www.jmscr.igmpublication.org
Index Copernicus Value: 79.54
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v7i4.161

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

A Pilot Study on the Comparative Patient Satisfaction with Tamsulosin and Silodosin Therapy in Benign Prostate Hyperplasia and to Evaluate the Impact of Patient Counselling

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Abstract
Objective: *To investigate the comparative patient satisfaction with Silodosin and Tamsulosin in men with lower urinary tract symptoms (LUTS) and Benign Prostate Hyperplasia and also to evaluate the impact of counselling among patients*
Patients and Methods: *30 patients were included in the study with 15 patients in each groups with Silodosin 8 mg once daily and Tamsulosin 0.4 mg once daily. Patients were interviewed during the first visit in the department, appropriate patient counselling was provided and were followed up in the next two visits. The patient satisfaction on treatment was assessed by using PPSM (Patient Perception of Study Medication) questionnaire and the impact of patient counseling on Quality of Life was assessed using IPSS Q8 (International Prostate Symptom Score) and BPH Impact Index (BII) at each visits.*
Results: *Both the therapies resulted in significant improvements in PPSM, BII and IPSS scores from baseline. Assessments using the PPSM questionnaire showed that both the drugs increase patient satisfaction significantly, but between group comparisons showed that a significantly higher proportion of patients were satisfied with Silodosin therapy than Tamsulosin therapy. IPSS scores improved more significantly in Silodosin group compared to Tamsulosin group showing more symptom relief in the former group than latter. There was significant improvement in BII scores and IPSS Q8 scores showing significant improvement in patients' quality of life.*
Conclusions: *The present data from the pilot study show that therapy with Silodosin and Tamsulosin provides significantly greater improvements in patient-reported, disease-specific QoL and treatment satisfaction but Silodosin was found to be the drug with more patient satisfaction in men with BPH symptoms and prostate enlargement. Patient counselling on BPH had an impact on the health related quality of life on both the groups.*
Keywords: *BPH Impact Index (BII), PPSM, Silodosin, Tamsulosin, LUTS, I-PSS.*

Introduction

Benign prostatic hyperplasia (BPH) refers to the proliferation of smooth muscles and epithelilal cells within the prostatic transition zone.[1] It is a complex disease and is often associated with Lower Urinary Tract Symptoms (LUTS) which includes nocturia, urgency, urinary frequency, urinary tract infections, benign prostatic obstruction.

BPH with LUTS is a chronic condition, which is potentially progressive. This progression includes an increase in prostate volume, deterioration in LUTS and maximum urinary flow rate (QMAX), increased risk of acute urinary retention (AUR) and BPH-related surgery and a deterioration of BPH-related quality of life [3,4]. Prevalance and severity of LUTS in the aging male can be progressive and is an important diagnosis in the health care of patients and welfare of society.[1] the recommended tests in the diagnosis of BPH are digital rectal examination, IPSS scoring, creatinine measurement/ renal ultrasound, uroflowmetry and post voidal residual urine volume.

The aim of the treatment is to improve patient's quality of life, and it depends on severity of symptoms of BPH. Watchful therapy is recommended for patients with mild symptoms, medical treatment for patients with mild to moderate symptoms, and surgery for patients who failed medication /conservative management and who have moderate to severe symptoms or who have complications of BPH. [2]

Both the alpha blockes- Tamsulosin and Silodosin are effective and comparable. But no study have been conducted to evaluate the patient satistfaction regarding these two drugs. Patient satisfaction is an indicator of safety of the drug, relative incidence of adverse effects and it indirectly help us to measure the patient compliance towards medication regimen. Patient counselling on BPH is fundamental to promote rational drug use and to improve their dietary and lifestyles habits. The aim of the study is to find out the comparative patient satisfaction with Tamsulosin and Silodosin therapy among BPH patients and to evaluate the impact of counselling on quality of life.

Methodology

A Prospective-observational study was conducted in patients, who were diagnosed with Benign Prostate Hyperplasia (BPH) during the study period. The study period was 3 months after getting clearance from Ethical Committee. The study was conducted in the Urology department of Cosmopolitan Hospital located in Thiruvananthapuram, Kerala.

