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Original Article

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# Comparative Study Between Tamsulosin and Silodosin in the Management of Symptomatic Benign Prostatic Hyperplasia

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**Conflicts of interest:** None

## Abstract

***Background:*** *Benign prostatic hyperplasia (BPH) is commonly seen in elderly male. á1 adrenoceptor antagonists is considered to be the first line treatment as pharmacological therapy, such as treatment with tamsulosin, which selectively blocks ála adrenoceptors. As the initial treatment for lower urinary tract problems associated with BPH, al-blockers are generally used.*

***Objective:*** *Aim of the study is to compare the efficacy of tamsulosin and silodosin in the management of symptomatic benign prostatic hyperplasia.*

***Methodology:*** *This quasi-experimental study carried out in the department of Urology, Sir Salimullah Medical College Mitford Hospital, during the period of January to December 2022.*

***Results:*** *Total 40 patients of 50-80 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 Tamsulosin 0.4mg daily at bed time for 2 months. Group B (n=20) was given Silodosin 8 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). Both the drugs are effective in relieving symptoms of BPH but Silodosin is superior to Tamsulosin in improvement of total IPSS ($p<0.001$) and Qmax ($p<0.01$) PVR ($p<0.01$) at the end point.*

***Conclusion:*** *Outcome of parameters at follow up after 2 months. Silodosin group showed significant improvement of IPSS ($p<0.05$) PVR ($p<0.001$) and Qmax ($p<0.001$) than Tamsulosin. The incidence of adverse events by administration of Silodosin was less than that by Tamsulosin. Silodosin appears to have more efficacy and safety than Tamsulosin in symptomatic BPH.*

**Keywords:** Tamsulosin, Silodosin, IPSS, Qmax, PVR, QoL.

## Introduction:

Worldwide elder men suffer from prostate related diseases among them benign prostatic hyperplasia (BPH) is commonly seen. α-1 adrenoceptor antagonists is considered to be the first line treatment as pharmacological therapy, such as treatment with tamsulosin, which selectively blocks α-1a adrenoceptors. As the initial treatment for lower

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urinary tract problems associated with BPH, á1-blockers are generally used. In Japanese population tamsulosin, silodosin and naftopidil are currently mostly used á1-blockers. Another switch therapy with á1-blockers can be initiated or the dose may be increased if first line therapy with tamsulosin dose not achieve a satisfactory response. Although Japanese studies have been reported the effectiveness of dose increase in the same patients but the numbers involved were very low[1,2].

α-1 adrenergic blockers and androgen antagonist are most commonly prescribed drugs in the treatment of BPH. Due to development of tolerance and requirement of multiple doses, now adays the non-selective and short acting á-blockers are not commonly used drugs. The subtype selective drugs tamsulosin (1000:1, α1-A: α1-B/α1-D) and silodosin (162:1, α1-A: α1-B) are used now[3].

There are limited study showing efficacy and direct comparisons between the two drugs. Among all clinically used α-blockers Silodosin has the greatest selectivity for α1-AR[4]. Various study showed silodosin is not be less to tamsulosin and it is also an alternative α1-AR blocker for treating BEP. Degree of bother and symptoms are the main parameter for the initiation of treatment. Silodosin improved the IPSS (International Prostate Symptom Score) in two weeks shown in a clinical trial. Watchful waiting is a reasonable treatment strategy for men with mild lower urinary tract symptom (LUTS) (IPSS: 0 to 7) or those who do not perceive their symptoms to be particularly bothersome. Lifestyle modification such as modifying fluid intake or toileting behavior can be used as conservative treatments in men with mild LUTS. In men with bothersome, moderate (IPSS: 8 to 19) to severe LUTS (IPSS: 20 to 35), surgical and medical therapies are the treatment options, and the choice of treatment depends on many factors such as the severity of disease, risk of progression, patient preference, and morbidity. Many studies have been carried out in the world regarding the treatment of BPH. Several international journal published regarding treatment issue[5].

A study shows 0.2 mg Tamsulosin is more often administered in Korea, Japan elsewhere in Asia, to take into account body size. In the West, Tamsulosin is most commonly administered at 0.4 mg per dose. In Japan patients with BPH associated with dysuria had shown a greater efficacy whose dose was increased the dose to 0.4 mg of Tamsulosin[6].

