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Original Article

A Comparative Study of Efficacy and Safety Between Tamsulosin and Terazosin in the Treatment of Symptomatic Benign Prostatic Hyperplasia

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Abstract

Background: Lower urinary tract symptoms suggestive of symptomatic Benign Prostatic Hyperplasia (BPH) are a very common disease in elderly men .The incidence of benign prostatic hyperplasia is age related**. Objectives**: To compare the efficacy and safety of Tamsulosin and Terazosin in the treatment of symptomatic Benign Prostatic Hyperplasia. **Methods:** This was a prospective study carried out in the Department of Urology, Chittagong Medial College Hospital, Chittagong, Bangladesh during the period of July to December 2014. Total 40 patients of 45-80 years of age were consequently selected according to inclusion criteria. After completion of baseline clinical evaluation and investigations, participants were divided into two groups, group A and group B. Group A (n=20) 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=20) was given Tamsulosin, 0.4 mg per day for 2 months. Efficacy was evaluated of each group after 2 month 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 and Terazosin 2 mg once daily for 8 weeks both are effective in relieving symptoms of BPH but Tamsulosin is superior to Terazosin in improvement of total IPSS ($p<0.001$) and Qmax ($p<0.01$) PVR ($p<0.01$) at the end point. **Results:** Outcome of parameters at follow up after 2 months. Tamsulosin group showed significant improvement of IPSS ($p<0.05$) PVR ($p<0.001$) and Qmax ($p<0.001$) than Terazosin. The incidence of adverse events by administration of Tamsulosin was less than that by Terazosin. **Conclusion:** Tamsulosin appears to have more efficacy and safety than Terazosin in symptomatic BPH.

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

INTRODUCTION

Lower urinary tract symptoms suggestive of symptomatic Benign Prostatic Hyperplasia (BPH) are a very common disease in elderly men[1]. The incidence of benign prostatic hyperplasia is age related[2]. 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[3]. As life expectancy is increasing, the number of patients with symptomatic BPH is also increasing.The clinical manifestation of 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 alpha1 adrenergic receptor[4].

A reduction in tone might be expected to reduce prostatic urethral pressure and to improve obstructive symptoms. Alpha blocker has now been prescribed for treatment of BPH for almost 20 years[5]. Prostatic urethra and urinary bladder neck constitute about 70% of alpha1 receptor[6]. Medical treatment for BPH may be in the form of alpha receptor blockers and 5 alpha reductase inhibitors. But it is now well known that alpha receptor blockers (Like Terazosin, Tamsulosin) is safe and more effective than 5 alpha reductase inhibitors and combination of the two[7]. Over the last decade, the incidence of surgery has declined in almost all countries and the incidence of medical treatments rising[8]. The goal of the study was to find out safety of a blockers to improve the IPSS score, Qmax and PVR, in symptomatic BPH.

MATERIALS AND METHODS

This was a prospective study conducted in the Department of Urology, Chittagong Medical College Hospital, Chittagong from July to December 2014. 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 45-80 years, IPSS 8 to 19, PVR 50 to 100 ml. Peak urine flow rate (Qmax) more than 10ml/sec but less than or equal to 15ml/sec, 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 (Serum creatinine > 2 mg/dl) large bladder diverticula, neurogenic bladder, stricture urethrae were excluded from the study.

A total 40 patient were randomly selected for this study, they were numbered in 1 to 40. Odd numbers were considered as 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 baseline investigations. The patients were supplied with Bengali version IPSS sheet and they were explained and helped in expressing their symptoms in numerical representations 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 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 were done to exclude UTI, 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. Uroflow metry was considered reliable when voided volume is more than 150 ml. Plain X-ray KUB was done to exclude urinary stone disease and any lesion in the vertebral column. TC,DC,ESR, Hb%, serum total protein and albumin were done to exclude any side effect 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=20) was given terazosin1mg daily for 3 days at bed time and then 2 mg daily at bed time for 2 months. Group B (n=20) was given tamsulosin 0.4mg per day for 2 months. Efficacy and safety were evaluated 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, MCC, PVR were done. IPSS score was also evaluated. Any side effects of the drugs were also recorded.