Inclusion Criteria

- BPH patients who are willing to participate in the study from OP & IP settings
- Patients of age greater than 50 yrs
- International Prostate Symptom Score (IPSS) score less than or equal to 23 who lacks absolute indication of surgical intervention were included in the study.

Exclusion Criteria

- Patients with raised Serum Prostate Specific Antigen level (>20ngml)/suspected prostatic malignancy
- Post void residual urine of>200ml, History of lower urinary tract malignancy/pelvic surgery
- Neurological conditions causing bladder dysfunction
- hepato-renal insufficiency are excluded from the study.

A Sample size of 30 was calculated using appropriate statistical analysis and 15 subjects were taken into each of the two groups. The first group received treatment with Silodosin 8 mg once daily and the other group received treatment with Tamsulosin 0.4 mg once daily. Patients were interviewed during the first visit in the department and appropriate patient counselling was provided regarding their disease, drugs and lifestyle modifications and were followed up for the one month study period.

All information relevant to the study was collected from case records and direct interview with patients. Data was collected by using a suitably designed proforma. The patient satisfaction on treatment with Tamsulosin and Silodosin was assessed by using PPSM (Patient's Perception of Study Medication) 1st and 2nd review. The impact of patient counseling

on Quality of Life was assessed using I-PSS Q8 and BPH Impact Index at each visits. The patients were reviewed after 1st month and 2nd month of taking the medication. At the end of the study all the parameters and scores were compared from baseline to end of the study.

IPSS is a symptom severity assessing tool which comprise of six questions concerning the symptom severity and one question concerning the quality of life and the total scores then divided as 0-7:mild, 8-19: moderate and 20-35: severe.[5]

BII is a tool used to assess the impact of presenting lower urinary tract symptoms on patient with 4 questions base on 0-4 point scale and the fourth question on 0-5 point scale. Total score of 0-13 range is then divided as 0-3; mild, 4-8; moderate and 9-13; severe.[6]

PPSM is a scale used to assess patient perception on study medication used for treatment of benign prostatic hyperplasia, developed by Glaxo Smith Kline (GSK). It is a 12 item questionnaire designed to quantify patient satisfaction in 4 areas- control of urinary symptoms (2 items), strength of urinary stream (2 items), 2 aspects of pain of urination (2 items each), effect on usual activities (2 items) and a single item asking about overall satisfaction. First 1-4 and 9-11 items comprise PPSM Global (score range:2-14), the rest (5-8) comprise of PPSM Pain (ranges from 1-7) and all of them together PPSM Total (scores range:7-77).[7]

Results

Statistical Analysis

The collected data on study variables from both groups were subjected to statistical analysis using appropriate statistical methods. The mean and standard deviation were used as descriptive statistics to summarise the raw data collected. For between group comparisons, based on each study parameters, independent sample t test has been applied. For within group comparisons, based on each study variables, paired t test has been used. The normality assumption of the data was verified by Kolmogorov – Smirnov test ($P < 0.05$). A calculated P value less than 0.05 is considered to be significant. All the analyses were carried out with the help of SPSS version 22.

Within group analysis

Table 1.1 Effect of treatment on patient satisfaction in Silodosin group

Parameter	Review	MEAN	S.D	t	P
PPSM Total	1st	19.80	7.57	7.07	0.000**
	2nd	12.46	3.90		
PPSM Global	1st	17.40	6.76	5.78	0.000
	2nd	11.26	3.08		
PPSM Pain	1st	2.40	2.74	3.15	0.007
	2nd	1.20	1.82		

** significant at 1% level. * not significant.

Table 1.2 Effect of treatment on patient satisfaction in Tamsulosin group

Parameter	Review	Mean	S.D	t	P
PPSM Total	1st	23.06	7.27	8.91	0.000
	2nd	17.13	5.51		
PPSM Global	1st	18.40	4.33	5.43	0.000
	2nd	15.33	3.97		
PPSM Pain	1st	4.66	4.04	4.78	0.000
	2nd	1.73	2.25		

