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Original Article

Silodosin or Tamsulosin? Which Drugs is to be Preferred in Patients with Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia?

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Abstract

Introduction: Tamsulosin is the most commonly used drug and silodosin is a newer agent with greater α-1A receptor selectivity. The study aimed to compare the efficacy and safety of Silodosin and Tamsulosin in patients with lower urinary tract symptoms (LUTS) due to Benign prostatic hyperplasia (BPH).

Materials and Methods: It was a hospital-based prospective randomized controlled study for 2 years. All the patients of age ≥50 with LUTS due to diagnosed cases of BPH were included. The baseline IPSS, peak flow rate (Q_{max}), and post-void residual volume (PVRV) were assessed at 1 week and 12 weeks of starting the medical therapy. Subsequently, the IPSS score, Q_{max}, and PVRV in the two groups were compared.

Results: A total of 87 patients were analyzed in our study. Forty-five patients were in the Silodosin group (Group S) and 42 in the Tamsulosin group (Group T). The majority of patients were in their 60s or 70s. The mean symptom duration of Group S was 10.9 ± 6.85 months and Group T 11.3 ± 9.96 months. The mean difference of study parameters from baseline to endpoint (at 12th week) in Group S and Group T were (IPSS (−9.7/−8.0, P = 0.0138), Q_{max} (+6.9/+5.6, P = 0.0029) and PVRV (−47.4/−45.3, P = 0.2733). Orthostatic hypotension was seen more in Tamsulosin Group 9 (21.43%) and abnormal ejaculations in the Silodosin Group 5 (11.11%).

Conclusion: Silodosin and Tamsulosin are equally effective in the treatment of LUTS due to BPH. Ejaculatory disorders were more common in the silodosin group and postural hypotension in the Tamsulosin group.

Key words: Benign prostatic hyperplasia, Lower urinary tract symptoms, Silodosin, Tamsulosin

INTRODUCTION

Lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) are a common problem of aging in males. BPH is the most common cause of LUTS usually starts in men in their 50s, and by the age of 70s 80% of men suffer from BPH-related LUTS.[1] The symptoms complex are divided into obstructive and storage symptoms. These symptoms complex are nonspecific and are identified by a variety of terms collectively called LUTS.[2] The symptoms are usually not life-threatening however in multiple studies have found to have significant effects on the quality of life.[3] The international prostate symptom score (IPSS) has been using for a long time to assess the severity of LUTS in men due to BPH.[4]

The management of LUTS symptoms includes lifestyle modifications, medical or surgical therapies. The surgical therapy is done to relieve the enlarged prostrate, however, apart from invasiveness, there are complications associated with the surgery and rarely permanent urinary incontinence has been reported in the literature.[5] Thus the emphasis has been put by the researchers on the medical therapy in symptomatic BPH and there is a need for continued research on medical management.

Currently, two main categories of drugs are used for the treatment of symptomatic BPH; one blocks

