RESEARCH ARTICLE

Comparative effectiveness of silodosin vs. tamsulosin in treating acute urinary retention in benign prostatic hyperplasia patients

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Abstract

Objective: To evaluate the effectiveness of silodosin and tamsulosin in patients with acute urine retention caused by benign prostatic hyperplasia.

Method: The prospective cohort study was conducted at the Sindh Institute of Urology and Transplantation, Karachi, from July to December 2022, and comprised male benign prostatic hyperplasia patients with acute urine retention. The patients were divided into group A receiving 0.4mg tamsulosin and group B receiving 8mg silodosin. The catheter was withdrawn after seven days. Trial without catheterisation success was measured by patients' post-void residue. All patients were reassessed for post-void residue at 4 weeks after a successful trial without catheterisation. Data was analysed using SPSS 21.

Results: Of the 130 male subjects with mean age 64.79±9.71 years, mean prostate volume 46.22±6.82ml and mean post-void residual 96±13ml on day 7 and 89.73±14.38ml on day 28, 65(50%) were in each of the two groups. Intergroup difference with respect to efficacy at four weeks was not significant (p=0.584).

Conclusion: The efficacy of tamsulosin and silodosin in individuals with benign prostatic hyperplasia was comparable.

Key Words: Acute urinary retention, Benign prostatic hyperplasia, Trial without catheter, Tamsulosin, Silodosin, Lower urinary tract symptoms.

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Introduction

Benign prostatic hyperplasia (BPH) is a common medical disorder characterised by the non-cancerous growth of the prostate gland.[1] Given its widespread occurrence and clinical implications, BPH is not merely a health concern, but a broader public health issue that necessitates ongoing attention.[2]

The prostate gland enlargement observed in males with BPH is benign and not indicative of malignancy. As it develops bigger, the gland may narrow the urethra. As the bladder wall thickness increases, detrusor muscle strength decreases, causing urine retension.[3] The global incidence of BPH rose from 5.48 million cases in 1990 to 11.26 million cases in 2019.[4] At the age of 60 years, 50% of males in India experience BPH.[5] According to another study, when men reach the age of 60 years, 50% of them show histological evidence of BPH. By their 70s, 28% of men experience moderate to severe lower urinary tract symptoms (LUTS) related to BPH.[6] Obesity has been linked to an increased risk of BPH. Obesity is one component of metabolic syndrome. Its exact origin is unknown, but it is believed to have multiple triggers. Two proposed mechanisms are the systemic inflammatory response and increased oestrogen levels.[7] This disease is associated with the development of LUTS, such as increased urinary frequency, urgency, reduced urine flow, and nocturia.[8,9] Patients with moderate to severe LUTS associated with BPH may find comfort with the use of alpha-1 blockers, including alfuzosin, doxazosin, silodosin, tamsulosin and terazosin. Common side effects of such medications may include erectile dysfunction, dizziness, weakness and hypotension.[10] Evidence has demonstrated that the therapeutic advantage of alpha-1 blockers does not depend on the initial size of the prostate. Alfuzosin, tamsulosin, and silodosin, which are three antagonists, are commonly prescribed for the treatment of BPH.[11] According to another study the overall success rate of trial without catheter (TWOC) was 62.5% (30 of 49). No significant difference was observed in the efficacy of tamsulosin, silodosin, and alfuzosin in catheter-free trials following acute urinary retention due to benign prostatic hyperplasia.[12]

At the Sindh Institute of Urology and Transplantation (SIUT) in Karachi. tamsulosin has been the usual medicine used for treating LUTS caused by BPH. The current study

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was planned to evaluate the effectiveness of silodosin and tamsulosin in patients with acute urine retention caused by BPH.

Patients and Methods

The prospective cohort study was conducted at the SIUT, Karachi, from July to December 2022, and comprised male BPH patients with acute urine retention. The patients were divided into tamsulosin group A and silodosin group B.

After approval from the institutional ethics review committee, the sample size was determined using the World Health Organisation calculator with significance level (α) 0.05 and statistical power 80%. The success rate of TWOC in the tamsulosin cohort was kept at 61%, whereas in the silodosin cohort, it was 76.7%.[13] The required sample size was 272, with 136 assigned to each group.

The sample was raised using non-probability sequential sampling technique. Those included were individuals aged at least 50 years, suffering their first episode of acute urinary retention (AUR) due to BPH, regardless of the duration. Cases of recurrent urinary retention, unsuccessful previous voiding attempts, a history of prostatic or bladder neck surgery, confirmed prostate cancer, documented urethral stricture, and a past history of neurogenic bladder. Individuals with renal failure, those currently receiving insulin therapy or oral hypoglycaemic agents, and individuals with a prior medical history of diabetes were excluded.

Each eligible patient was approached for informed consent. Those who furnished it were randomly assigned to one of the two groups. Until the targetted sample size was reached, an equal number of patients were enrolled in both the groups.

Patients in group A were given tablet tamsulosin 0.4mg once daily at bedtime, while those in group B were administered silodosin capsules 8mg once daily at bedtime. In both the groups, the trial lasted seven consecutive days after which TWOC was provided to each and every patient. Post-void residue (PVR) was used to assess the success or failure of TWOC. After four weeks, each patient with successful TWOC was subjected to a further examination and assessment of PVR. Adverse symptoms, such as headache, nausea, dizziness, light-headedness, diarrhoea, joint pain, and back discomfort were managed employing analgesics, anti-emetics and anti-spasmodic drugs. The outcome was considered successful if the patient no longer needed a catheter and could urinate via the urethra after 4 weeks.

Data related to age, occupation, residence, weight, height, body mass index (BMI), prostate volume, length of BPH, serum creatinine, PVR volume after 7 days, PVR volume after 28 days, and TWOC success, was recorded using a pre-designed proforma.

Data was analysed using SPSS 21. Data was expressed as mean ± standard deviation or as frequencies and percentages, as appropriate. Chi-square test was used to compare the data. PM<0.05 was deemed statistically significant.

Results

Of the 130 male patients approached, none refused to participate. The response rate, as such, was 100%. Of the total, 65(50%) were in each of the two groups. The overall mean age was 64.79±9.71 years, mean height was 1.66±0.11 meters, mean weight was 70.16±8.12kg, mean creatinine level was 1.20±0.416, mean prostate volume was 46.22±6.82ml, mean PVR on day 7 was 96±13ml and on day 28 it was 89.73±14.38ml (Table 1).

Table-1: Demographic and clinical data of the patients

	Minimum	Maximum	Mean ± STD Deviation
Age (years)	51	85	64.79 ± 9.71
Height (Meter)	1.45	1.87	1.66 ± .118
Weight (kg)	53	83	70.16 ± 8.12
BMI	15.49	35.56	24.92 ± 4.36
Creatinine	.30	1.90	1.20 ± .416
Luts(Duration)	1.0	14	6.93 ± 4.17
Prostate Volume (ml)	35.30	59.30	46.22 ± 6.82
PVR 7DAYS	65	120	96.56 ± 13.00
PVR 28DAYS	61	120	89.73 ± 14.38

BMI: Body mass index, LUTS: Lower urinary tract symptoms, PVR: Post-void residue..

Patients with LUTS for less than 6 months comprised 24 (36.9%) in the Tamsulosin group and 27 (41.5%) in the Silodosin group, whereas those with LUTS for 6 months or more constituted 41 (63.1%) and 38 (58.5%), respectively

Table-2: Comparison of LUTS Duration and Prostate Volume Between Tamsulosin and Silodosin Groups.

	Tamsulosin [n=65] f(%)	Silodosin [n=65] f(%)	Total [N=130] f(%)	p Value
Duration LUTS Category				
<6 months	24 [36.9]	27 [41.5]	51 [39.2]	
>=6 months	41 [63.1]	38 [58.5]	79 [60.8]	0.719
Prostate Volume Category				
<45 ml	27 [41.5]	32 [49.2]	59 [45.4]	
>=45 ml	38 [58.5]	33 [50.8]	71 [54.6]	0.481

LUTS: Lower urinary tract symptoms.

(p=0.719). In the cohort with prostate volume <45 mL, 27 (41.5%) were administered Tamsulosin and 32 (49.2%) received Silodosin, but in the group with volume ≥45 mL, 38 (58.5%) were treated with Tamsulosin and 33 (50.8%) with Silodosin (p=0.481). No notable discrepancies were detected. (Table 2).

Efficacy was observed in 43 (66.2%) participants in the Tamsulosin cohort and 40 (61.5%) participants in the Silodosin cohort. Non-efficacy was noted in 22 (33.8%) participants and 25 (38.5%) participants in the respective cohorts. The p-value (0.584) suggests no statistically significant difference between the cohorts. (Table 3).

Table-3: Efficacy Outcomes of Tamsulosin and Silodosin at 4 Weeks.

Efficacy at 4 weeks	Group			p Value
	Tamsulosin [n=65] f(%)	Silodosin [n=65] f(%)	Total [N=130] f(%)	
Yes	43 [66.2]	40 [61.5]	83 [63.8]	0.584
No	22 [33.8]	25 [38.5]	47 [36.2]	
Total	65 [100]	65 [100]	130 [100]	

Discussion

BPH is a prevalent cause of male voiding problems. This is a condition that becomes more common with age. Approximately 80% of males aged 70 and above get BPH.[14,15] Prostate enlargement hampers the normal physiological and functional condition, and disrupts daily activities. AUR is the most frequent urological complication linked to BPH. It refers to the sudden and distressing inability to urinate spontaneously. BPH is typically non-fatal.[15-16] Silodosin enhanced the quality of life for those with LUTS associated with BPH and objectively enhanced the maximum flow rate. In another study, silodosin was found to be an effective treatment for LUTS in men with BPH.[17]

In the current study, contrary to the prevailing notion, silodosin was not found to possess superior efficacy or distinctive properties compared to tamsulosin. Silodosin, is more economically efficient and less expensive compared to tamsulosin.

The current investigation also revealed that the efficacy of tamsulosin and silodosin in TWOC terms in individuals with BPH was comparable. There was no noticeable change in PVR volume between the two groups.

Another study demonstrated the efficacy of alfuzosin and tamsulosin in the treatment of BPH and urinary retention.[18] A recent study examining the factors influencing TWOC following AUR discovered that the patients' age, intravesical prostatic protrusion, prostate volume, and residual volume were autonomous indicators of successful TWOC.[19] One study found a significant link between the International Prostate Symptom Score (IPSS) assessment of the previous intensity of LUTS and the success of TWOC.[20] The efficacy of tamsulosin in trials without catheterisation was marginally superior to that of silodosin, yet comparable. No statistical differences were seen between the tamsulosin and silodosin treatment groups concerning IPSS, PVR, and PFR. However, the current study demonstrated comparable findings with a somewhat greater success rate in the tamsulosin group compared to the silodosin group.[21]

The current data revealed that both silodosin and tamsulosin exhibited good tolerability. To our knowledge, the current study is the first to directly compare the two medications for TWOC in AUR cases.

The current study, however, has limitations, like an inadequate small sample. The SIUT diagnoses roughly 10-15 patients with BPH each month. During the study span of six months, 130 participants were recruited, with an equal distribution of 65 persons in each group. Due to practical constraints, the study could not enrol 272 patients to meet the sample size requirements. This may have affected the generalisability of the findings. Besides, conducting the study exclusively in one hospital may have induced bias as a result of certain institutional practices and patient demographics that may not accurately reflect other environments. The duration of the follow-up period was restricted to 4 weeks, which did not encompass long-term results.

Conclusion

Contrary to the prevailing notion, both tamsulosin and silodosin exhibited comparable efficacy and had similar properties.

Disclaimer: The text is based on an academic thesis.

Conflict of Interest: None.

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AUTHOR'S CONTRIBUTION:
HUH: Concept and design.
TURG, NK, AJ, AS & AH: Data acquisition and analysis, drafting, final approval and agreement to be accountable for all aspects of the work.