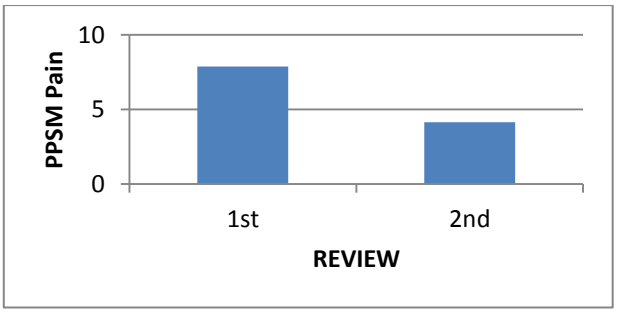
Table 1.3 Effect of treatment on IPSS in Silodosin group

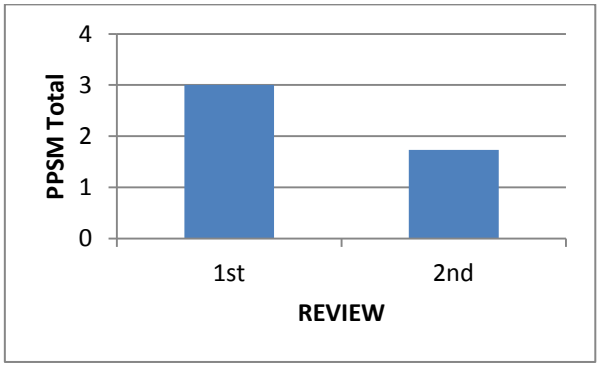
PARAMETER	VISIT	MEAN	S.D	T	P
IPSS	1st	12.53	5.69	9.72	0.000
	2nd	6.53	3.87		

Table 1.4 Effect of treatment on IPSS in Tamsulosin group

Parameter	Visit	MEAN	S.D	t	P
IPSS	1st	23.00	17.80	11.76	0.000
	2nd	17.00	10.86		

PPSM- Silodosin Group





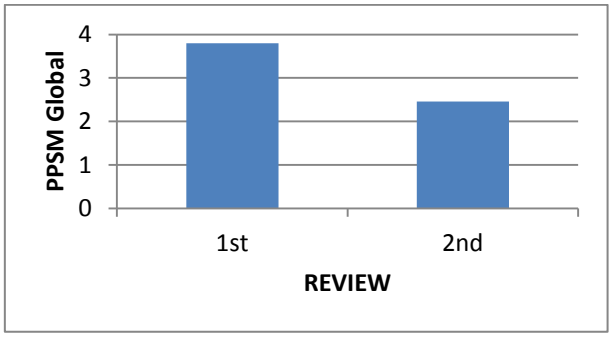


Figure 1.1 Effect of treatment on patient satisfaction in Silodosin group

From table 1.1, paired t test showed that the treatment had significant effect on improving patient satisfaction in Silodosin 8 mg group by PPSM Total (t=7.07, P<0.01) , PPSM Global (t= 5.78, P<0.01) and by PPSM Pain(t= 3.15, P <0.01). Before the treatment, the satisfaction levels by PPSM was, PPSM Total- 19.8 ± 7.57 (somewhat satisfied), PPSM global- 17.40 ± 6.76 (satisfied) and of PPSM Pain-2.40± 2.74(very satisfied) but after the treatment, it significantly improved to the values 12.46 ± 3.90 (very satisfied)for PPSM Total,11.26 ± 3.08 (very satisfied) for PPSM Global, and 1.20± 1.82(very satisfied) respectively.

Similarly, from table 1.2, we can see that the treatment made significant improvement of patient satisfaction in Tamsulosin 0.4 mg group too by PPSM Total (t=8.91, P<0.01) , PPSM Global (t= 5.43, P<0.01) and by PPSM Pain (t= 4.78, P <0.01).Before the treatment, the satisfaction levels by PPSM was, PPSM Total- 23.06± 7.27 (somewhat satisfied), PPSM global- 18.40 ± 4.33 (satisfied) and of PPSM Pain 4.66 ± 4.04 (very satisfied) but after the treatment, it significantly PPSM Total (t=8.91, P<0.01) , PPSM Global (t= 5.43, P<0.01) and by PPSM Pain(t= 4.78, P <0.01).Before the treatment, the satisfaction levels by PPSM was, PPSM Total- 23.06 ± 7.27 (somewhat satisfied), PPSM global- 18.40 ± 4.33 (satisfied) and of PPSM Pain 4.66 ± 4.04 (very satisfied) but after the treatment, it significantly improved to the values 17.13 ± 5.51 (satisfied) for PPSM Total,15.33 ± 3.97(satisfied) for PPSM Global, and 1.73 ± 2.25 (very satisfied) respectively. This shows that both the drugs were capable of making the patient satisfied through decreasing the disease symptoms

