 0.4 mg once daily and continued for 6 weeks. In follow up visits after 6 weeks, IPSS,  $Q_{max}$  and PVR were repeated for evaluation of outcomes.

**Results:** Out of 94 patients, 10 did not come for follow up. Mean age of the sample was 43 years. Presenting complaints were increased frequency (n=67, 79.8%), Urgency (n=62, 73.8%), Nocturia (n=64, 54.8%), Feeling of incomplete bladder emptying (n=17, 20.2%), Poor stream (n=15, 17.9%), Hesitancy (n=5, 6.0%), and Intermittency (n=2, 2.4%). Mean PVR and IPPS decreased and  $Q_{max}$  improved significantly with p value <0.01. Efficacy was 90.5%. It was 52(96.3%) in pre-menopausal and 24(80.0%) in postmenopausal women. Only Two patients experienced drowsiness.

**Conclusion:** Tamsulosin significantly decrease IPSS, PVR and improve  $Q_{max}$  so they should be used as first line treatment for moderate to severe LUTS in women.

**Key Words:** Female, Tamsulosin, Lower urinary tract symptoms (LUTS).

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## INTRODUCTION

Lower urinary tract symptoms (LUTS) are a common health problem causing considerable inconvenience and distress to many women<sup>1,2</sup>. Several studies revealed that (LUTS) are common among females. LUTS affect 15.5% to 53.7% of the adult women and it can severely compromise their social life<sup>3,4</sup>. Many patients have transient symptoms, but a significant number of patients have ongoing problems<sup>5</sup>. LUTS may be categorized into irritative and obstructive symptoms. It is often attributed to aging and associated with age related changes such as decreased bladder capacity and loss of estrogen<sup>6</sup> but it is also a common health problem among women in younger age group.

Treatment of LUTS includes conservative management and medical treatment such as  $\alpha$ -blockers, 5 $\alpha$ -re-

ductase inhibitors, muscarinic receptor antagonists etc. Initially  $\alpha$ -adrenoceptor antagonists were used in the urologic field to treat patients with lower urinary tract symptoms suggestive of benign prostate hyperplasia. Later on, many trials have provided evidence of the efficacy and tolerability of  $\alpha$ -adrenoceptor antagonists in female patients with lower urinary tract symptoms<sup>7</sup>. Recent studies show that  $\alpha_1$ -adrenoceptor antagonists effectively improve symptoms and voiding parameters in women with functional bladder outlet obstruction or detrusor underactivity<sup>8,9</sup>.

Because  $\alpha_1$ -adrenoceptors are gender-independent and appear to play roles in lower urinary tract function at multiple sites and levels, including the bladder neck and external urethral sphincter; it seems logical that  $\alpha_1$ -adrenoceptor antagonists could be used in women with voiding dysfunction<sup>10,11</sup>.

## METHODOLOGY

This descriptive study was conducted in institute of kidney diseases Hayatabad medical complex Peshawar from April 2011 to September 2012. All female patients with age  $\geq 13$  years were included in the study. We excluded the following. Patients with neurogenic LUTS, pregnant ladies, cesarean section or vaginal delivery 6 months prior to enrolment, patients on anticholinergic treatment, genitourinary cancer, neurogenic bladder, Parkinson's disease, multiple sclerosis, a history of surgery on the lower urinary tract such as bladder surgery, treatment for urinary incontinence or other urinary conditions, an anatomical deformation of the lower urinary tract (e.g., pelvic organ prolapsed) or regular use of a catheter for urine drainage.

Detailed histories were taken and thorough examinations including pelvic and neurologic examinations were performed. Routine base line investigations, urine analysis, urine culture, urodynamics and ultrasound for postvoid residual volume were also performed. Base line IPSS,  $Q_{max}$  and PVR were recorded for each patient before starting treatment. Tamsulosin was initiated at 0.4 mg once daily dose and continued for 6 weeks. Outcomes were evaluated using IPSS Questionnaire,  $Q_{max}$  and PVR after 6 weeks and comparing with pre-treatment records. Mean IPSS score less than 8; mean PVR less than 18 ml and mean  $Q_{max}$  more than 15 ml/sec were considered as efficacious.