Statistical analysis was carried out using Statistical Package for Social Science (SPSS) software. All results were expressed as means± SD or in frequency as applicable. The results were complied and analysed using students t- test and chi-square 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) International Prostate Symptom Score (IPSS) and Post Voidal Residue (PVR) (Table I).

Table 1 : Comparison of base line data of two groups, Group A (Terazosin) & Group B (Tamsulosin).

Parameters	Patient group	Mean±SD	p value
Age	Terazosin (n=20)	64.23±6.63	0.95
	Tamsulosin (n=20)	64.13±6.29	
Q max	Terazosin (n=20)	12.32±1.05	0.44
	Tamsulosin (n=20)	12.55±2.6	
IPSS	Terazosin (n=20)	15.84±1.85	0.78
	Tamsulosin (n=20)	15.71±1.90	
PRV	Terazosin (n=20)	88.55±21.28	0.81
	Tamsulosin (n=20)	87.26±23.05	

In the follow up visit after 2 months, patients treated with terazosin, mean values of IPSS, Qmax and PVR were 9.52±1.86 points, 15.35±1.05 mi/sec and 52.58±13.10ml respectively. Mean value change of IPSS, Qmax and PVR were 6.32±2.90 points, 3.03±0.98 ml/sec and 30.06±12.38 ml respectively. In comparison to baseline mean values, IPSS, Qmax and PVR values were significantly changed ($p<0.05$ in IPSS and $p<0.001$ in Qmax and PVR) (Table 2).

Table 2 : Terazosin group in follow up visit.

Parameters	Baseline	At follow up	Change from baseline	Mean change %	p-value
IPSS	15.84±1.85	9.52±1.86	6.32±2.90	39.8±17.78	p<0.05
Q max	12.32±1.05	15.35±1.05	3.03±0.98	24.61±7.97	p<0.001
PVR	88.65±21.28	52.58±13.10	30.06±12.38	40.7±13.90	p<0.001

In follow up visit after 2 months, patients treated with tamsulosin, 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 significantly changed in comparison to baseline studies (p<0.001) (Table 3).

Table 3 : Tamsulosin group in follow up visit.

Parameters	Baseline values	At follow up visit	Change from baseline	Mean change%	p-value
IPSS	15.71±1.90	8.48±1.15	7.23±1.76	46.02±10.21	p<0.001
Q max	12.55±1.26	16.52±1.23	3.97±0.66	32.20±5.33	p<0.001
PVR	87.26±23.05	43.03±12.50	44.23±16.91	50.68±14.54	p<0.001

Mean percentage improvement of IPSS in terazosin group was 39.80±17.78 points and in tamsulosin group was 46.02±10.21 points. In comparison of IPSS change, tamsulosin group showed significantly better response than terazosin group in follow up visit (p<0.05) (Table 4).

Table 4 : Comparison of IPSS between the two groups in follow up visit.

Group	Baseline values	At follow up visit	p value in same group	Change from baseline	Mean change%	p value in comparison between the two groups
Terazosin	15.84±1.85	9.52±1.86	p<0.001	6.32±2.90	39.80±17.78	p<0.05
Tamsulosin	15.71±1.90	8.48±1.15	p<0.001	7.23±1.76	46.02±10.20	

Mean percentage improvement of Qmax in terazosin group was 24.61±7.97 ml/sec andin tamsulosin was 32.20±5.33 ml/sec. In comparison tamsulosin group showed significantly higherflow rate in follow up visit (p<0.001) (Table 5).

Table 5 : Comparison of change of Qmax between the two groups in follow up visit.

Group	Baseline values	At follow up	p value the same group	Change from baseline	Mean change%	p value in Q max change between the groups
Terazosin	12.32±1.05	15.35±1.05	p<0.001	3.03±0.98	24.61±7.97	p<0.001
Tamsulosin	12.55±1.26	16.52±1.23	p<0.001	3.97±0.66	32.20±5.33	

Mean percentage reduction of PVR in terazosin group was 40.71±13.9 and in tamsulosin it was 50.68±14.54. In comparison of PVR change, tamsulosin group showed significantly better response than terazosin in follow up visit (p<0.001) (Table 6).