PPSM- Tamsulosin Group

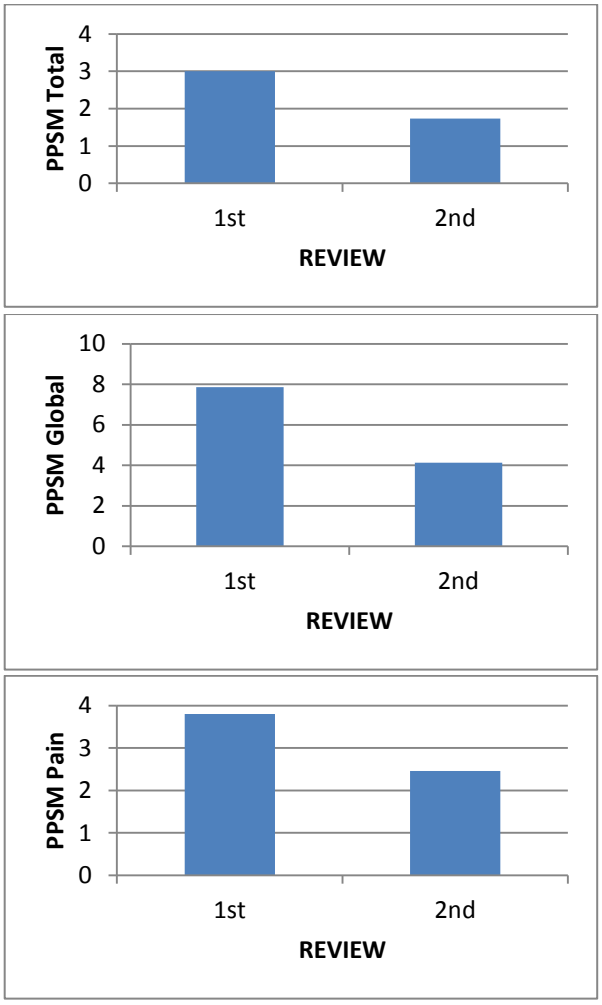


Figure 1.2 Effect of treatment on patient satisfaction in Tamsulosin group

From table 1.3 and table 1.4, paired t test shows significant effect on improving patient symptom status (measured using IPSS) in Silodosin 8 mg group (t= 9.72, P <0.01) as well as in Tamsulosin 0.4 mg group (t=9.72, P<0.01). Before the treatment, the IPSS score was 12.53 ± 5.69(moderate) in Silodosin 8 mg group and 23.00± 17.80 (severe) in

Tamsulosin 0.4 mg group. But after the treatment, it significantly improved to the values 6.53 ± 3.87 (mild) in Silodosin 8 mg group and 17.00± 10.86 (moderate) in Tamsulosin 0.4 mg group. Both the treatments had a positive impact on patient symptoms

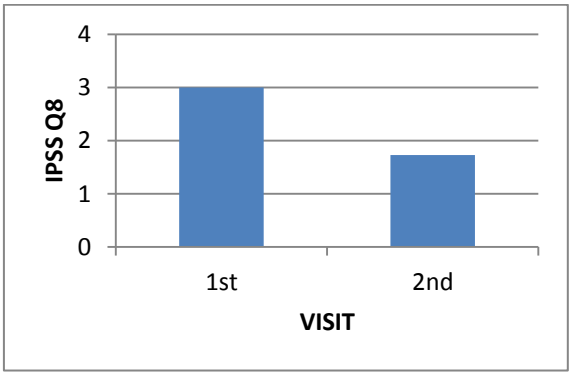
Table 1.5 Effect of patient counselling on quality of life in Silodosin

Parameter	Visit	Mean	S.D	T	P
IPSS Q8	1st	3.80	1.08	10.58	0.000
	2nd	2.46	1.12		
BII	1st	9.86	1.55	16.38	0.000
	2nd	5.80	1.93		

Table 1.6 Effect of patient counselling on quality of life in Tamsulosin group

Parameter	Visit	Mean	S.D	T	P
IPSS Q8	1st	3.00	0.75	10.71	0.000
	2nd	1.73	1.03		
BII	1st	7.86	0.47	18.10	0.000
	2nd	4.13	0.42		