### Lower urinary tract symptoms

Women with lower urinary tract symptoms were assessed using International Prostate Symptom Score. The IPSS is a self-administered questionnaire which uses 7 urologic symptoms and The patients respond to each item using a 6 point scale ranging from 0 (not at all) to 5 (almost always), and the scores are summed to obtain a total score ranging from 0 to 35. Nocturia was evaluated separately which is defined as urinating at least twice nightly. Total score is score of IPSS  $\geq 8$  was defined as LUTS.

Data was analyzed using SPSS version 17. Mean  $\pm$  SD was calculated for numerical variables such as age. Frequencies and percentages were calculated for categorical variables such as frequency, urgency of Micturition etc. and 95% confidence intervals for the association between tamsulosin and LUTS. An analysis was performed using the paired t-test to compare pre to post-treatment changes in IPSS,  $Q_{max}$  and PVR. P values of  $<0.01$  were considered statistically significant.

## RESULTS

Out of 94 patients, 10 did not come for follow up. Mean age was 43(range 14-86) years. Presenting complaints were increased frequency (n=67, 79.8%), Urgency (n=62, 73.8%), Nocturia (n=64, 54.8%), Feeling of incomplete bladder emptying (n=17, 20.2%), Poor stream (n=15, 17.9%), Hesitancy (n=5, 6.0%), and Intermittency (n=2, 2.4%). Mean Post void residual volume (PVR) and IPSS decreased significantly [Range from 9-35( $\leq 7$ )]; while  $Q_{max}$  improved significantly [In 56 patients  $Q_{max}$  increased for more than 50%]. Efficacy was 90.5%. It was 52(96.3%) in pre-menopausal and 24(80.0%) in post-menopausal women. Only Two patients experienced drowsiness.

## DISCUSSION

Studies are available which shows that  $\alpha_1$ -blockers are superior to placebo in the treatment of female LUTS. The results of our study show that the  $\alpha_1$ -blocker has a beneficial effect on  $Q_{max}$ , IPSS score and post void residual volume. We used tamsulosin to see its effects on urinary stream in female patients who presented with weak urinary stream.

We found that tamsulosin has significantly improved the  $Q_{max}$  because of its relaxing effects on bladder neck and urethra. In the current study  $Q_{max}$  was increased from 8.2 to 15.6 ml/sec ( $P < 0.01$ ). Several studies are available in support of our findings. Lee et al<sup>7</sup> conducted a study on female patients who presented with lower urinary tract symptoms for at least 3 months. He used

**Table 1: Comparison of urodynamic data before and after treatment**

Investigation	Before treatment	After treatment	P value
PVR (mL)	120	18	$<0.01$
Mean IPSS	23.5	7.6	$<0.01$
Qmax (mL/s)	8.2	15.6	$<0.01$

tamsulosin (a selective  $\alpha_{1A}/_{1D}$ -adrenoceptor antagonist) to evaluate the potential therapeutic effects of  $\alpha_1$ -blocker in female patients with poor urinary stream. After 8 weeks of treatment, he observed that 33.0% patients showed a  $Q_{max}$  increase of more than 50% with minimal adverse effects. He concluded that Tamsulosin is effective in female patients with voiding dysfunction regardless of obstruction grade. In another study Reitz et al<sup>12</sup> recorded urethral pressure through, microtip pressure transducer catheters before and after the administration of tamsulosin. The oral administration of 0.4 mg tamsulosin significantly reduced the mean and maximal urethral pressure acquired over the entire urethra. When the proximal, middle and distal third of the urethra were analyzed separately, there was a significant pressure reduction in all three segments; supporting our statement that tamsulosin can significantly improve  $Q_{max}$ . In a prospective pilot study conducted by Thomas et al<sup>13</sup>, fifteen women with functional bladder outlet obstruction were treated with alpha blockers. Symptoms and urodynamic parameters were assessed before and 4 weeks after the initiation of  $\alpha$ -blocker therapy. There was a significant increase in the median maximum flow rate from 9 to 20 ml per (p = 0.0005). He concluded that alpha blockers had a significant symptomatic and urodynamic effect in two-thirds of patients. Kumar et al<sup>14</sup> in his study concluded that (50%) patients showed improvement in  $Q_{max}$  (p < 0.01) with  $\alpha$ -blocker therapy only. However, the other 50% of patients underwent bladder neck incision or remained on clean intermittent self-catheterization due to an inadequate response. According to the study of Pischedda et al, Fifty-six percent of their study patients showed significant improvements in  $Q_{max}$ .<sup>9</sup>