Table 6: Comparison of change of PVR between the two groups in follow up visit.

Group	Baseline values	follow up values	p value in the same group change	Change from baseline	Mean change%	p value between the two groups
Terazosin	88.65±21.28	52.58±13.10	p<0.001	36.06±12.38	40.70±13.9	p<0.001
Tamsulosin	87.26±23.05	43.03±12.50	p<0.001	44.23±16.91	50.68±14.54	

In this study, among terazosin group, postural hypotension, dizziness, headache, hypotension (Lying), rhinitis and asyhenia were 9.6%, 19.35%, 12.90%, 6.45%, 0%, 6.45% respectively. In the tamsulosin group, these were 0%, 6.45%, 3.2%, %, 3.2% and 3.2% respectively (Table 7).

Table 7: Adverse effects of terazosin and tamsulosin in follow up visit.

Effects	Terazosin group (%)	Tamsulosin group (%)
Postural hypotension	9.67	0
Dizziness	19.35	6.45
Headache	12.90	3.2
Hypotension (Lying position)	6.45	0
Rhinitis	0	3.2
Asthenia	6.45	3.2

DISCUSSION

Benign prostatic hyperplasia is a condition of ageing male. It is well established that incidence of BPH risk increases with age. Alpha receptor blockers generally improve urinary symptoms andpeak urinary flowrates 2 to 4 weeks after introduction of the therapy[9].

In this study age range was 45-80 yrs. with a mean for terazosin group was 64.23±6.63 yrs. and tamsulosin group was 64.13±6.29 yrs. The results of age of two group were statistically insignificant (p>0.05).

Base line mean of IPSSS in terazosin group was 15.84±11.85 and in tamsulosin group was 15.71±1.90 points.Base line Qmax of terazosin group was 12.32±1.05 ml/sec and tamsulosin was 12.55±1.26 ml/sec respectively. Base line PVR of terazosin group was 88.55±21 ml and tamsulosin group was 87.26±23.25 ml. All baseline parameters like Qmax, IPSS, PVR in both the groups were statistically insignificant. So these factors did not affect study.

Patients having specific drugs in particular group continuously for 2 months and follow up done by taking different parameters.Mean IPSS after 2 months in terazosin group was 9.52±1.86 and 8.48±1.15 in tamsulosin group. Both showed significant improvement from base line values (p<0.05). There was more percentage reduction of IPSS points in tamsulosin at follow up visit in comparison with terazosin (46.02±10.21 Vs 39.8±17.78) (p<0.05). Qmax improvement was higher in tamsulosin than terazosin in follow up visit (32.20±5.33 % Vs 24.61±7.97) (p<0.001).

Mean PVR after 2 months in terazosin group was 52.58±13.10 ml and tamsulosin group was 43.03±12.5 ml. Percentage improvement of PVR was higher in tamsulosin group (50.68±14.54 Vs 40.7±13.9) ($p<0.001$). Results of this study revealed maximum effect of terazosin and tamsulosin in between 8-12 weeks. This result is compatible with another study[10]. A study showed maximum urinary flow rate improved to a greater extent in tamsulosin group (1.6ml/sec. 16%) than placebo[11]. Similar effect has been found in other studies[12,13]. A separate study done with 1-10mg of terazosin titration doseshowed 13% more Qmax improvement in terazosin group than placebo (Terazosin minus placebo)[14].

The most common adverse effect we found was headache, asthenia, dizziness and postural hypotension. Terazosin group showed more postural hypotension, headache than tamsulosin group. This study results are compatible with other study[15].

They also showed incidence of adverse effects by administration of tamsulosin was less than that of terazosin group (13% and 50% respectively ($p<0.01$). This is supported by findings of other studies[16, 17, 18, 19].

CONCLUSION

It can be concluded that tamsulosin 0.4mg once daily dose and terazosin 1-2mg 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 ($p<0.05$), Qmax ($p<0.001$) and PVR ($p<0.001$) at the end point. The incidence of adverse events by administration of tamsulosin was less than that by terazosin. So, tamsulosin appears to have more efficacy and safety than terazosin in symptomatic BPH.

DISCLOSURE

All the authors declared no competing interest.