Recently, a more selective α1-AR, silodosin, was developed in Japan. Silodosin was confirmed to be 38 times more selective toward α1A adrenergic receptors than α1B adrenergic receptors[7,8]. A phase III clinical trial found that silodosin improved the IPSS within the first 2 weeks of usage[9], and another trial confirmed that the efficacy of 8 mg/day silodosin was comparable to that of 0.4 mg/day tamsulosin[10]. Few trials have compared silodosin with tamsulosin in clinical practice[7]. Clinical use of silodosin was only recently initiated in Indonesia, this study was considered as a pioneer study of the efficacy of silodosin in BPH.

**Objective:**

Our aim is to compare the efficacy of 8 mg/day silodosin with that of 0.4 mg/day tamsulosin in cases with BPH with moderate–severe LUTS.

**Materials and Methods:**

We conducted a quasi-experimental study in Department of urology, Sir Salimullah Medical College Mitford Hospital, Dhaka over a period of one year from January 2022 to December 2022. Total number of patients was forty. Ambulatory BPH patients aged 50 years and above who had IPSS score 8 and above, QOL index 3 and more and maximum urinary flow rate <15ml/sec were included in the study. Patients with neurogenic bladder, stricture urethra, large post voidal residue >100ml or taking anticholinergic drugs 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 Tamsulosin (Group A) and even number as Silodosin (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.

All collected data will be checked and verified thoroughly to reduce the inconsistency. The data will be coded, categorized and entered into software. Quality of data will always be ensured. Collected data will be transferred to master table as per the specific objectives and key variables. Analysis of data will be done by Statistical Package for Social Science" (SPSS 23). For tabular chart and graphical representation Microsoft word and Microsoft Excel will be used.

Analysis will be carried out using the chi-square test and logistic regression for categorical data. The t test for 2 independent samples will be carried out for numerical data. Descriptive statistics of frequencies and percentages will be used to describe the variables. The results were compiled and analysed using students t- test and chi-square test as appropriate. The level of $P < 0.05$ will be considered as a cut – off value for significance.

Quality and reliability of collected data were re-checked. Appropriate Statistical analysis, calculation and test were carried out to relate variable according to the objectives of the study.

**Results:**

A total of 40 patients were enrolled in our study, and of them, 20 patients were assigned to silodosin as SPG(Silodosin receiving patient group) and 20 patients were assigned to tamsulosin as TPG(Tamsulosisn receiving patient group). All baseline parameters were seen in both groups. There was no significant difference in mean age, base line peak urine flow rate (Qmax), International Prostate Symptom Score (IPSS), QoL(Quality of life) score and Post Voidal Residue (PVR) (Table-I)

Follow up of all patients were done after two month. Patients treated with Tamsulosin, mean values of IPSS, Qmax, PVR and QoL score were 7.25±2.91 points, 16.35±1.18 ml/sec, 13.85±9.52 ml and 1.85±0.489 points respectively. Mean value change of IPSS, Qmax, PVR and QoL were 2.6±10.65 points, 2.75±7.62 ml/sec, 12.7±8.91 ml and 1.2±1.04 points respectively. In comparison to baseline mean values, IPSS, Qmax, PVR and QoL values were significantly changed ($p<0.001$ in IPSS, $p<0.05$ in Qmax, $p<0.05$ in PVR and $p<0.05$ in QoL) (Table-II).

In follow up visit after one month, patients those who were treated with Silodosin, mean values of IPSS, Qmax, PVR and QoL score were 2.90±0.78 points, 19.25±1.07 ml/sec, 5.50±8.72 ml and 0.35±0.489 points respectively. Mean value change of IPSS, Qmax, PVR and Qol score were 9.75±8.42 points, 6.05±5.27 ml/sec, 20.75±13.45 ml and 3.40±1.14 scores respectively in Silodosin group. In this visit, all mean values of variables were significantly changed in comparison to baseline studies ($p<0.001$) (Table-III).

**Table-I:** *Comparison of base line data of two groups, Group A (Tamsulosin) and Group B (Silodosin)*

| Parameters | Patient group | Mean±SD | P Value |
|---|---|---|---|
| Age | Tamsulosin (n = 20) | 62.65 ± 4.64 | .154 |
| | Silodosin (n = 20) | 62.60±3.71 | |
| Q max | Tamsulosin (n = 20) | 13.60 ± 1.09 | p < 0.05 |
| | Silodosin (n = 20) | 13.20 ± 1.43 | (significant) |
| IPSS | Tamsulosin (n = 20) | 9.85±2.6 | p < 0.05 |
| | Silodosin (n = 20) | 12.65 ± 2.47 | (significant) |
| PRV | Tamsulosin (n = 20) | 26.55 ± 5.93 | p < 0.05 |
| | Silodosin (n = 20) | 26.25±9.01 | (significant) |
| QoL Score | Tamsulosin (n = 20) | 3.05 ± .510 | p < 0.05 |
| | Silodosin (n = 20) | 3.75±.550 | (significant) |

