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Research Article

# COMPARISON OF EFFICACY OF TAMSULOSIN AND SILODOSIN IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA: A PROSPECTIVE STUDY

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***ABSTRACT***

*The objective of the study was to compare the efficacy of 0.4mg Tamsulosin and 8mg Silodosin once daily dosing in patients with Benign Prostatic Hyperplasia (BPH) treated for 4 weeks. A Prospective Observational study which included 91 men who all were newly diagnosed with Benign Prostatic Hyperplasia. Maximum Urinary flow Rate ($Q_{max}$), Voided Volume were measured as Uroflowmetric parameters for assessment at the beginning and after 1 month of therapy. International Prostate Symptom Score and Quality of Life were assessed before therapy, after 48 hrs and after 1 month of therapy. The mean age of patients ranged from 50-88 years. There was a sustained and Significant Improvement in International prostate symptom score (IPSS) and Quality of Life (QOL) in all patient groups during the study. On comparing, Silodosin is found have faster onset of action and improvement in quality of life. Orthostatic hypotension and Headache was significant adverse reaction seen in Tamsulosin and Silodosin respectively. None of the patients discontinued the drug due to side-effects. Silodosin is a selective drug of choice for the treatment of Benign Prostatic Hyperplasia. It is well tolerated and faster reduction the symptoms.*

***KEYWORDS:*** *Benign Prostatic Hyperplasia, Tamsulosin, Silodosin, Uroflowmetry, International Prostate Symptom Score (IPSS), Quality of Life.*

## INTRODUCTION

First line medical treatment for benign prostatic hyperplasia consists of $\alpha_1$-adrenergic receptor antagonists (α-blockers) and 5α reductase inhibitors (5ARI).α-blockers relieve bladder outlet obstruction by relaxing the peri urethral prostatic smooth muscle and allowing for improved urinary flow. 5ARIs have shown to reduce disease progression, prevent complications from benign prostatic hyperplasia (including acute urinary retention and prostate related surgery), and improve lower urinary tract symptoms starting after six months of treatment [1]. Alpha-blockers are a widely used class of medications for the treatment of LUTS secondary to BPH. 98% of alpha-blockers are associated with the stromal elements of the prostate and are thus thought to have the greatest influence on prostatic smooth muscle tone [2]. Stromal tissue, also known as smooth muscle tissue, is embedded with *α*1-adrenergic receptors [3].

BPH, the actual hyperplasia of the prostate gland, develops as a strictly age-related phenomenon in nearly all men, starting at approximately 40 years of age [4]. Common risk factors for BPH include increasing age, functioning testicles, metabolic syndrome, family history of BPH, obesity, history of diabetes, and black race [5]. The common signs and symptoms include voiding and storage symptoms. Although uncommon, serious complications of BPH may occur, including acute urinary retention, renal insufficiency, urinary tract infections, haematuria, bladder stones, and renal failure [6]. Treatment goals are to improve bothersome symptoms, prevent symptom progression, and reduce longer term complications (including acute urinary retention, incontinence, recurrent urinary tract infections, renal insufficiency, and the need for surgery) [7]. Treatment options for patients with bothersome moderate (e.g., IPSS 8 – 18) and severe (e.g., IPSS 19 – 35) symptoms of BPH include watchful waiting / lifestyle modification, as well as medical, minimally invasive or surgical therapies [8]. Silodosin is a new α1-adrenergic receptor antagonist that is selective for the $\alpha_{1A}$-adrenergic receptor. By antagonizing $\alpha_{1A}$-adrenergic receptors in the prostate and urethra, silodosin causes smooth muscle relaxation in the lower urinary tract [6]. Tamsulosin, an $\alpha_1$ adrenoceptor blocking agent, exhibits selectivity for $\alpha_1$ receptors in the human prostate [9].