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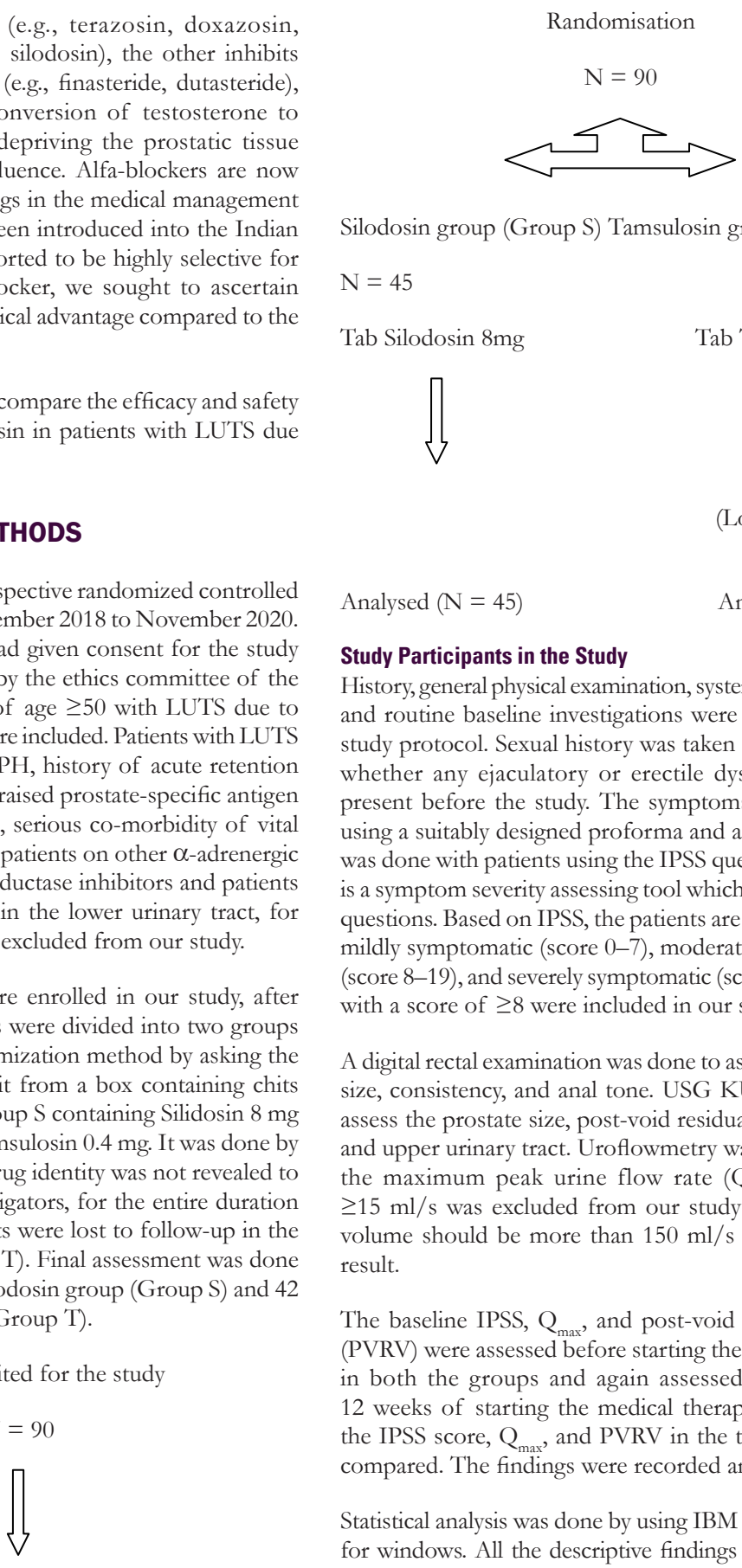
the α1-adrenoreceptors (e.g., terazosin, doxazosin, alfuzosin, tamsulosin, and silodosin), the other inhibits the enzyme 5α-reductase (e.g., finasteride, dutasteride), thereby preventing the conversion of testosterone to dihydrotestosterone and depriving the prostatic tissue of trophic androgenic influence. Alfa-blockers are now considered as first-line drugs in the medical management of BPH.[6] Silodosin has been introduced into the Indian market recently and is reported to be highly selective for the α1A-adrenoceptor blocker, we sought to ascertain whether this offers any clinical advantage compared to the older drug Tamsulosin.

Hence, our study aimed to compare the efficacy and safety of Silodosin and Tamsulosin in patients with LUTS due to BPH.

MATERIALS AND METHODS

It was a hospital-based prospective randomized controlled study for 2 years from December 2018 to November 2020. All the enrolled patients had given consent for the study and the study was cleared by the ethics committee of the institute. All the patients of age ≥50 with LUTS due to diagnosed cases of BPH were included. Patients with LUTS due to cause other than BPH, history of acute retention of urine in past 6 months, raised prostate-specific antigen level at baseline >4 ng/ml, serious co-morbidity of vital organs and non-ambulant, patients on other α-adrenergic antagonists, and 5-alpha reductase inhibitors and patients with a history of surgery in the lower urinary tract, for example., TURP and were excluded from our study.