Quality of Life- Silodosn Group



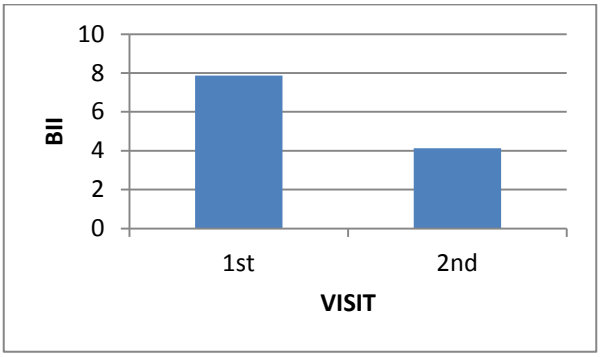


Figure 1.5 Effect of patient counselling on quality of life in Silodosin group

Quality of Life- Tamsulosin Group

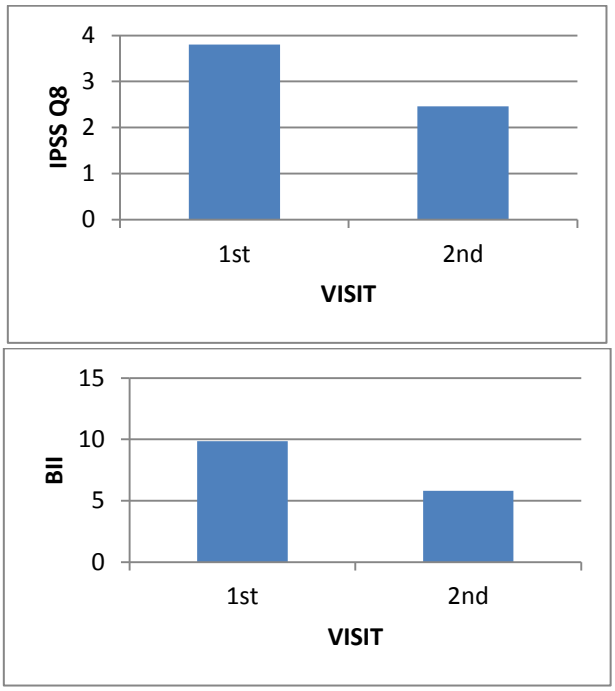


Figure 1.6 Effect of patient counselling on quality of life in Tamsulosin group

From table 1.5 and table 1.6, paired t test shows significant effect on improving patient's Quality of life in Silodosin 8mg group by IPSS Q8 (t= 10.71, P <0.01) and BII (t=18.10, P<0.01) as well as in Tamsulosin 0.4 mg group by IPSS Q8 (t=10.58, P<0.01) and BII (t=16.38, P<0.01). Before the treatment, the IPSS Q8 score was 3.00 ± 0.75(mostly dissatisfied) and BPH Impact Index was 7.86± 0.57(moderate) in Silodosin 8 mg group and IPSS Q8 score 3.80± 1.08 (mostly dissatisfied) and BPH Impact Index 9.86± 1.55(severe) in Tamsulosin 0.4 mg group. But after the treatment, it significantly improved to the values 1.73 ± 1.03 of IPSS Q8 score (mostly satisfied) and BII of 4.13± 0.42 (mild) in Silodosin 8 mg group and IPSS Q8 score 2.46± 1.12 (mostly satisfied) and BII 5.80 ±1.93 (moderate) in Tamsulosin 0.4 mg group. Both the treatments had a positive impact on patient symptoms.

Between Group Analysis (t- test)

Table 2.1 Comparison of Silodosin group and Tamsulosin group based on percentage improvement of patient satisfaction due to the treatment analysed using independent t test.

Table 2.1 comparison of improvement in patient satisfaction in S and T groups

Parameter	Group	Mean	S.D	T	P
PPSMTotal	S	33.72	13.12	2.080	0.047*
	T	25.68	7.21		
PPSM Global	S	30.66	15.15	2.818	0.009**
	T	16.86	11.39		
PPSM Pain	S	28.33	36.97	1.267	0.215_{ns}
	T	46.00	39.33		

*Significant at 5%. ** Significant at 1%. **NS** – Not significant.

Table 2.2 Comparison of IPSS improvement in both groups

Parameter	Group	Mean	S.d	T	P
IPSS	S	52.87	19.12	2.09	0.046*
	T	40.37	13.05		

*Significant at 5%.

From table 2.1, independent t test showed that the percentage improvement in patient satisfaction differ significantly between groups by PPSM Total (t= 2.080, P<0.05) and PPSM Global (t= 2.818, P<0.05). Silodosin 8 mg group reported a higher level of parentage improvement in patient satisfaction (PPSM Total, 33.72±13.12 and PPSM Global, 30.66±15.15) as compared to Tamsulosin 0.4 mg group (PPSM Total, 25.68±7.21 & PPSM Global, 16.86±11.39). But there don't exist any significant difference in percentage improvement of satisfaction by PPSM Pain due to treatment between Silodosin 8 mg and Tamsulosin 0.4 mg groups (t=1.267, P>0.05). i.e., the two groups reported approximately the same level of improvement in PPSM Pain due to the treatment.

Table 2.2 Comparison of Silodosin 8 mg group and Tamsulosin 0.4 mg group based on percentage improvement of patient symptoms due to the treatment which is measured by IPSS, analysed using independent t test. From table 2.2, independent t test showed that the percentage improvement in patient symptom status differ significantly between groups by IPSS (t= 2.09, P<0.05). Silodosin 8 mg group reported a higher level of percentage improvement in patient symptom status(measured by IPSS 52.87±19.12) as compared to Tamsulosin 0.4 mg group (IPSS 40.37±13.05).

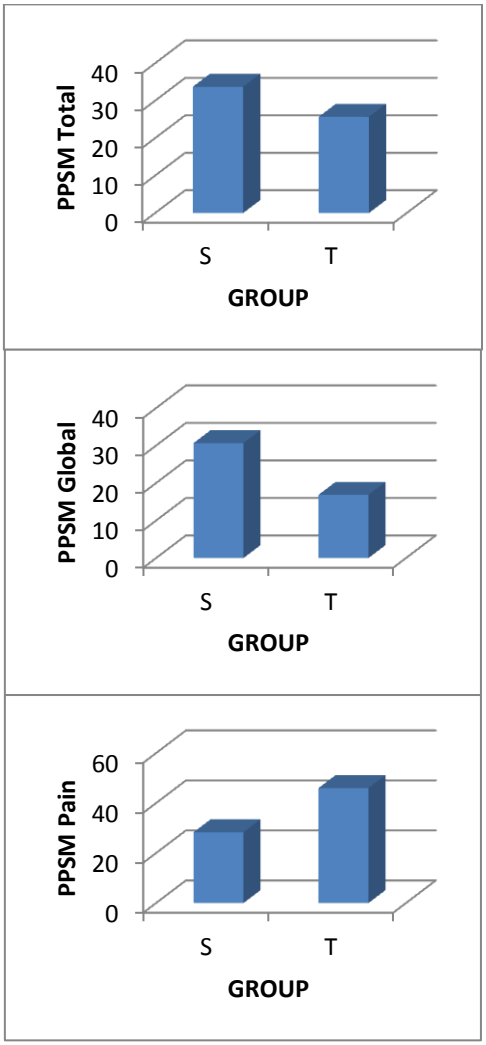


Figure 2.1 comparison of improvement in patient satisfaction in S and T groups

Discussion

The increasing recognition of the importance of patient reported outcomes (PRO) in recent years has led to the development of a large number of PRO questionnaires. Within the treatment of BPH, this has included measures such as the Boyarsky Score [8], the International Prostate Symptom Score (IPSS) [9] and the BPH Impact Index (BII)[10], which have become accepted standard measures in the field.

Patient satisfaction with treatment, which includes patients' evaluations of the process and outcome of their treatment experience, is increasingly being evaluated in clinical trials and disease management programs[11,12]. Measuring satisfaction with medication provides important outcome information from the patient's perspective as to their experience with the therapy and their willingness to ask their physician for the treatment.

In this study on the comparative patient satisfaction with Silodosin vs Tamsulosin therapy using PPSM on BPH patients showed that within the Silodosin group there was statistically significant change fom 1st review PPSM Total (some satisfied), PPSM Global (satisfied) and PPSM Pain (very satisfied) to very satisfied in 2nd review. Similarly within the Tamsulosin group it was proven that all the PPSM parameters have statistically significant change in 2nd review. This showed that both drugs were comparable of making patient satisfied. The symptom severity measured using I-PSS showed significant reduction in scores (Silodosin group- from moderate to mild and Tamsulosin group- fom severe to moderate), which implies both the dugs have positive impact on patients.

On the evaluation of impact of patient counselling on quality of life, it was found that both the Tamsulosin and Silodosin group have improvement in I-PSS Q8 from mostly dissatisfied to mostly satisfied and BII from moderate to mild.This showed there was an impact on quality of life with counselling. On the comparison of percentage improvement of I-PSS and PPSM between the groups, it was found that Silodosin 8 mg group reported a higher level of perentage improvement in symptom severity and patient satisfaction than Tamsulosin 0.4 mg group. But there don't exist any significant difference in percentage improvement of satisfaction by PPSM Pain due to treatment between Silodosin 8 mg and Tamsulosin 0.4 mg groups ($t=1.267$, $P>0.05$). i.e., the two groups reported approximately the same level of improvement in PPSM Pain due to the treatment.

Though pain is rarely reported in connection with BPH, it is a feature of prostatitis, which is also common in older men[13] and can often be confused with BPH in the older male population[14]. In a study comparing men with prostatitis and BPH, pain during urination was a feature for 54% and 29% of the groups respectively[15].

In a study by Fancesco et.al on the efficacy, safety and satisfaction with Silodosin showed that approximately half of the patients had an improvement in symptoms reported as more frequent and bothersome at baseline, with three-quarters of patients reporting satisfaction with the treatment. These observations confirm the efficacy of silodosin in treating BPH patients with moderate/severe LUTS in a real life setting.[16]

On a study by Bakin et.al - The Combination of Avodart® and Tamsulosin (*Comb AT*) *study* showed that the patient satisfaction with Combined therapy resulted in significantly greater improvements in BII and IPSS Q8 from baseline than did dutasteride from 3 months and compared with tamsulosin from 9 months (BII) or 12 months (IPSS Q8). Assessments using the PPSM questionnaire showed that a significantly higher proportion of patients were satisfied with and would request dutasteride and tamsulosin combined therapy than with each monotherapy at 24 months.[17]

On a placebo-controlled study by Oelke et.al, evaluating tadalafil or tamsulosin (as an active control) for LUTS/BPH, tadalafil 5 mg once-daily for 12 weeks resulted in treatment satisfaction that was statistically significantly greater vs placebo for the overall Treatment Satisfaction Score TSS-BPH score and the 'Satisfaction with Efficacy' domain, with no statistically significant differences for the 'Satisfaction with Dosing' or 'Satisfaction with Side-Effects' domains.[18]

Thus, this pilot study on the comparative patient satisfaction with Tamsulosin vs Silodosin showed that Silodosin was the drug which satisfied patient on a higher margin and also proved that effective could improve the health related quality of life

Several limitations should be considered when intepreting the present results. One limitation of the study is the absence of a placebo arm, which might have resulted in slightly over-estimated responses. The decision not to include a placebo arm was mainly based on ethical considerations. Each drug had already shown superiority over placebo in other trials. The patients' responses to the QoL and particularly to the PPSM questionnaire might potentially have been influenced by the suggestive nature of the questions. However, this limitation is inherent to all such questionnaires, which remain the only instruments for obtaining valuable

information on the benefits of therapies as perceived by the patient. The consistent effects observed across all questionnaires and the symptom measures strengthen the confidence in the study results, even without a placebo arm. about a quarter of patients had received recent prior α-blocker therapy, which may have impacted treatment differences, however, the reasons for patients' discontinuation of prior therapy, which might provide insight into these differences, are unknown.

Conclusion

In summary, the present data from the pilot study show that therapy with Silodosin and Tamsulosin provides significantly greater improvements in patient-reported, disease-specific QoL and treatment satisfaction but Silodosin was found to be the drug with more patient satisfaction in men with BPH symptoms and prostate enlargement. Patient counselling on BPH had an impact on the health related quality of life on both the groups.

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