The aim of our study is to compare the efficacy of Tamsulosin and Silodosin in the treatment of Benign Prostatic Hyperplasia. The objectives includes to study the prevalence of different grades of BPH, assessing the severity of BPH using IPSS

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score, compare the efficacy of Tamsulosin and Silodosin using IPSS score and Uroflowmetry, assessing the Quality of Life of patients with BPH before and after Tamsulosin and Silodosin therapy and the side effects of Tamsulosin and Silodosin.

## MATERIALS AND METHODS

The study was conducted as a prospective observational at the outpatient department of Urology at a tertiary care teaching hospital in Kerala. The study was conducted over a period of 6 months, from November 2017 to April 2018 and a total of 91 patients were included in the study. Approval from Ethical Committee was obtained to conduct the study. The inclusion criteria included newly diagnosed BPH patients with age >50 years, who were prescribed with Tamsulosin or Silodosin. Patients with Prostate cancer, Prostatitis, other cases of bladder outlet obstruction such as stricture or urethral stone, neurogenic bladder and those who were not willing to participate were excluded from the study. Signed Informed consent was obtained from all participants prior to the study.

Specially designed data entry form was used to collect patient demographics, medical and medication history, relevant information on the disease, associated symptoms and signs, investigation and treatment plan. Out of the 92 patients included, 44 patients were given with Tamsulosin 0.4mg and 47 patients were given with Silodosin 8mg once daily after dinner.

The primary endpoint for the evaluation of efficacy and Quality of life was the change in total IPSS [10] from baseline after 48hrs. The secondary endpoints to assess the efficacy and safety were (a) changes in objective parameters including post void residual volume as assessed on ultrasonography, change in peak urine flow (Qmax), voided volume assessed using Uroflowmetry [11]. (b) Changes in the subjective symptoms as assessed IPSS and QOL. The subjective evaluation was carried out at baseline, at 48 hrs and month after the drug therapy. All the objective parameters were measured at the baseline and 1 month after the drug therapy. The IPSS included severity based 7 questions with scores ranging from 0 to 5 and 1 question related to Quality of life. Uroflowmetry is performed by having a person urinate into a special funnel that is connected to a measuring instrument. The measuring instrument calculates the amount of urine, rate of flow in seconds, and length of time until completion of the void. Safety assessment was done by including the most common ADRs of both drugs in case report form. We lost follow-up of 3 patients, 2 from Tamsulosin group and 1 from Silodosin group (figure 1). Statistical Analysis was done using Graph-Pad prism Software version 7. One-way Anova and Two-way ANOVA were used to compare the mean values among the given groups.

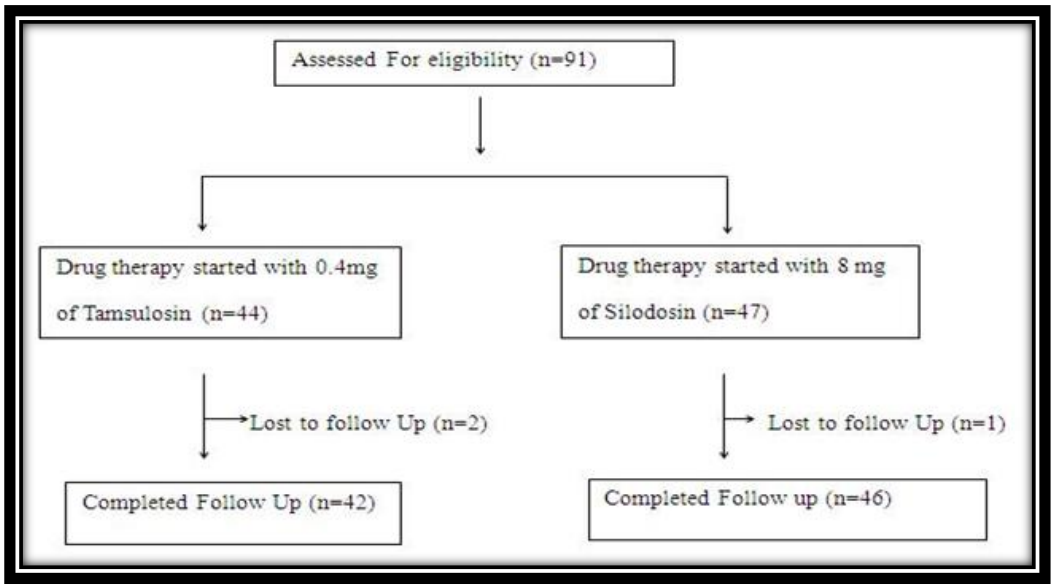


**Fig. 1: Flow of study participants through the study**

## RESULTS

It was clearly understood that BPH increases as the age progresses. Categorising the patients into 3 groups showed, out of 88 patients enrolled into the study, 34 patients belonged to the category of age group >70 yrs followed by 33 patients in 60-69 age group. Therefore, the theoretical aspect of BPH increases in ageing men can be proven right.

Categorizing the patients based on the clinical grading's, which are found out with the help of Digital Rectal examination [12], where a finger will be inserted through the rectum to determine whether Prostate Gland can be easily felt. From our studymost patients belonged to grade 2(52.27%) BPH. ***Lodh B et al (2016)*** [12] in their study also categorized BPH into grade I, grade II, grade III and grade IV based on the encroachment into the rectum.

From table 1, appraising the severity of BPH using IPSS-mild, moderate and severe, Silodosin has shown has shown higher significance when compared to Tamsulosin where, Silodosin has displayed faster onset of action after 48hrs of therapy.

**Table No. 1: Assessing the severity of BPH using IPSS after Tamsulosin and Silodosin therapy**

| Symptomatic grade of BPH (based on IPSS) | Group | Mean± SEM | | | P value | |
|---|---|---|---|---|---|---|
| | | Baseline | After 48 hrs | After 1 month | Baseline vs 48hrs | Baseline vs 1month |
| Mild | TAM | 0 | 0.2353±0.23 | 2.088±0.57 | ns | ns |
| | SILO | 0 | 0.452±0.25 | 3.42±0.47 | ns | ns |
| Moderate | TAM | 3.588±1.14 | 7.44±1.39 | 14.21±4.02 | * | **** |
| | SILO | 2.52±0.96 | 11.17±1.05 | 6.95±1.04 | **** | ** |
| Severe | TAM | 23.97±0.44 | 17.24±1.68 | 0 | **** | **** |
| | SILO | 24.98±0.39 | 5.90±1.54 | 0 | **** | **** |

Study conducted by ***Myakita et al(2010)*** [13] at the end of 4th week of their study, found reduction in residual urine volume noted only with Silodosin. Whereas ***Rajendran et al (2017)*** [14] compared tamsulosin with silodosin in Prostatomegaly has showed a significant reduction in Residual Urine volume in both groups. From our study as mentioned in Table 2. both Tamsulosin (p<0.001) and Silodosin (p<0.001) produced reduction in Post Void Residual Volume after 1 month, no Significant difference can be observed between the two drugs as tamsulosin and Silodosin produced 43.07±2.25 and 41.39±1.53 respectively. Both drugs were equally comparable.

**Table No. 2: PVR, Voided Volume and Qmax in Tamsulosin and Silodosin at baseline and 4 weeks**

| Parameters | Groups | Mean ± SEM | | Baseline versus 1 month (P value) |
|---|---|---|---|---|
| | | Baseline | After one month | |
| Post void residual (ml) | TAM | 60.33±3.32 | 43.07±2.25 | *** |
| | SILO | 67.13±2.10 | 41.39±1.53 | *** |
| Voided Volume(ml) | TAM | 169.9±5.58 | 198.2±5.13 | *** |
| | SILO | 160.2±5.00 | 227.8±5.45 | *** |
| Qmax(ml/sec) | TAM | 13.38±0.64 | 22.33±0.53 | *** |
| | SILO | 13.76±0.56 | 24.17±0.32 | *** |

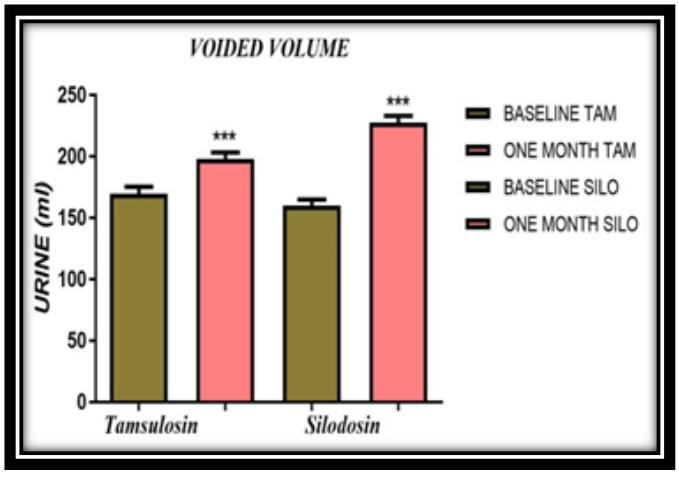


**Fig. 2(a): Voided Volume**

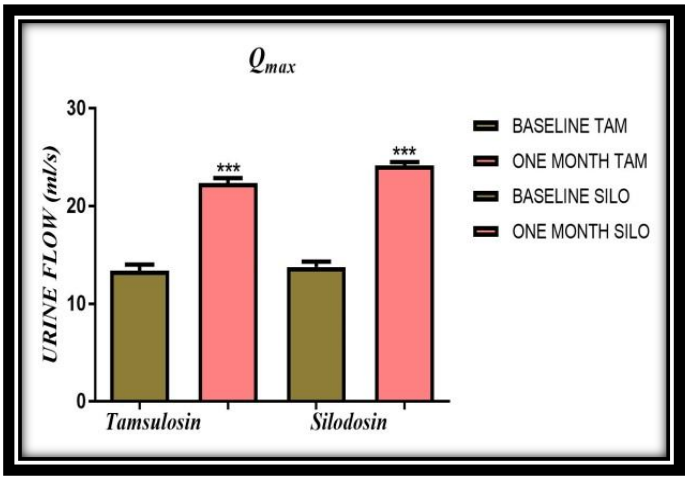


**Fig. 2(b): Maximum Flow Rate (Qmax)**

***Fig. 2 Change in (a) Voided volume and (b) Maximum Volume rate (Qmax) values are expressed in mean±SEM, *P<0.05, **P<0.01, ***P<0.001, ns- no significant vs Baseline.***

Comparing the amount of Urine Voided after the therapy with Tamsulosin (198.2±5.13, p<0.001) and Silodosin (227.8±5.45, p<0.001), Silodosin showed more improvement than Tamsulosin, but statistical significance was comparable as mentioned in Table 2 and Fig 2(a). Where as in the study conducted by ***Pande S et al (2014)*** [15] there was no significant change observed in voided volume in both tamsulosin and silodosin treated group.

The Maximum flow rate (Qmax) showed a particular increase in both Tamsulosin (22.33±0.53, p<0.001) and Silodosin (24.17±0.32, p<0.001) with silodosin providing more improvement but the statistical significance is comparable as mentioned in Table 2 and fig 2(b). ***Karthikeyan VS et al (2017)*** [16] in their study also found out that the maximum flow rate (Q max) was improved significantly by silodosin.