A total of 90 patients were enrolled in our study, after randomization the patients were divided into two groups by the double-blind randomization method by asking the patients to pick up the chit from a box containing chits already assigned either Group S containing Silidosin 8 mg or Group T containing Tamsulosin 0.4 mg. It was done by a junior resident and the drug identity was not revealed to the patients and the investigators, for the entire duration of the study. Three patients were lost to follow-up in the Tamsulosin group (Group T). Final assessment was done in the 45 patients in the Silodosin group (Group S) and 42 in the Tamsulosin group (Group T).



Study Participants in the Study

History, general physical examination, systemic examination, and routine baseline investigations were done as per the study protocol. Sexual history was taken and asked about whether any ejaculatory or erectile dysfunctions were present before the study. The symptoms were recorded using a suitably designed proforma and a direct interview was done with patients using the IPSS questionnaire. IPSS is a symptom severity assessing tool which comprises eight questions. Based on IPSS, the patients are categorized into mildly symptomatic (score 0–7), moderately symptomatic (score 8–19), and severely symptomatic (score 20–35). IPSS with a score of ≥8 were included in our study.

A digital rectal examination was done to assess the prostate size, consistency, and anal tone. USG KUB was done to assess the prostate size, post-void residual urine (PVRU), and upper urinary tract. Uroflowmetry was done to know the maximum peak urine flow rate (Q max). A Q_{max} ≥15 ml/s was excluded from our study and the voided volume should be more than 150 ml/s for a significant result.

The baseline IPSS, Q_{max}, and post-void residual volume (PVRV) were assessed before starting the medical therapy in both the groups and again assessed at 1 week and 12 weeks of starting the medical therapy. Subsequently, the IPSS score, Q_{max}, and PVRV in the two groups were compared. The findings were recorded and analyzed.

Statistical analysis was done by using IBM SPSS Version 21 for windows. All the descriptive findings are presented in

mean ± SD and percentage. The Chi-square test was used as a test of significance of the study for comparing the outcome variables. $P < 0.05$ was taken as statistically significant.

RESULTS

The final assessment was done in 87 patients. 45 patients were in the Silodosin group (Group S) and 42 patients were in the Tamsulosin group (Group T).

The majority of patients were in their sixties or seventies and the mean age of patients in Group S was 61.4 ± 7.88 years and in group T was 62.6 ± 7.55 years. Mean symptom duration at presentation for Group S was 10.9 ± 6.85 months and for group T it was 11.3 ± 9.96 months. Both the groups were comparable in age and duration of symptoms [Table 1].

There was a significant decrease in the scores of IPSS from the baseline at 1 and 12 weeks in both groups. The mean change of IPSS from baseline to study endpoint (at 12th week) for Group S was 8.7 ± 3.32 and for Group T it was 10.4 ± 2.52 with a statistically significant result (P – <0.0001) [Table 2 and Figure 1].

The flow rate increased significantly from baseline in both groups. The mean change of peak flow rate (Q_{max}) from baseline to study endpoints (at 12th week) for Group S was 16.4± 3.21 and for Group T was 14.5 ± 2.81, with a significant $P < 0.0001$ [Table 3 and Figure 2].

The PVRV decreased significantly from baseline in both groups. The mean change of PVRV from baseline to study endpoints (at 12th week) for Group S was 37.8 ± 12.23 ml and for Group T it was 42.6 ± 10.12 ml. Both the groups show a significant decrease in the PVRV ($P < 0.0001$) [Table 4 and Figure 3].

Overall side effects were more observed in the Tamsulosin group (p-value >0.05). Orthostatic hypotension and abnormal ejaculation were the most common side effects. Orthostatic hypotension was the most common side effect in Group T 3(7.14%) at 1 week and 6(14.28%) at 12 weeks. Abnormal ejaculations were the most common in Group S 1(2.22%) at 1 week and 4(8.88%) at 12 weeks. Fatigue with myalgia was observed in 7(16.66%) cases of Group T and 4(9.52%) in Group S. The side effects were mild and all were managed conservatively [Table 5 and Figure 4].

The mean changes of IPSS from baseline to endpoint of both the groups were estimated and the mean difference was calculated between the two groups. The mean difference of IPSS from baseline to endpoint (12th week) in Group S was [-9.7] and Group T was [-8.0] and the difference was statistically significant (P = 0.0138) [Table 6].

