



Alpha blockers in the management of acute urinary retention in prostatomegaly: a prospective observational study

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Background

Acute urinary retention (AUR) from prostatomegaly presents clinical challenges. Alpha blockers like tamsulosin and silodosin effectively alleviate AUR symptoms by relaxing bladder and prostate smooth muscles, and enhancing urine flow.

Objective

The study aims to assess the incidence of AUR in prostatomegaly patients, compare the efficacy of various alpha blockers in AUR management, and investigate associated side effects and adverse drug reactions.

Patients and methods

A total of 60 patients with confirmed prostatomegaly-induced AUR, determined by ultrasonography, were enrolled. The study evaluated the efficacy of alpha-blockers through pre- and postultrasonography assessments of prostate size and regular follow-ups at different intervals (5, 7, 8, and 15 days). Statistical analysis, including paired *t*-tests, was conducted to compare the efficacy of tamsulosin and silodosin.

Result and conclusion

Tamsulosin and silodosin were compared, revealing a significant reduction in prostate size for both drugs. However, tamsulosin demonstrated a greater paired difference (11.16) compared with silodosin (9.96). Cohen's D values further supported the superior efficacy of tamsulosin (2.52) over silodosin (1.49). Tamsulosin also exhibited fewer side effects (five patients) compared with silodosin (eight patients), establishing it as the more effective alpha-blocker with minimal side effects in AUR with prostatomegaly patients. Patients aged 61–70 and smokers showed increased AUR risk. Tamsulosin outperformed silodosin in reducing prostate size, relieving AUR symptoms, and minimizing side effects, demonstrating effectiveness in AUR management.

Keywords:

acute urinary retention, alpha blocker, prostatomegaly, silodosin, tamsulosin

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Introduction

Urinary retention (UR) represents a clinical condition wherein an individual faces challenges in fully evacuating the bladder. This incapacitating situation can arise from diverse medical factors, with prostate-related complications predominantly affecting men and conditions like cystocele impacting women. An enlarged prostate gland, exerting pressure on the urethra and consequently impeding the normal flow of urine [1].

Urinary retention, a condition characterized by the inability to fully empty the bladder, manifests in two distinct forms: acute urinary retention (AUR) and chronic urinary retention (CUR). In cases of CUR, individuals experience difficulty in completely voiding urine despite being able to initiate the process. AUR, on

the other hand, is often associated with benign prostatic hyperplasia (BPH), where patients find themselves unable to urinate despite a full bladder [1–4].

The likelihood of recurrence within a 6-month timeframe looms at ~20%, highlighting the need for comprehensive understanding and effective management of AUR. Interestingly, sex disparities exist, with women exhibiting a lower risk for AUR compared with men. The annual incidence among women is notably low, affecting only three out of every 100 000 individuals [5].

Several baseline variables serve as indicators for AUR in patients with BPH. These include advanced age, severe

lower urinary tract symptoms (LUTS), low peak flow rate, increased postvoid residual volume, an enlarged prostate, elevated serum prostate-specific antigen levels, and the coexistence of diabetes mellitus (DM) and hypertension (HTN). These factors collectively contribute to the complexity and varied presentation of AUR in BPH patients [6]. The diagnostic landscape for AUR encompasses various modalities, including ultrasonography (USG), electromyography, urodynamic tests, serum blood urea nitrogen, and cystoscopy [7].

The management of AUR often involves the insertion of a urinary catheter through the penis. Trial without catheter (TWOC) approach has emerged as a global standard in the care of male patients grappling with BPH and AUR. This method, involving the removal of the catheter after 1-3 days, demonstrates a remarkable success rate, allowing ~40% of patients to successfully void. Additionally, the strategic use of alpha-blockers preceding TWOC has demonstrated notable benefits in the effective management of AUR. This publication delves into the significance of TWOC and the adjunctive role of alpha blockers in enhancing the therapeutic approach to AUR in the context of BPH [3,8].

Alpha-blockers have emerged as a cornerstone in the therapeutic arsenal for patients experiencing AUR associated with prostatomegaly. Particularly prevalent in men with enlarged prostate glands and concomitant high blood pressure, alpha-blockers such as alfuzosin, tamsulosin, and silodosin play a crucial role in alleviating difficulties related to urinary voiding [9,10].

Need for the study

This prospective observational study is crucial to address the pressing need for a comprehensive understanding and effective management of AUR in the context of prostatomegaly. AUR, marked by an enlarged prostate gland causing difficulties in urination, can lead to substantial discomfort and potential complications if untreated. By evaluating the effectiveness of alpha-blockers in reducing prostate size and meticulously assessing side effects and adverse drug reactions in Indian patients—a population underrepresented in existing research aim to fill critical knowledge gaps. Additionally, this study seeks to quantify the extent to which alpha-blockers improve symptoms of UR, providing invaluable insights for clinicians and contributing to the refinement of tailored interventions, ultimately enhancing patient outcomes in this underexplored facet of urological care.

Materials and methods

Study design and site

This observational study was conducted at the Urology Department of Dhiraj General Hospital, a tertiary care hospital in Vadodara, Gujarat, India, spanning from November 2022 to May 2023, with ethical approval granted by the ethics committee of Sumandeep Vidyapeeth Deemed to be University (SVIEC/ON/Phar/BNPG21/NOV/22/13).

Sampling

Screening 144 patients in the urology department for AUR with prostatomegaly, 60 participants meeting stringent inclusion and exclusion criteria were enrolled after obtaining informed consent. The process of patient enrolment has been shown in Fig. 1 in the form of Flow chart.

Inclusion and exclusion criteria

Inclusion criteria

Male patients aged 50–80 years experiencing AUR due to prostaomegaly: AUR is commonly seen in the age group of 50–80 due to prostaomegaly therefore the particular age group has been selected.

Prostate size exceeding 30 grams: The prostate size greater than 30 g is considered prostatomegaly as per the BPH guideline.

Exclusion criteria

The patient has other causes of AUR like urethral stricture, bladder stone, urethral stone, etc.: Since the study was only focused on Prostaomegaly the other factors responsible for the AUR must be excluded.

Patients not giving consent for the study

Sample size calculation

According to Cochran's formula for finite population i.e. $n=53$

But since we had two groups, we have included 60 patients i.e. 30 patients in each group.

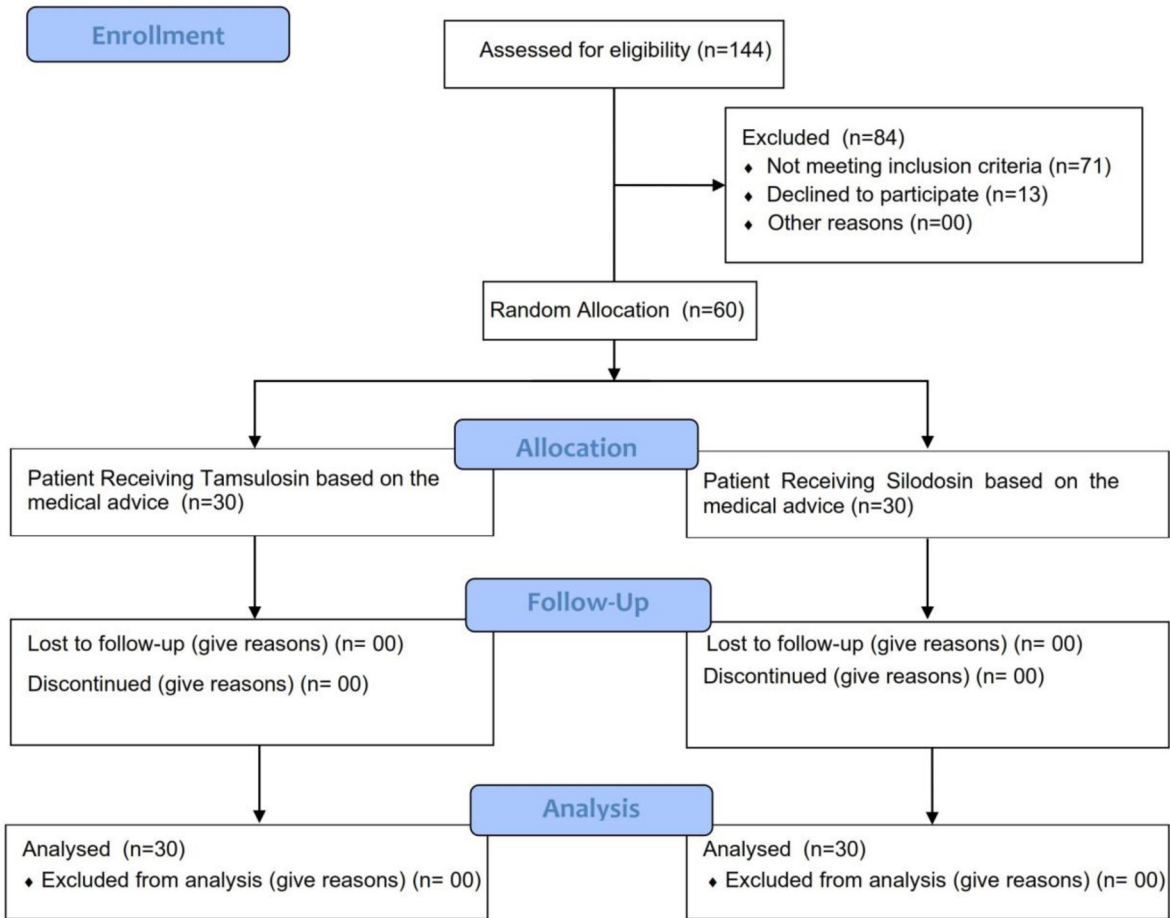
Step 1: Calculation for infinite population

$$n = \frac{Z^2 P(1 - P)}{d^2}$$

$$n = \frac{(1.96)^2 (0.077)(1 - 0.077)}{(0.05)^2}$$

$$n = 109$$

Figure 1



Enrolment flow diagram.

Step 2: Calculation for the finite population

$$n^1 = \frac{n}{\frac{1+Z^2P(1-P)}{d^2P}}$$

$$n^1 = \frac{109}{\frac{1+(1.96)^2(0.077)(1-0.077)}{(0.05)^2} 80}$$

$$n^1 = 53$$

Study process

Catheterization was uniformly performed in all 60 patients, with subsequent administration of either tamsulosin (0.4 mg) or silodosin (8 mg) to distinct groups. Observations and follow-ups at intervals of 5-, 7-, 8-, and 15-days postcatheterization were conducted, evaluating improvements, catheter removal, and urine passage. The reduction in prostate size and symptom alleviation were meticulously assessed through pre and post USG reports. Quantitative data analysis, employing percentage representation and mean with standard

deviation, utilized a paired *t*-test for statistical significance, complemented by graphical representations for clarity and enhanced data interpretation. The challenge of selection bias may remain as source of bias since the physician can use his experience and thoughts while prescribing either of alpha blockers to the patient.

Result

Incidence of acute urinary retention with prostatomegaly

Total of 144 patients, among whom 60 cases were identified with AUR and prostatomegaly, constituting 41% of the total urology department patients. Patient screening occurred daily over 5 months until the predetermined sample size was achieved. The meticulous screening process ensured comprehensive representation and adherence to the study's objectives, providing a robust foundation for the subsequent analyses and observations. Major confounders were identified and incorporated into exclusion criteria.

Age-wise distribution

The descriptive statistics and frequencies for various characteristics of the study population are presented in the Table 1. The age of the participants ranged from 50 to 80 years, with a mean age of 66.73 ± 4.99 (Mean \pm SD). Categorizing patients into three age groups revealed 13.3% in the 50–60 years category, 65.0% in the 61–70 years category, and 21.7% in the 71–80 years category Fig. 2.

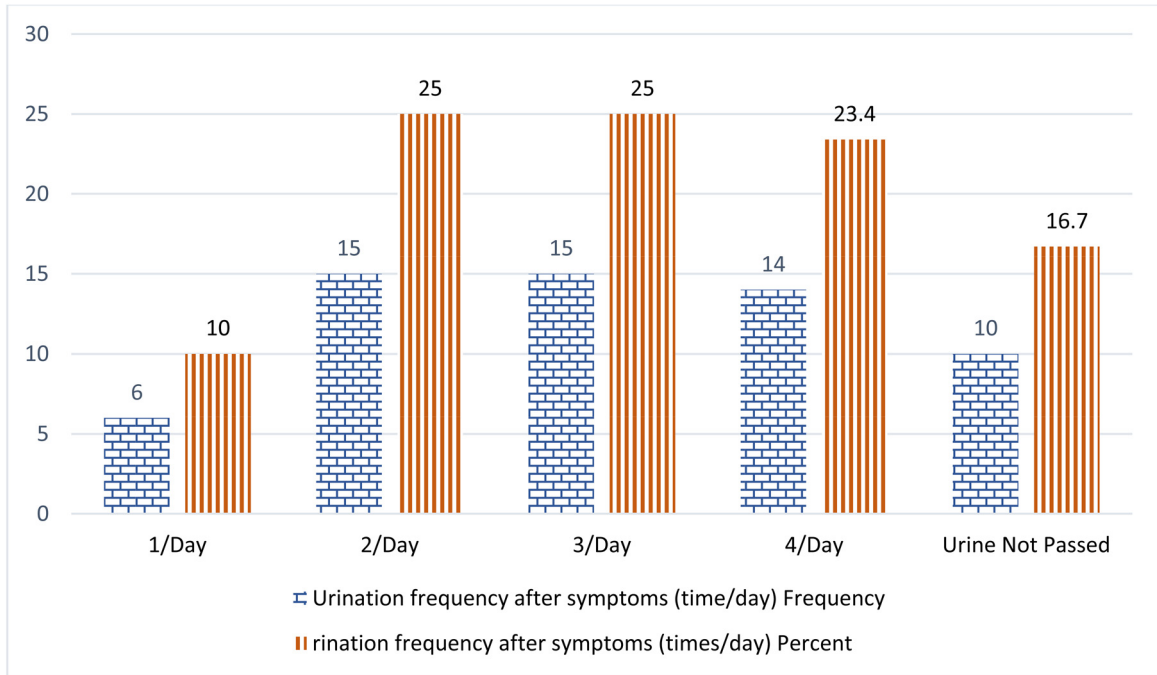
Social habits

Concerning social habits, 16.7% reported alcohol consumption, 10.0% acknowledged tobacco use, and 28.3% reported smoking. The frequency of urination after experiencing symptoms varied, with the most common ranges being two times per day (25.0%), three times per day (25.0%), and four times per day (23.4%). Notably, 16.7% reported 'urine not passed,' potentially indicating insufficient urination.

Table 1 Baseline characteristics

Characteristics	N (% Percentage)		
Age			
50–60		8 (13.3)	
61–70		39 (65.0)	
71–80		13 (21.7)	
Age mean \pm SD=66.73 \pm 4.99			
Social habit			
Alcohol		10 (16.7)	
Tobacco		6 (10.0)	
Smoking		17 (28.3)	
Frequency of urination after symptoms			
1 times/day		6 (10.0)	
2 times/day		15 (25.0)	
3 times/day		15 (25.0)	
4 times/day		14 (23.4)	
Urine not passed		10 (16.7)	
Symptoms of lower urinary tract infection			
Burning		14 (23.4)	
A feeling of incomplete bladder emptying		2 (3.4)	
Nocturia		5 (8.5)	
No symptoms		39 (65.0%)	
Other symptoms			
Hematuria		18 (30.0)	
Bladder palpable		15 (25.0)	
Lithuria		3 (5.0)	
Redness on external genitalia		9 (15.0)	
Data of catheterization	Total	Tamsulosin	Silodosin
F/U 7 days	31	16	15
F/U 10 days	20	8	12
F/U 5 days	6	5	1
F/U 15 days	2	1	1
F/U 8 days	1	0	1
Data according to prostate grade			
1		41 (68.3)	
2		19 (31.7)	
Data according to pretreatment USG			
Tamsulosin		Mild 20 (66.6)	
		Moderate 10 (33.3)	
Silodosin		Mild 21 (70.0)	
		Moderate 09 (30.0)	
Data according to post-treatment USG			
Tamsulosin		Mild 30 (100.00)	
		Moderate 0	
Silodosin		Mild 30 (100.00)	
		Moderate 0	

Figure 2



Frequency of urination after symptoms.

Symptoms of lower urinary tract infection

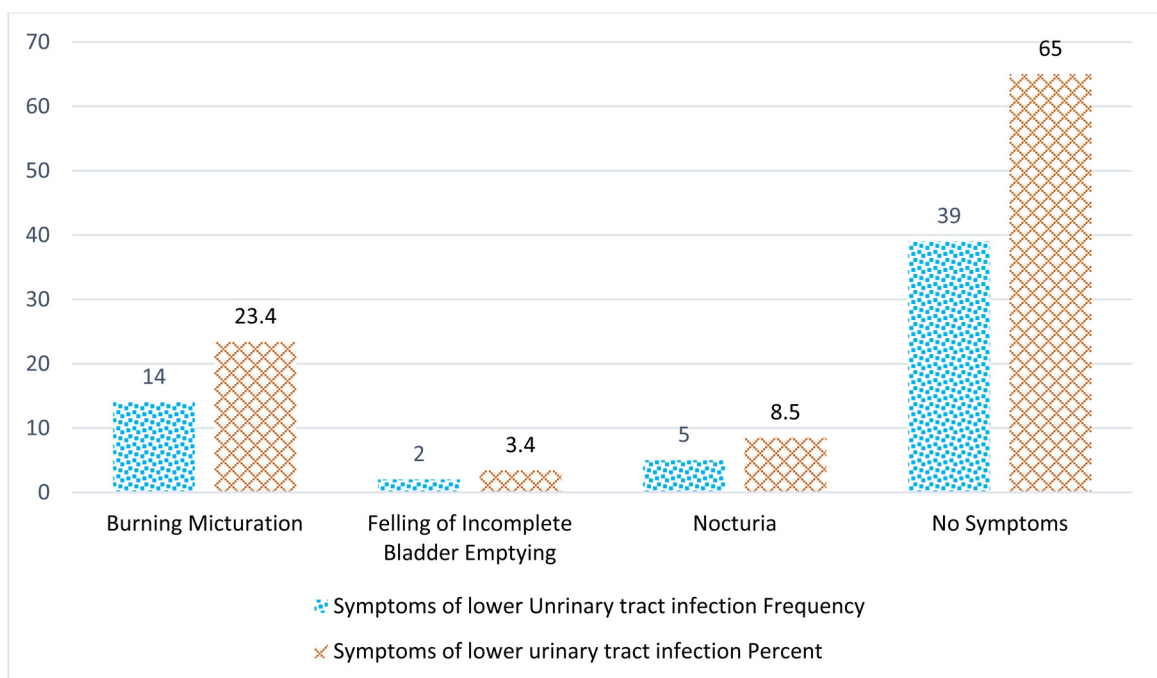
Burning micturition emerged as the predominant symptom (23.4%), followed by a feeling of incomplete bladder emptying (3.4%) and nocturia (8.5%). Surprisingly, 65.0% of participants reported no lower urinary tract infection symptoms. Haematuria was reported by 30.0%, while bladder palpability and

lithuria were reported by 25.0% and 5.0%, respectively. Redness on external genitalia was present in 15.0% of participants as shown in Fig. 3.

Drug prescribing pattern

Follow-up assessments at different intervals revealed varying cases, with tamsulosin being more frequently

Figure 3



Symptoms of lower urinary tract infection.

prescribed than Silodosin in catheterization cases. The study outcomes offer comprehensive insights into the demographic and clinical characteristics of the study population, providing the effectiveness of tamsulosin and Silodosin in the management of AUR.

Other symptoms

Apart from UTI symptoms patients have been reported with other symptoms as shown in Figs 4 and 5 i.e., haematuria was reported by 30.0% of participants, while 25.0% reported a palpable bladder, and only 5.0% reported lithuria. Redness on external genitalia was present in 15.0% of individuals. In the first follow-up at 7 days, 31 cases were recorded, with tamsulosin prescribed to 16 patients and silodosin to 15. At the 10-day follow-up, 20 cases were observed, with 8 on tamsulosin and 12 on silodosin. Follow-up at 5 days showed 6 cases, 5 on tamsulosin and 1 on silodosin. At 15 days, only 2 cases were reported, each with a different medication, while at 8 days, there was a single case prescribed silodosin, indicating a higher prevalence of tamsulosin prescriptions in this catheterization cohort.

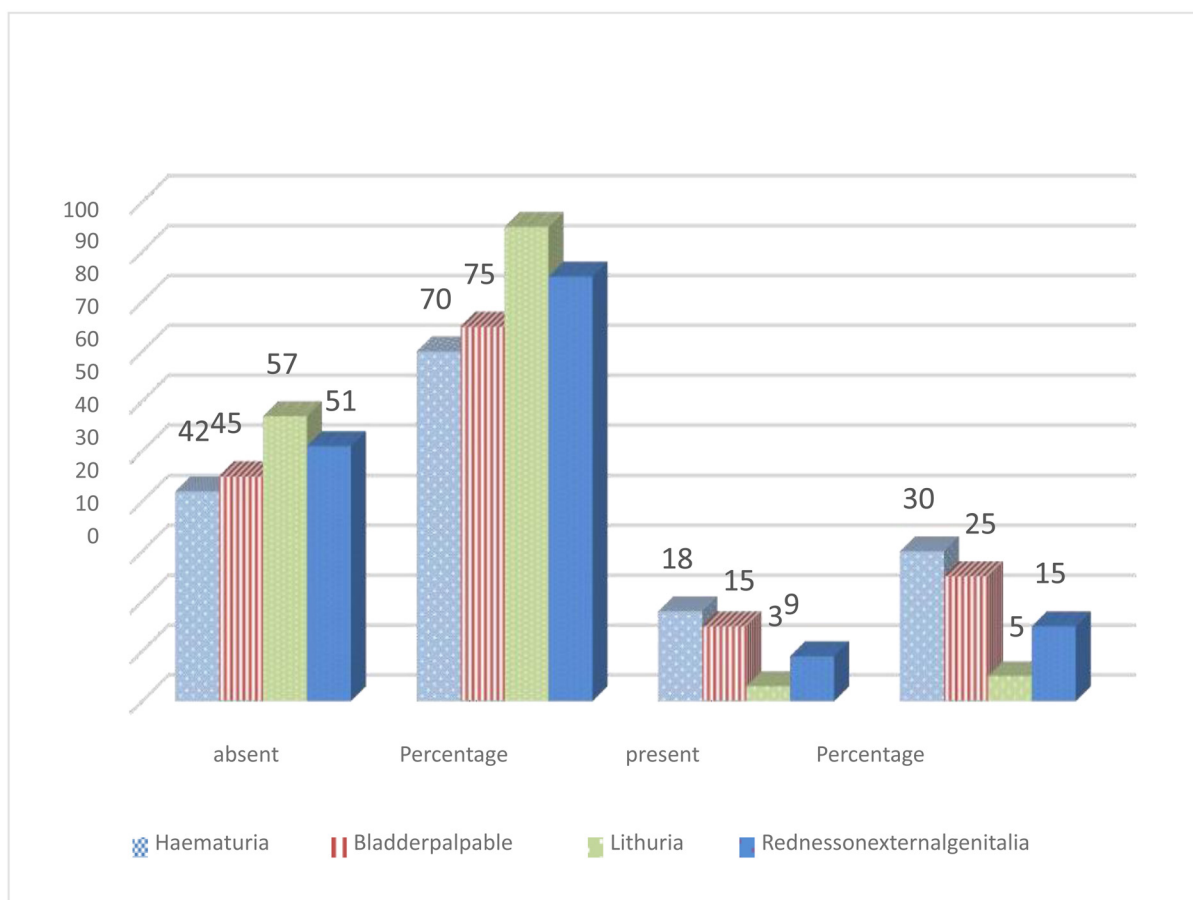
Grading of prostatomegaly

Prostate grades within the sample population revealed grade 1.0 as the most prevalent, constituting 68.3% of cases, while Grade 2.0 comprised 31.7%. Pre-treatment USG size analysis for tamsulosin indicated 66.6% mild cases and 33.3% moderate cases. Silodosin pretreatment results showed 70.0% mild cases and 30.0% moderate cases. Post-treatment USG size analysis for both tamsulosin and Silodosin revealed 100% mild category cases, with no individuals exhibiting USG levels other than mild after treatment. These findings underscore the effectiveness of both drugs in achieving a reduction in prostate size, particularly in cases characterized by mild enlargement.

Post treatment prostate size comparison

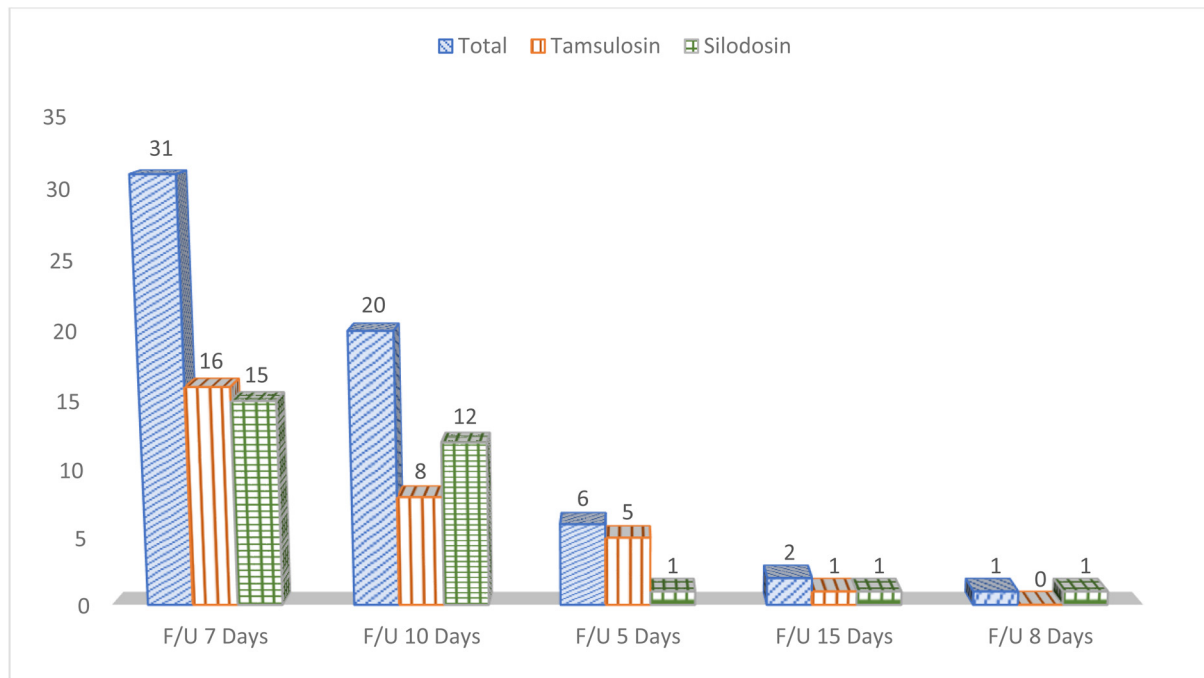
The comprehensive data on pre- and post-treatment USG sizes for patients receiving tamsulosin and Silodosin, showcased the mean and standard deviation (SD) values. For tamsulosin, the mean pre-treatment USG size was 39.63 ± 4.62 , demonstrating a significant reduction to 28.46 ± 2.17

Figure 4



Other symptoms.

Figure 5



Data of catheterization.

post-treatment. Similarly, silodosin exhibited a decrease from a mean pretreatment USG size of 41.1 ± 8.3 to 31.13 ± 2.28 post-treatment Table 2 and Fig. 6.

The paired difference for tamsulosin, indicating an improvement of 11.16, aligns with a large Cohen's d effect size of 2.52, emphasizing a substantial treatment impact. Silodosin, with a paired difference of 9.96, demonstrated a slightly smaller average improvement, reflected in a Cohen's d effect size of 1.49, still classified as large. Both medications showcased significant effects on the measured parameter Fig. 7.

In summary, tamsulosin and silodosin exhibited notable effectiveness in improving the measured parameter, with tamsulosin demonstrating a slightly larger effect size. This suggests that tamsulosin was marginally more effective in achieving the desired treatment outcome compared with silodosin,

providing valuable insights into the comparative efficacy of these medications in the context of AUR with prostatomegaly.

In this study, out of the 30 (50%) patients receiving tamsulosin, five (16.66%) individuals reported experiencing side effects. