

## A COMPARATIVE STUDY OF TERAZOSIN AND TAMSULOSIN IN MEDICAL TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA (BPH)

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### Abstract

This study was designed to compare the efficacy and safety of terazosin and tamsulosin in the treatment of symptomatic benign prostatic hyperplasia. A clinical trial was carried out in the out patients department of urology, Bangabandhu Sheikh Mujib Medical University (BSMMU) during the period from January 2003 to January 2004. Total 62 patients of 45-80 years of age, were consequently selected. After completion of baseline clinical evaluation and investigations, participants were divided into two groups, group A and group B. Group A (n=31) was given terazosin 1mg daily for 3 days at bed time and then 2 mg daily at bed time for 2 months. Group B (n=31) was given tamsulosin, 0.4 mg per day for 2 months. Efficacy was evaluated of each group after 2 months follow up and lastly a comparison was made between them. The parameters monitored were international prostate symptoms score (IPSS), maximum urine flow rate (Qmax) and post voidal residual volume (PVR). Tamsulosin 0.4 mg once daily dose and terazosin 1-2 mg incremental dose at least for 8 weeks both are effective in relieving symptoms of BPH but tamsulosin is superior to terazosin in improvement of total IPSS (p<.001) and Qmax (p<.001), PVR (<.01) at the end point.

Outcome of parameters at followup after 2 months. Tamsulosin group showed significant improvement reduction of IPSS (P<0.001), Qmax (P<0.001), reduction of PVR (P<0.01) then terazosin. The incidence of adverse events by administration of tamsulosin was less then that by terazosin. So tamsulosin appears to be safer and more effective than terazosin in symptomatic BPH.

**Key words :** Tamsulosin; Terazosin; IPSS; Qmax; PVR

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### Introduction

Lower urinary tract symptoms suggestive of symptomatic benign prostatic hyperplasia (BPH) are a very common disease in elderly men<sup>1</sup>. The incidence of benign prostatic hyperplasia is age related<sup>2</sup>. The prevalence of histologic BPH in autopsy studies is about 20% in men aged 41-50 years, 50% in men aged 51-60 years and over 90% men above the age of 80 years<sup>3</sup>. As the life expectancy is increasing, the number of patients with symptomatic BPH is also increasing.

The clinical manifestation BPH included lower urinary tract symptoms, poor bladder emptying, urinary retention, detrusor instability, urinary tract infection, haematuria and renal insufficiency.

Dynamic obstruction is caused by increased muscle tone of the bladder neck and prostate which is regulated by  $\alpha 1$  adrenergic receptor <sup>4</sup>.

A reduction in tone might be expected to reduce prostatic urethral pressure and to improve obstructive symptoms.

a blocker has now been prescribed for treatment of BPH for almost 20yrs <sup>5</sup>. prostatic urethra, urinary bladder neck constituting about 70% of its  $\alpha 1$  A receptor <sup>6</sup>.

Medical treatment for BPH may be in the form of  $\alpha 1$  receptor blockers and 5 $\alpha$  reductase inhibitor. But it is now well known that  $\alpha 1$  receptor blockers (like terazosin, tamsulosin) is safe and more effective than 5 $\alpha$  reductase inhibitors and combination of the two (leporetal)<sup>7</sup>.

Over the last decade, the incidence of the surgery has declined in all most all countries and the incidence of medical treatment is rising<sup>8</sup>. The goal of study was to findout safety of a blockers to improve the IPSS sore Qmax and PVR, in symptomatic BPH.

### Materials and method

This was a randomized clinical trial conducted in the department of urology, Bangabandhu Sheikh Mujib Medical University (BSMMU) Dhaka form January 2003 to January 2004. Study population included the patients who attended outpatient department of urology, BSMMU, Dhaka with symptomatic BPH.

The method and purpose of the study were explained to the patients and only those who agreed were finally Selected. Written consent was taken from each respondent. The inclusion criteria were, male between 45 to 80 yrs. IPSS 8 to 19, PVR 50 to 100ml. Peak urine flow rate (Qmax) more than 10ml /S but less then or equal to 15ml/S, voided volume of at least 150 ml.

Patients with carcinoma prostate, refractory retention of urine, recent U.T.I., recent gross haematuria, bladder stone, hydroureteronephrosis, renal insufficiency (S.creatinine >2mg/dl), large bladder diverticula, neurogenic bladder. Stricture urethra, were excluded from the study.

A total 62 patient were randomly selected for this study, they are numbered in 1 to 62. Odd numbers were considered as a terazosin (group A) and even number as tamsulosin (group B). All history and examination followed a similar protocol. A detail data sheet was completed and this included particulars of the patients, results of the physical examinations and relevant base line investigations. The patients were supplied with Bengali version IPSS sheet and they were well explained and helped in expressing their symptoms in numerical representation of IPSS.

Thorough physical examination was done with special attention to urogenital system and nervous system. Blood pressure (BP) was measured in lying and standing position to exclude postural hypotension. Digital rectal examination was done in the urology OPD to determine the prostate size and to exclude carcinoma prostate, perianal sensation, anal tone and bulbocavernosus reflex, sensory and motor response. Jerks and reflexes were examined to detect any neurological deficit.

Urine R/M/E, C/S, PSA, Serum creatinine was done to exclude U.T.I, carcinoma prostate renal failure. USG of the KUB and prostate with MCC and PVR was done to see the change in kidney urinary stone disease bladder wall thickness, prostate size echotexture and any hypoechoic lesion in the prostate. Uroflowmetry was considered reliable when voided volume is more than 150ml. plain x-ray K.UB was done to exclude urinary stone disease and any lesion in the vertebral column.

In suspected case, neuropathic bladder was excluded by voiding cystometry and urethral stricture was excluded by retrograde urethrogram.

TC, DC, ESR, Hb%, Serum total protein and albumin were done to exclude any side effects of terazosin and tamsulosin.

After completion of baseline clinical evaluation and investigation, participants were divided into two groups, group A and group B. Group A (n=31) was given terazosin 1 mg daily for 3 days at bed time and then 2 mg daily at bed time for 2 months. Group B (n=31) was given tamsulosin 0.4 mg per day for 2 months. Efficacy was evaluated of each group after 2 months and comparison was made between them. During follow up visit after 2 months BP (both in lying and standing) was recorded. Uroflowmetry was done. USG of kidney, ureter, urinary bladder, prostate, PVR, MCC were done. IPSS score was also evaluated. Blood count like TC, DC, Hb% PCV, Serum total protein and albumin were done to exclude adverse effects. Any side effects of the drugs were recorded.

All statistical analysis was carried out using SPSS software. All results were expressed as mean  $\pm$  SD or in frequency as applicable. The results were compiled and analyzed using students 't' test and chi-squared test as appropriate. Results were considered significant if  $p < 0.05$ .

### Results

There was no significant difference in mean age, base line peak urine flow rate (Qmax), base line international prostate symptoms score (IPSS) and base line post voidal residue (PVR).

**Table I :** Comparison of base line data of two groups, group A (Terazosin) & group B (Tamsulosin)

Parameters	Patient group	Mean $\pm$ SD	p-value
Age	Terazosin (n=31)	64.23 $\pm$ 6.63	0.95
	Tamsulosin (n=31)	64.13 $\pm$ 6.29	
Qmax	Terazosin (n=31)	12.32 $\pm$ 1.05	0.44
	Tamsulosin (n=31)	12.55 $\pm$ 26	
IPSS	Terazosin (n=31)	15.84 $\pm$ 1.85	0.78
	Tamsulosin (n=31)	15.71 $\pm$ 1.90	
PVR	Terazosin (n=31)	88.55 $\pm$ 21.28	0.81
	Tamsulosin (n=31) (Unpaired 't' test)	87.26 $\pm$ 23.05	

### A. Terazosin group

In the follow-up visit after 2 months, treated with terazosin, the mean values of IPSS, Qmax and PVR were 9.52 $\pm$ 1.89 points, 15.35 $\pm$ 1.05 ml/sec and

52.58±13.10 ml respectively. Mean value change of IPSS, Qmax and PVR were 6.32±2.90 points, 3.03±0.98 ml/sec and PVR 36.06±12.38ml respectively in terazosin group. In comparison to baseline mean values, IPSS, Qmax and PVR values were significantly changed ( $p<0.05$ ) (Table II).

#### B. Tamsulosin group

In follow-up visit, after 2 months, treated with tamsulosin, the mean values of IPSS, Qmax and PVR were 8.48±1.15 points, 16.52±1.23 ml/sec and 43.03±12.5 ml respectively. Mean value change of IPSS, Qmax and PVR were 7.23±1.76 points, 3.97±0.66 and 44.23± 16.91 ml respectively in tamsulosin group. In this visit, all mean values of variables were significant change ( $p<0.05$ ), in comparison to baseline studies (Table III).