Table 1: The age and symptoms duration of the study

Parameter	Group S (*n*=45)	Group T (*n*=42)	*P*-value
1 Age (years)			
Range	50.0–78.0	50.0–79.0	
Mean±SD	61.4±7.88	62.6±7.55	0.471
2 Symptom duration (months)			
Range	3.0–29.0	3.0–48.0	
Mean±SD	10.9±6.85	11.3±9.96	0.827

SD: Standard deviation, S: Silodosin, T: Tamsulosin

Table 2: The serial change in IPSS in the two groups

Group (n)	Baseline	1st week follow-up	After 12 weeks	Baseline versus 1st week (*P* value)	Baseline versus 12 week (*P* value)
Group S (*n*=45) Mean ± SD	18.4±3.32	12.4±3.20	8.7±2.78	<0.0001	<0.0001
Group T (*n*=42) Mean ± SD	18.4±3.94	13.9±3.33	10.4±2.52	<0.0001	<0.0001

IPSS: International prostate symptom score, SD: Standard deviation, S: Silodosin, T: Tamsulosin

Table 3: The serial change in peak flow rate (Qmax) in the two groups

Group	Baseline	1st week follow-up	After 12 weeks	Baseline versus 1st week (*P* value)	Baseline versus 12 week (*P* value)
Group S (*n*=45) Mean ± SD	9.5±1.32	11.1±2.52	16.4±3.21	0.0003	<0.0001
Group T (*n*=42) Mean ± SD	8.9±1.94	10.2±2.09	14.5±2.81	0.0041	<0.0001

SD: Standard deviation, S: Silodosin, T: Tamsulosin

Table 4: The change in post-void residual volume in the two groups

Group	Post-void residual urine (ml)				
	Baseline	At 1st week	After 12 weeks	Baseline versus 1st week (*P*-value)	Baseline versus 12 week (*P* value)
Group S (*n*=45) Mean±SD	85.2±9.20	52.4±8.52	37.8±12.23	<0.0001	<0.0001
Group T (*n*=42) Mean±SD	87.9±8.63	55.3±7.20	42.6±10.12	<0.0001	<0.0001

SD: Standard deviation, S: Silodosin, T: Tamsulosin

There was an increase in the peak flow rate in both the study groups. The mean difference of peak flow rate (Q_{max}) from baseline to endpoint (12th week) the Group S (n = 45) was (+6.9) and Group T (n = 42) was (+5.6) and the mean difference was 1.300 (100%CI, −2.1437–−0.4563) with the statistically significant result (P = 0.0029) [Table 7].

The PVRV decreases from baseline to endpoint of the study in both groups. The mean difference of PVRV from baseline to endpoint (12th week) in Group S was (−47.4) and Group T was (−45.3) and the difference was not statistically significant (P = 0.2733) [Table 8].

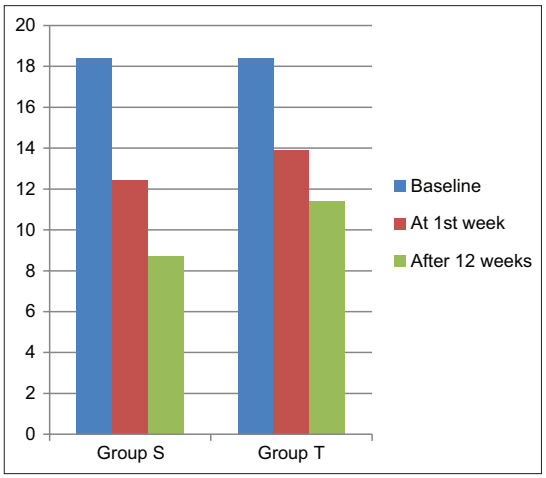


Figure 1: The serial change in international prostrate symptom score in the two groups