**Table II:** *Tamsulosin group in follow up visit*

| Parameters | Baseline | At follow up | Change from baseline | Mean Change % | P Value |
|---|---|---|---|---|---|
| IPSS | 9.85 ± 2.6 | 7.25±2.91 | 2.6±10.65 | 26.39±1.19 | p <0.001 (significant) |
| Q max | 13.60±1.09 | 16.35 1.18 | 2.75±7.62 | 16.82±11.45 | p <0.05 (significant) |
| PRV | 26.55 ±5.93 | 13.85±9.52 | 12.7±8.91 | 47.83±7.4 | p <0.05 (significant) |
| QoL Score | 3.05.510 | 1.85±.489 | 1.2±1.04 | 39.32.942 | p <0.05 (significant) |

**Table-III:** Silodosin group in follow up visit

| Parameters | Baseline | At follow up | Change from baseline | Mean Change % | P Value |
|---|---|---|---|---|---|
| IPSS | 9.85±2.6 | 7.25±2.91 | 2.6±10.65 | 26.39±1.19 | p <0.001 (significant) |
| Q max | 13.60±1.09 | 16.35±1.18 | 2.75±7.62 | 16.82±11.45 | p <0.05 (significant) |
| PRV | 26.55 ± 5.93 | 13.85±9.52 | 12.7±8.91 | 47.83±7.4 | p <0.05 (significant) |
| QoL Score | 3.05.510 | 1.85±.489 | 1.2±1.04 | 39.32.942 | p <0.05 (significant) |

Mean percentage improvement of IPSS in Tamsulosin group was 26.39±1.19 points and in Silodosin group was 77.07±3.1 points. In comparison of IPSS change, Silodosin showed significantly better response than Tamsulosin group in follow up visit (p<0.05) (Table-IV).

Mean percentage improvement of Qmax in Tamsulosin group was 16.82±11.45 ml/sec and in Silodosin was 31.43±10.33 ml/sec. In comparison Silodosin group showed significantly high flow rate in follow up visit (p<0.05) (Table-V).

Mean percentage reduction of PVR in Tamsulosin group was 47.83±7.4 and in Silodosin it was 79.04±2.18. In comparison of PVR change, Silodosin group showed significantly better response than Tamsulosin in follow up visit (p<0.05) (Table-VI).

In this study, mean percentage of QoL in Tamsulosin group was 39.32±0.942 and in Silodosin group it was 90.66±11.09 points. In comparison of QoL change Silodosin group showed significantly better response in follow up visit (p<0.05) (Table-VII).

**Table-IV :** Comparison of IPSS between the data of two groups in follow up visit

| Group | Baseline value | At follow up in same group | P value | Change from baseline | Mean Change % | P Value |
|---|---|---|---|---|---|---|
| Tamsulosin | 9.85±2.6 | 7.25±2.91 | P <0.05 | 2.6±10.65 | 26.39±1.19 | p <0.05 (significant) |
| Silodosin | 12.65±2.47 | 2.90±0.78 | P | 9.75±8.4 | 77.07 ±3.1 | <0.052 |

**Table-V:** Comparison of Qmax between the data of two groups in follow up visit

| Group | Baseline value | At follow up | P value in same group | Change from baseline | Mean Change % | P Value |
|---|---|---|---|---|---|---|
| Tamsulosin | 13.60 ±1.09 | 16.35 ±1.18 | P<0.05 | 2.75 ±7.62 | 16.82±11.45 | p <0.05 (significant) |
| Silodosin | 13.20 ± 1.43 | 19.25 ± 1.07 | P <0.05 | 6.05 ±5.27 | 31.43 ±10.33 | |

**Table-VI:** *Comparison of PVR between the data of two groups in follow up visit*

| Group | Baseline value | At follow up | P value in same group | Change from baseline | Mean Change % | P Value |
|---|---|---|---|---|---|---|
| Tamsulosin | 26.55 ± 5.93 | 13.85±9.52 | p <0.05 | 12.7 ± 8.91 | 47.83 ±7.4 | p <0.05 (significant) |
| Silodosin | 26.25 ±9.01 | 5.50±8.72 | P <0.05 | 20.75 ±13.45 | 79.04 ±2.18 | |

**Table-VII:** *Comparison of QoL between the data of two groups in follow up visit*

| Group | Baseline value | At follow up | P value in same group | Change from baseline | Mean Change % | P Value |
|---|---|---|---|---|---|---|
| Tamsulosin | 3.05 ±.510 | 1.85 ±.489 | P <0.05 | 1.2 ±1.04 | 39.32 ±.942 | p<0.05 (significant) |
| Silodosin | 3.75 ±.550 | .35 ±.489 | <0.05 | 3.40 ±1.14 | 90.66 ±11.09 | |

There are some common side effects of the both drugs. TPG presented with more side effect than SPG (Table VIII).