In our study, PVR was reduced from 120 to 18ml/sec (P<0.01), which was supported by several studies. Hajebrahimi et al<sup>15</sup> in a parallel design double blind clinical trial compared the effects of tamsulosin and prazosin on clinical and urodynamic parameters in women with voiding dysfunction. Forty patients were randomly assigned to three months of treatment with tamsulosin 0.4 mg daily (n = 20) or prazosin 1–2 mg daily (n = 20). He noted that PVR in the tamsulosin group declined by 23.5 ml. Kyu-Sung Lee<sup>7</sup> reported a decline of PVR from 69.13+85.45 of baseline to 39.88+48.39 after 8 week treatment (p value < 0.001). Similarly the study of Pischedda et al<sup>9</sup> and Kumar et al<sup>14</sup> also showed a statistically significant improvement in postvoid residual urine volume (p < 0.01).

In the current study of 84 patients, IPSS was reduced from 23.5 to 7.6, which is a statically significant value. Our results are comparable to other studies. After 8-week of treatment, Kyu-Sung Lee<sup>7</sup> concluded that mean IPSS decreased significantly from 23.9±6.09 to

16.1±8.17 and storage symptoms and voiding symptoms were also improved. In his study the IPSS in 72 patients (67.9%), decreased by more than 5 points. Both scores changed significantly as well. Similarly Pummangura et al<sup>16</sup> conducted a randomized double-blind study comparing tamsulosin (70) versus placebo (70) for 1 month. In his study mean change from baseline of IPSS (standard deviation, SD) were -5.6 (6.3) in the tamsulosin group and -2.6 (6.1) in the placebo group. The difference was statistically significant (p = 0.008). He concluded that Tamsulosin is more efficacious than placebo in the treatment of LUTS in women. Pischedda et al<sup>9</sup> and Kumar et al<sup>14</sup> also noted significant improvement in LUTS and concluded that Clean intermittent self-catheterization and  $\alpha$ -blockers are the initial treatment options for functional bladder neck obstruction. Hajebrahimi S<sup>15</sup> observed a large decrease of IPSS from 14.65 ± 6.02 to 8.41 ± 4.23 (P < 0.01) in the tamsulosin group.

In the current study 2 out of 84 patients experienced drowsiness; no other side effects were noted. In the study Lee et al<sup>7</sup>, adverse effects were dizziness (3 cases), de novo stress urinary incontinence (3 cases), aggravation of underlying stress urinary incontinence (1 case), and fatigue (1 case). Hajebrahimi<sup>15</sup> also noted that only one patient experienced drowsiness with tamsulosin; no other side effects were noted.

The present study demonstrates that IPSS,  $Q_{max}$ , PVR were improved significantly after tamsulosin treatment in female patients with non-neurogenic LUTS. Thus, the use of  $\alpha_1$ -blockers in women with non-neurogenic voiding dysfunction appears reasonable and it should be used as first line treatment for moderate to severe LUTS in women. Randomized controlled studies are needed to provide further evidence of efficacy of tamsulosin treatment in female patients with non-neurogenic LUTS.

## CONCLUSION

Tamsulosin therapy significantly decrease IPSS, PVR and improve  $Q_{max}$ , so they should be used as first line treatment for moderate to severe LUTS in women.

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#### CONTRIBUTORS

TA planned the study, and wrote the manuscript. AR supervised the study. MAK helped in statistical analysis and data interpretation. All authors contributed significantly to the final manuscript.