**Table No. 3: Changes Observed in the objective and subjective parameters in each group**

| Parameters | Groups | Mean ± SEM | | | Baseline vs 48hrs (P value) | Baseline vs 1 month (P value) |
|---|---|---|---|---|---|---|
| | | Baseline | After 48hrs | After 1 month | | |
| Incomplete emptying | TAM | 3.61±0.15 | 2.95±0.15 | 1.68±0.12 | ** | *** |
| | SILO | 3.69±0.11 | 2.89±0.16 | 1.43±0.09 | *** | *** |
| Frequency | TAM | 3.31±0.15 | 2.63±0.11 | 1.53±0.10 | *** | *** |
| | SILO | 3.52±0.13 | 2.63±0.12 | 1.23±0.07 | *** | *** |
| Intermittency | TAM | 3.29±0.14 | 2.70±0.13 | 1.51±0.11 | ** | *** |
| | SILO | 3.30±0.11 | 2.54±0.09 | 1.21±0.09 | *** | *** |
| Urgency | TAM | 2.97±0.17 | 2.41±0.14 | 1.19±0.10 | * | *** |
| | SILO | 3.19±0.13 | 1.84±0.10 | 0.80±0.08 | *** | *** |
| Weak stream | TAM | 3.±0.15 | 2.56±0.15 | 1.24±0.10 | * | *** |
| | SILO | 3.08±0.13 | 2.47±0.12 | 1.06±0.10 | ** | *** |
| Straining | TAM | 3.09±0.19 | 2.53±0.16 | 1.19±0.13 | * | *** |
| | SILO | 2.91±0.14 | 2.41±0.16 | 1.06±0.10 | * | *** |
| Nocturia | TAM | 3.22±0.17 | 2.82±0.17 | 1.41±0.13 | Ns | *** |
| | SILO | 3.50±0.13 | 1.91±0.09 | 0.82±0.08 | *** | *** |
| QOL | TAM | 3.61±0.15 | 2.95±0.15 | 1.68±0.12 | ** | *** |
| | SILO | 3.69±0.11 | 2.89±0.16 | 1.43±0.09 | *** | *** |