Follow-up visit after two months (change of Qmax).

In the follow-up visit, after two months mean Qmax in terazosin group (n=31) was 15.35±1.05 ml/sec. In comparison to baseline mean Qmax this value shows significant change ( $p<0.05$ , in paired 't' test). Similarly, mean Qmax in the tamsulosin group was 16.52±1.23 ml/sec. In comparison to baseline, this

value also shows significant change ( $p<0.05$ ). Qmax change in terazosin group from baseline was 3.03±0.98 ml/sec and in tamsulosin group was 3.97±0.66 ml/sec. Both groups had significant increase in mean Qmax ( $p<0.001$  in 't' test) in the follow up visit (Table IV).

In this study, mean percentage improvement of Qmax in terazosin group was 24.61±7.97 ml/sec and in tamsulosin was 32.20±5.33 ml/sec. In comparison, therefore, the tamsulosin group showed significantly higher flow rate ( $p<0.05$  in unpaired 't' test). So, in follow-up visit after two months tamsulosin was more effective than terazosin group.

Follow-up visit after 2 months (change of IPSS).

In the second follow-up visit, mean IPSS in terazosin group (n=31) was 9.52±1.86 points. In comparison to baseline mean IPSS this value shows significant change ( $p<0.05$  in paired 't' test). Similarly, mean IPSS in the tamsulosin group was 8.48±1.15 points. In comparison to baseline, this value also shows significant change ( $p>0.05$ ). IPSS change in terazosin group from baseline was 6.32±2.90 points and tamsulosin group was

**Table II** : Results of terazosin group in follow up visit after two months

	Baseline (Mean ± SD)	Second follow-up (Mean± SD)	Change from baseline (Mean± SD)	Mean % Change ± SD	p-value
IPSS (Points)	15.84 ± 1.85	9.52 ± 1.86	6.32 ± 2.90	39.8 ± 17.78	p<.001
Qmax (ml/s)	12.32 ± 1.05	15.35 ± 1.05	3.03 ± .98	24.61 ± 7.97	p<.001
PVR (ml)	88.65±21.28	52.58±13.10	30.06 ± 12.38	40.7±13.9	p<.001
BP (S) mmHg	140.70±11.4	129.84±10.2	10.81±13.97	6.759±8.73	p<.001
Standing (D)	86.00±21.76	81.61±5.06	4.39±6.98	4.61±7.35	p<.001
BP (S) mmHg	137.26±	12.06±9.56	11.19±13.41	8.15±9.76	p<.001
Lying (D)	83.32±5.03	78.42±4.42	4.90±6.19	5.88±7.43	p<.001

(Paired 't' test)

S=systolic pressure, D= Diastolic pressure

**Table III** : Results of tamsulosin group in follow up visit after two months

	Baseline (Mean ± SD)	Second follow-up (Mean± SD)	Change from baseline (Mean± SD)	Mean % Change ± SD	p-value
IPSS (Points)	15.71±1.90	8.48±1.15	7.23±1.76	46.02±10.21	P<.001
Qmax (ml/s)	12.55±1.26	16.52±1.23	3.97±0.66	32.20±5.33	P<.001
PVR (ml)	87.26±23.05	43.03±12.5	44.23±16.91	50.68±14.54	P<.001
BP-mmHg S	141.61±14.8	130.48±12.7	11.131±16.72	6.95±10.4	P<.01
Standing (D)	85.32±6.96	81.71±7.39	3.61±11.49	3.80±12.1	P>.05
BP (S)	136.13±13.95	124.52±23.7	11.61±26.7	8.46±18.99	P>.05
mmHg Lying (D)	82.23±6.08	78.71±6.17	3.52±9.49	4.22±11.39	P>.05

(Paired 't' test)

S=systolic pressure, D=Diastolic pressure.

7.23±1.76 points. Both groups had significant decrease in mean IPSS ( $p<0.001$  in 't' test) in the second visit (Table -V).

In this study, mean percentage improvement of IPSS in terazosin group was 39.8±17.78 points and in tamsulosin was 46.02±10.21 points. In comparison of IPSS change, therefore tamsulosin group showed significantly better response than terazosin in second visit ( $p<0.01$  in unpaired 't' test).

Follow-up visit after two months (change of PVR) In the follow-up visit after two months mean PVR in terazosin group (n=31) was 52.58±13.10 ml. In comparison to baseline mean PVR this value shows significant change ( $p<0.05$  in paired 't' test). Similarly, mean PVR in the tamsulosin group was 43.03±12.5 ml. In comparison to baseline, this value also shows significant change ( $p<0.05$ ). PVR change in terazosin group from baseline was 36.06±12.38 ml and tamsulosin group was 44.23±16.91 ml. Both groups had significant decrease in mean PVR ( $p<0.01$  in 't' test) in the second visit (Table-VI).

**Table IV :** Comparison of Qmax between terazosin group and tamsulosin group on different follow-up visit

Group	Baseline (Mean± SD)	second follow-up (Mean± SD)	P (in the same group comparison with baseline)	Change from baseline (Mean± SD)	Mean % change ± SD	P-value (in comparison of Qmax change between terazosin and tamsulosin)
Terazosin	12.32 ± 1.05	15.35 ± 1.05	P<.001	3.03 ± 98	24.61 ± 7.97	P<.001
Tamsulosin	12.55 ± 1.26	16.52 ± 1.23	P<.001	3.97 ± 0.66	32.20 ± 5.33	

(Paired 't' test)

**Table V :** Comparison of IPSS between terazosin group and tamsulosin group on different follow-up visit

Group	Baseline (Mean± SD)	second follow-up (Mean± SD)	P (in the same group comparison with baseline)	Change from baseline (Mean± SD)	Mean % change ± SD	P-value (in comparison of Qmax change between terazosin and tamsulosin)
Terazosin	15.84±1.85	9.52±1.86	P<.001	6.32±2.90	39.8±17.78	P<.05
Tamsulosin	15.71±1.90	8.48±1.15	P<.001	7.23±1.76	46.02±10.20	

(Paired 't' test)

**Table VI :** Comparison of PVR between terazosin group and tamsulosin group on different follow-up visit

Group	Baseline (Mean± SD)	second follow-up (Mean± SD)	P (in the same group comparison with baseline)	Change from baseline (Mean± SD)	Mean % change ± SD	P-value (in comparison of Qmax change between terazosin and tamsulosin)
Terazosin	88.65±21.28	52.58±13.10	P<.001	36.06±12.38	40.7±13.9	P<.001
Tamsulosin	87.26±23.05	43.03±12.5	P<.001	44.23±16.91	50.68±14.54	

(Paired 't' test)

In this study, mean percentage improvement of PVR in terazosin group was  $40.71 \pm 13.9$  ml and in tamsulosin was  $50.68 \pm 14.54$  ml. In comparison of PVR change, therefore, tamsulosin group showed significantly better response than terazosin in second follow-up visit ( $p < 0.01$  in unpaired 't' test).

Adverse effect of terazosin and tamsulosin group during 2 months of therapy.

In this study, among terazosin group, postural hypotension, dizziness, headache, hypotension (lying) rhinitis and asthenia were 9.6%, 19.35%, 12.90%, 6.45%, 0%, 6.45% respectively. In the tamsulosin group, these were 0%, 6.45%, 3.2%, 0%, 3.2% and 3.2% respectively (Table VII).

**Table VII :** Adverse effect of terazosin and tamsulosin group.

Asset	Terazosin Percentage (%)	Tamsulosin Percentage (%)
I) Postural hypotension	9.67	0
II) Dizziness	19.35*	6.45*
III) Headache	12.90**	3.2**
IV) Hypotension (lying position)	6.45	0
V) Rhinitis	0	3.2
VI) Asthenia	6.45	3.2

\*  $P < 0.05$  in -Z- test

\*\*  $P < 0.05$  in -Z- test

### Discussion

Benign prostatic hyperplasia is a condition of ageing male. It is well established the incidence of BPH risk increase with age.

Alpha receptor blockers generally improve urinary symptoms and peak urinary flow rates 2 to 4 week after introduction of the therapy<sup>9</sup>. So the present study "A comparative study of terazosin and tamsulosin for symptomatic benign prostatic hyperplasia (BPH) were designed for 2 months period.

In this study age range was 52-78 yrs. with a mean for terazosin group was  $64.23 \pm 6.63$  yrs and tamsulosin group was  $64.13 \pm 6.29$  yrs. The results of age of two group were statistically insignificant ( $P > 0.05$ ).

Baseline mean of IPSS in terazosin group was 15.8411.85 and in tamsulosin group was  $15.71 \pm 1.90$  points.

Base line Qmax of terazosin group was  $12.32 \pm 1.05$  ml/Sec and tamsulosin was

$12.55 \pm 1.26$  ml/Sec respectively.

Base line PVR of terazosin group was  $88.55 \pm 21.28$  ml and tamsulosin group was  $87.26 \pm 23.25$  ml.

All baseline parameters like Qmax, IPSS PVR in terazosin and tamsulosin group were statistically insignificant. So these factors did not affect study.

Patients having specific drugs in specific group for continuously for 2 months and follow up done by taking different parameters.

Mean IPSS after 2 months in terazosin group  $9.52 \pm 1.86$  points. This shows significant improvement from base line value ( $P < 0.05$ ) and in tamsulosin group mean IPSS was  $8.48 \pm 1.15$  points which was also a significant improvement from base line value ( $P < 0.05$ ).

Follow up visit after 2 months mean IPSS improvement from base line was  $6.32 \pm 2.90$  points for terazosin and  $7.23 \pm 1.76$  points for tamsulosin. Therefore the tamsulosin group showed significant reduction of IPSS score than terazosin ( $P < 0.001$ ).

The percentage improvement of IPSS in terazosin group was  $39.8 \pm 17.78$  points and tamsulosin group was  $46.02 \pm 10.21$  points. Mean Qmax after 2 months in terazosin group was  $15.35 \pm 1.05$  ml/Sec and in tamsulosin group was  $16.52 \pm 1.23$  ml/Sec. This was significant higher in both group from base line.

Qmax improvement from base line was  $3.05 \pm 0.98$  ml/Sec for terazosin,  $3.97 \pm 0.66$  ml/Sec for tamsulosin group. Here also the tamsulosin group showed significant higher flow rate than terazosin ( $P < 0.001$ ).

The percentage improvement of Qmax in terazosin group from base line was  $24.61 \pm 7.97$  ml/Sec. and for tamsulosin was  $32.20 \pm 5.33$  ml/Sec.

Mean PVR after 2 months in terazosin group was  $52.58 \pm 13.10$  ml and tamsulosin group was  $43.03 \pm 12.5$  ml. PVR improvement from base line was  $36.06 \pm 12.38$  ml for terazosin  $44.23 \pm 16.91$  ml for tamsulosin.

The percentage improvement of PVR in terazosin group was  $40.7 \pm 13.9$  ml and in tamsulosin group was  $50.68 \pm 14.54$  ml.

Many of this studies revealed maximum effect of terazosin and tamsulosin in between 8-12 weeks. This results is compatible with the study of Brawer et al<sup>10</sup>.

A study done by Chappie et al (1996)<sup>11</sup>. They have

found maximum urinary flow rate improved to a greater extent in tamsulosin group (1.6 ml/sec. 16%) than the placebo. Similar effect has been found in the study done by Schulman et al (2001)<sup>12</sup>, Abrams et al (1999)<sup>13</sup>. A study by Elhilali et al (1996)<sup>14</sup>, with 1-10 mg of terazosin titration dose, Qmax improvement was 13% more in terazosin group than placebo (terazosin minus placebo).

#### Complication

The most common adverse effects we found were, headache, asthenia, dizziness, rhinitis and retrograde delayed ejaculation. Tarazosin group showed more postural hypotension, headace than tamsulosin group.

In other study, postural hypotension, headache, asthenia is much more common with terazosin. This study compatible with study done by Na et al, (1998)<sup>15</sup>. They also showed incidence of adverse effect by administration of tamsulosin was less than that of terazosin group (13 and 50% respectively, (p<0.01). This is supported by study done by DeMey and Terpstra, (2000)<sup>16</sup>, Tewari and Narayan, (1999)<sup>17</sup>, Okada et al (2000)<sup>18</sup> Tsujii et al (2000)<sup>19</sup>. In another study by Lee, (2000)<sup>20</sup>.

#### Conclusion

It can be concluded that tamsulosin 0.4 mg once daily dose and terazosin 1-2 mg incremental dose at least for 8 weeks both are effective in relieving symptoms of BPH but tamsulosin is superior to terazosin in improvement of total IPSS (p<.001) and Qmax (p<.001), PVR (<.01) at the end point. The incidence of adverse events by administration of tamsulosin was less than that by terazosin. So tamsulosin appears to be safer and more effective than terazosin in symptomatic BPH.

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