**Table VIII :** *Comparison of side effects in two groups in follow up visit*

| Side effect | TPG | SPG |
|---|---|---|
| Drowziness | 20% | 10% |
| Back pain | 15% | 5% |
| Diarrhoea | 10% | 0% |
| Runny nose | 20% | 10% |
| Dry orgasm | 10% | 30% |

**Discussion:**

In elderly men, benign prostatic hyperplasia (BPH) is the most common cause of LUTS. There are many drugs which improve quality of life by reducing symptom of patient. The most commonly used drugs in the management of BPH are á-1 adrenergic blockers and androgen antagonist. Non selective drugs develop tolerance in the long run. So, the subtype selective drugs tamsulosin and silodosin are most prescribing drugs now[11]. After introduction of these drugs (á1 receptor blocker) improve urinary symptoms usually takes 2 to 4 weeks' time[12].

In this study age range was 55-80 yrs. with a mean for Tamsulosin group was 62.65±4.64 yrs. and Silodosin group was 62.60±3.71 yrs. The results of age of two group were statistically insignificant (p>0.05). It was similar to other studies.

Yamanishi et al., in his research on 194 elderly men, compared the efficacy of silodosin and tamsulosin after 12 months of drug administration and added that silodosin improved lower urinary tract symptoms and urinary flow rate significantly in sufferers with BPH[13]. Efficacy of both drugs were significantly different. Another randomized crossover study done by Watanabe et al. differentiating tamsulosin and silodosin in 84 (n = 42 per group) Japanese patients over four weeks for each drug concluded that patients preferred silodosin over tamsulosin[14]. A prospective randomized crossover comparative study of 46 patients by Yokahama et al. with 23 patients in each group of tamsulosin and silodosin found that silodosin has better efficacy[15]. These results are similar to our study.

A randomized crossover comparison of the short-term efficacy and safety of 8 mg of silodosin for 28 days and 0.4 mg of tamsulosin 28 days was done by Takeshita et al. in 34 Japanese patients over 50 years and an IPSS of more than 8. He concluded that silodosin has better efficacy than tamsulosin[16]. Since various studies had produced divergent results, we compared the efficacy and safety of 0.4 mg of tamsulosin and 8 mg silodosin. Our results have clearly shown that silodosin is safe and more efficacious in comparison to tamsulosin.

Yu et al. conducted trial and found that, out of 170 (81.3%) study completed male patients, 86.2% in the silodosin group versus 81.9% in the tamsulosin group achieved a ≥25% reduce in IPSS (P = 0.53). The mean difference in IPSS change from baseline was "0.60 (95% confidence interval "2.15 to "0.95) (silodosin minus tamsulosin) showed silodosin was non-inferior to tamsulosin[17].This study results also similar to us.

Miyakita et al. crossover study and concluded that Qmax increased in both groups initially after 4 weeks, at the end of study no significant improvement occurred in both groups[18]. In our study, Qmax showed a significant improvement in both groups with silodosin producing more significant mean change 31.43% (P = 0.05).

Miyakita et al. also concluded that QOL score significantly improved in both at initial and crossover the period with silodosin[19]. Kawabe et al. also added a significant improvement of the QOL score in patients with silodosin in relative to placebo.27 In our study with silodosin, the QOL is significantly improved

(mean of 3.4±1.14 with P = 0.05) compared to tamsulosin in the initial treatment period and also at the crossover period.

This prevalent recognition that Sildosin has an advantage, it appears that both the drugs have nearly comparable adequacy and profile.

**Conclusion:** It can be concluded that tamsulosin 0.4mg once day by day estimation and Silodosin 8mg incremental measurement at slightest for 8 weeks both are practical in relieving symptoms of BPH but Silodisin is prevalent to Tamsulosin in progression of include up to IPSS ($p < 0.05$) Qmax ($p < 0.001$) and PVR ($p < 0.001$) at the conclusion point. The rate of antagonistic events by organization of Silodosin was less than that by Tamsulosin. So, Silodosin appears up to have more legitimacy and safety than Tamsulosin in symptomatic BPH.

**Recommendation:** Our study recommend Silodosin in the treatmnet of symptomatic BPH. Further, multi-center study should be done in a large population to see the efficacy of both the drugs.

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