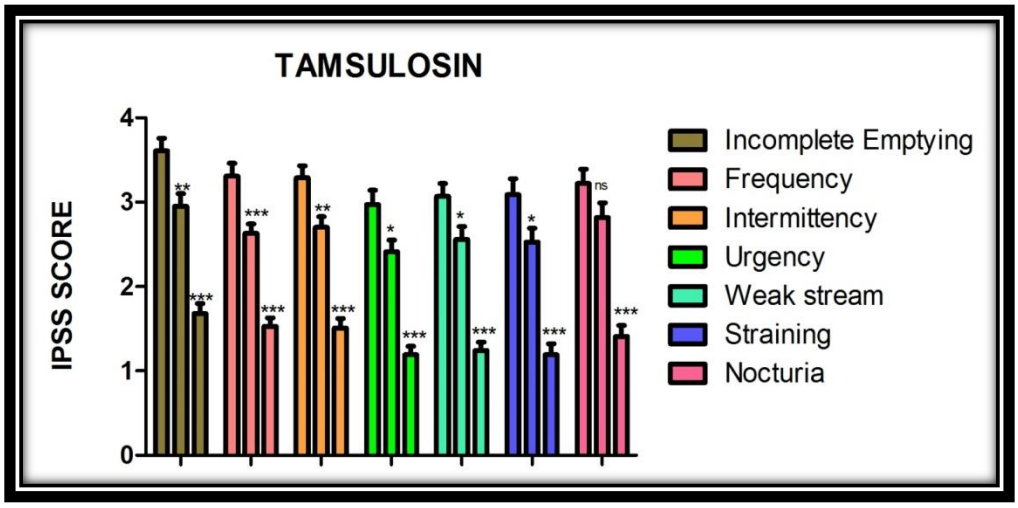


**Fig. 3(a): Change in IPSS of Tamsulosin**

***Values are expressed in mean±SEM, *P<0.05, **P<0.01, ***P<0.001, ns- no significant vs Baseline***

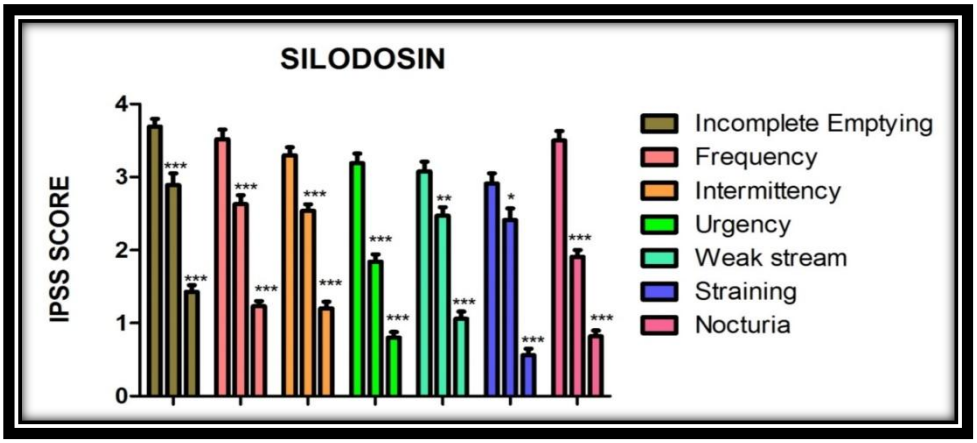


**Fig. 3(b): Change in IPSS of Silodosin**

***Values are expressed in mean±SEM, *P<0.05, **P<0.01, ***P<0.001, ns- no significant vs Baseline***

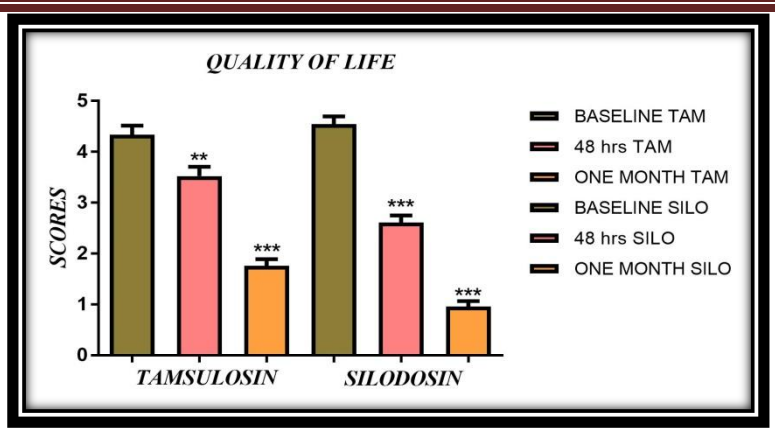


**Fig. 3(c): Change in Quality of Life**

***Values are expressed in mean ± SEM, *P<0.05, **P<0.01, ***P<0.001, ns- no significant vs Baseline***

Our study correlates with the study conducted by ***Rajendran RV et al (2017)*** [14] which concluded that silodosin has significantly Improved both storage and voiding symptoms in study population and scored over tamsulosin in the analysis of IPSS in nocturia, urgency, maximum flow rate and the residual urine volume also showed an objective improvement. Likewise, as mentioned in Table 3, Fig 3(a) & 3(b) Silodosin shows predominant significance in incomplete emptying, urgency and nocturia.

In the study conducted by ***Manohar CS et al (2017)*** [17] silodosin significantly improved the QOL index suggesting that silodosin is objectively effective. Our study has produced kindred results with Silodosin ($p<0.001$) scoring significantly over Tamsulosin ($p<0.01$) after 48hrs of therapy as mentioned in Table 3. Silodosin after 48hrs of therapy has a high significance value over tamsulosin as mentioned in Table 3& Fig 3 (c). ***Nabi N et al (2016)*** [18], found that silodosin significantly improved the QOL scores from the early stage of administration.

***Manohar CS et al (2017)*** [17] alsoconcluded that silodosin is the most efficacious alpha-1-adrenoceptor blocker with a rapid onset of action and had consistent improvement in LUTS in Indian men. Silodosin also improved the QOL of patients and maximum flow rate. However, silodosin has more adverse events in the form of abnormal ejaculation and dizziness when compared to tamsulosin.

The study conducted by ***Cho HJ et al (2014)*** [19] showed that silodosin is safe and effective in the long-term treatment of nocturia. Retrograde or abnormal ejaculation was the most commonly reported ADRs. Out of 42 patients in Tamsulosin group, 40 patients have experienced ADR with the most common being Orthostatic Hypotension (90.40%) followed by Dizziness, Fatigue and Headache. Whereas in silodosin Group, out of 46 patients 20 of them experienced ADR, with the most common being Dizziness, Abnormal ejaculation and Fatigue.

## DISCUSSION

The optimal initial treatment for patients with moderate or severe LUTS caused by BPH involves the use of α-blockers which acts mainly on dynamic component of obstruction. In men with large glands, 5 α-reductase inhibitors such as finasteride and dutasteride may be beneficial that acts on the static component of obstruction.

Uro selective α-blockers Tamsulosin and Silodosin are the preferred drugs for LUTS related to BPH due to their preferential action over α-1A receptors that is predominantly present in prostate and bladder base.

***Avijit Hazra et al (2014)*** [15], found that there was no significant reduction in post void residual urine volume. ***Karthikeyan VS et al (2017)***, compared Tamsulosin, Silodosin and Alfuzosin and found reduction in Silodosin group. In our study, the residual urine volume was reduced in both groups but there was no significant reduction.

***Chapple et al*** [20] observed an increase in Qmax in both groups but the conclusion was there was no significant difference between the two groups. ***Yu et al*** [21] also shows similar result as that of the former, where, the changes were equally comparable. The crossover study by Miyakita et al, showed increase in Qmax at the end of 4 weeks but at the end no significant improvement was obtained. Rajendran et al. displayed significant improvement in both groups with silodosin producing more change. In our study, silodosin produced more improvement but it was statistically comparable with that of tamsulosin.

The trial conducted by ***Chapple et al.*** found that IPSS were significantly greater in Silodosin than in Tamsulosin. ***Kawabeet al.*** [22] compared silodosin, Tamsulosin and placebo, where he found decrease in IPSS from baseline in Silodosin group starting from 1st week. ***Marks et al.*** [23] concluded that Silodosin displays faster improvement in LUTS. Rajendran et al. at the end found that the overall reduction of IPSS at 4th week suggest Silodosin is more efficacious. Silodosin significantly improved the QoL index in patients making it suggestive that it is both subjectively and objectively effective. ***Pande et al*** and ***Takeshita et al.*** [22] found Silodosin and Tamsulosin has similar efficacy. Novara et al. [25] observed Silodosin shows significant improvement in IPSS and QoL Rossi and Roumeguere [26] found that IPSS voiding symptoms were significantly improved in Silodosin compared with Tamsulosin and Placebo. Our study showed that Silodosin shows significant improvement in IPSS and QoL where Silodosin shows higher improvement in Nocturia and urgency as well as significant improvement in QoL which proves Silodosin has faster onset of action compared to Tamsulosin.

According to ***Pande et al, Kawabe et al, Rajendran et al,*** and ***Karthikeyan et al*** the most common ADE found in Silodosin and Tamsulosin is abnormal ejaculation and

Orthostatic Hypotension respectively. All the other ADE including headache, dizziness and nasal congestion were mild and not bothersome. In our study Orthostatic hypotension was the main ADE found in patients taking Tamsulosin and headache was the major ADE in Silodosin patients, as patients were found reluctant in sharing their personnel life.

The major limitation in our study was the limited number of study population. Abnormal ejaculation is the most common ADE of Silodosin but only 5 patients from our study shared their personnel life, all the other patients refused to do so.

Silodosin is the most efficacious alpha-1 adrenergic receptor blocker with a rapid onset of action and had consistent improvement in lower urinary tract symptoms associated with BPH especially in case of nocturia. Silodosin also improves the quality of life, post void residual volume, voided volume and maximum flow rate among patients with BPH after therapy.

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