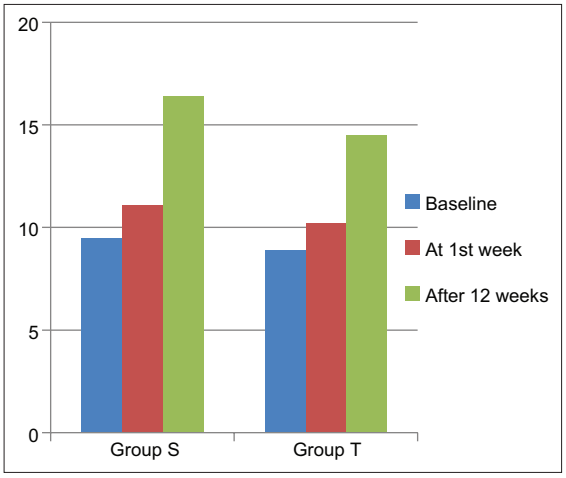


Figure 2: The serial change in peak flow rate (Q_{max}) in the two groups

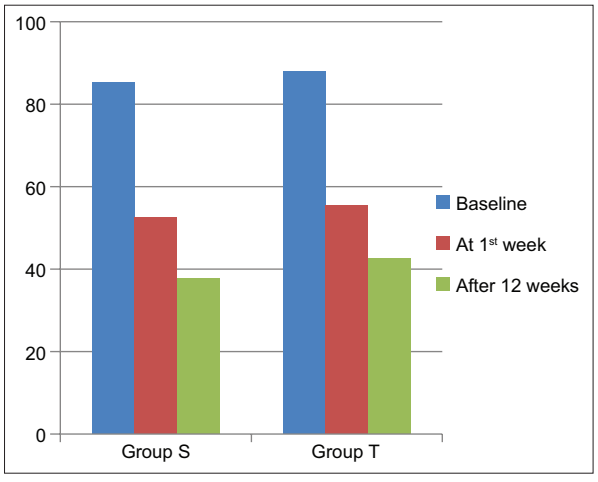


Figure 3: The change in post-void residual volume in the two groups

DISCUSSION

BPH is characterized by the proliferation of glandular epithelial tissue, smooth muscle, and connective tissue

Table 5: Side effects of drugs in the two groups

Side effects	At 1 and 12 week	Group S *n*=45	Group T *n*=42	*P*-value
Abnormal ejaculation	1 week	1 (2.22)	0	1*
	12 week	4 (8.88)	2 (4.76)	0.677*
Dizziness	1 week	8 (17.77)	5 (11.90)	0.443#
	12 week	5 (11.11)	4 (9.52)	1*
Nasal congestion	1 week	0	0	-
	12 week	1 (2.22)	2(4.76)	0.608*
Orthostatic hypotension	1 week	1 (2.22)	3(7.14)	0.349*
	12 week	2 (4.44)	6(14.28)	0.148*
Fatigue/myalgia	1 week	1 (2.22)	3(7.14)	0.349*
	12 week	3 (6.66)	4 (9.52)	0.707*

Fisher Exact test, #Chi-square test, SD: Standard deviation, S: Silodosin, T: Tamsulosin

Table 6: Comparison of IPSS changes from baseline to endpoint (12th week) of the study between the two groups

Study parameters	Group S (*n*=45)	Group T (*n*=42)
Change of IPSS* from baseline to endpoints (Adjusted mean)	−9.7	-8.0
Standard deviation	3.2	3.1
Mean difference between the two groups (95% CI*)	−1.700 (−3.0447–−0.3553)	
P-value	0.0138*	

IPSS: International prostate symptom score, SD: Standard deviation, S: Silodosin, T: Tamsulosin

Table 7: Comparison of Peak flow rate (Q max) changes from baseline to endpoint (12th week) of the study between the two groups

Study parameters	Group S (*n*=45)	Group T (*n*=42)
Change of peak flow rate (Qmax) from baseline to endpoints (Adjusted mean)	+6.9	+5.6
Standard deviation	2.13	1.80
Mean difference between the two groups (95% CI*)	1.300 (−2.1437–−0.4563)	
P-value	0.0029*	

P<0.05 is statistically significant, SD: Standard deviation, S: Silodosin, T: Tamsulosin

within the prostatic transitional zone.[7] Male LUTS may be caused by a variety of conditions, which include BPE and BPO. It has been proposed that the male LUTS is caused by direct bladder outlet obstruction from enlarged tissue (static component), and from increased smooth muscle tone/resistance within the enlarged gland (dynamic component). As the symptoms complex are divided into obstructive and storage symptoms. Voiding symptoms have often been attributed to the physical presence of BOO and detrusor overactivity is thought to be a contributor to the storage symptoms seen in LUTS.[8] The management of LUTS symptoms includes lifestyle modifications, medical or surgical therapies. Based on the AUA/EAU/CAU, alpha-blockers are the first-line therapeutic options for men with bothersome symptoms who desire treatment.[9,10] They act principally by blocking the α1A-adrenoreceptors, which are most prevalent in the prostatic smooth muscle and cause relaxation.[11] Multiple drugs are available and each has its advantage and disadvantages. Tamsulosin is the most commonly used drug, Alfuzosin in sexually active males and silodosin is a newer agent with greater α-1A receptor selectivity.[12]

Table 8: Comparison of PVRV (ml) from baseline to endpoint (12th week) of the study between the two groups

Study parameters	Group S (*n*=45)	Group T (*n*=42)
Change of post-void residual urine (ml) from baseline to endpoints (Adjusted mean)	47.4	45.3
Standard deviation	9.30	8.40
Mean difference between the two groups (95% CI*)	−2.100 (−5.8869–1.6869)	
P-value	0.2733*	

P<0.05 is statistically significant, SD: Standard deviation, S: Silodosin, T: Tamsulosin, CI: Confidence interval

In our study, the majority of patients were in their sixties to seventies and the mean age of patients and the duration of the symptoms were comparable in both groups ($P < 0.05$). Wang *et al*.[13] did the first systematic review and network meta-analysis comparing the effectiveness of different oral drug therapies for LUTS/BPH and they recommended alpha-blockers for short-term treatment for LUTS/BPH. Manohar *et al*.[14] studied three drugs as monotherapy in symptomatic LUTS due to BPH in 269 patients and their outcome variables were improvements in IPSS, QoL, Qmax, PVR, and also adverse drug events (ADE). They found silodosin, the most efficacious alpha-1 adrenoceptor blocker, and had consistent improvement in LUTS at 3 months in Indian men. The first double-blind, placebo-controlled, RCT comparing tamsulosin and silodosin were reported in 2006.[15]

Changes in IPSS

In our current study, there was a significant decrease in the scores of IPSS from baseline in both the study groups. The mean change of IPSS from baseline for group S was −9.7 and for group T it was −8 at the study endpoint (12th week). The mean difference between the two groups was −1.700 (95% CI, −3.0447–−0.3553) and the change was significantly superior in the silodosin group (P – 0.0037) [Table 6]. Pande *et al*.[16] evaluated the efficacy of silodosin and Tamsulosin in Sixty-one patients and found silodosin comparable to tamsulosin in the treatment of LUTS due to BPH. Takeshita *et al*.[17] also found silodosin has similar efficacy to Tamsulosin in improving IPSS and they found nocturia was improved much by silodosin. Similar other studies also concluded that the silodosin was better than a placebo and not inferior to Tamsulosin in their study.[15,18]

Maximum Flow Rate

In our study, the mean maximum flow rate increase from the baseline in Group S was (+6.9 ml/s) and Group T was

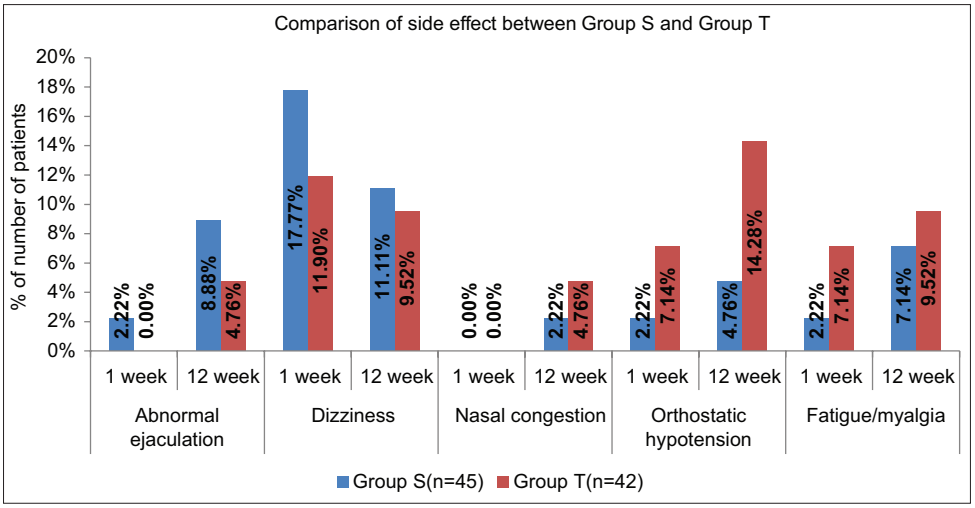


Figure 4: Side effects of drugs in the two groups

(+5.6 ml/s). The mean difference between the two groups was 1.300 (100% CI, 2.1437–−0.4563), and the silodosin group showing significant improvement (P = 0.0029) [Table 7]. A study by Takeshita *et al*.[17] also found the silodosin objectively improved Q_{max} as compared to Tamsulosin. Chapple *et al*.[19] reported the mean change from baseline to end was 3.77 mL/s for silodosin, 3.53 mL/s for tamsulosin, and 2.93 mL/s for placebo with non-significant changes of flow between the silodosin and Tamsulosin group.

PVRV change

There was a significant improvement in the PVRV in the two groups. The mean changes from baseline to endpoint of the study (12th week) in Group S was (−47.4ml) and Group T was (−45.3ml) and the mean difference between the two groups was −2.100 (100%CI, −5.8869–1.6869) but was not statistically significant (P = 0.27) [Table 8]. Other studies[20] also found similar results in terms of PVRU.

ADE

Overall side effects were more observed in the Tamsulosin group as compared to the silodosin group (P > 0.05). Orthostatic hypotension and abnormal ejaculation were the most common side effects. Orthostatic hypotension was the most common side effect in Tamsulosin Group 3 (7.14%) at 1 week and 6 (14.28%) at 12 weeks. Abnormal ejaculations were the most common in Silodosin Group 1 (2.22%) at 1 week and 4(8.88%) at 12 weeks. Fatigue with myalgia was observed in 7 (16.66%) cases of the Tamsulosin Group and 4 (9.52%) in the Silodosin Group [Table 5]. The side effects were mild and all were managed conservatively. In a study on silodosin, the most common ADE was abnormal ejaculation in 22% of patients.[21] The reason for abnormal ejaculation may be because of the presence of widely distributed $alfa_{1A}$-adrenoceptors in the epididymis, vas deferens, seminal vesicle, prostate gland, prostatic urethra, and bladder neck. Zhang *et al*.[22] observed that Orthostatic hypotension was observed only with tamsulosin in 3% of patients, but not with alfuzosin and silodosin. A study by Jayakumar *et al*.,[23] also found a similar side effect profile, and the most common side effect of tamsulosin and silodosin was postural hypotension.

The study has been conducted for the 1st time in our institute till now and definitely, it helps in the proper selection of drugs for the management of patients with LUTS in BPH. As Silodosin has comparable efficacy as compared to Tamsulosin in LUTS due to BPH, we can think of Silodosin 8 mg as an alternative in the management of such patients.

Limitation

The study period was small to assess for the prostrate size and the placebo arm was not kept for the ethical reasons of the institute.

CONCLUSION

All the study parameters (IPSS, Q max PVRU) at the treatment endpoint (12th week) of our study were improved with both the drugs. However, the improvement of IPSS and Q max was significantly more in the Silodosin group. Postural hypotension was more seen in Tamsulosin and ejaculatory disorders were more common in silodosin.

AUTHORS' CONTRIBUTIONS

NA planned the study, collected the data, and analyzed and prepared the report of the study. KS helped in writing, reviewing, and editing the manuscript. PL helped in data collection and reviewing the manuscript.

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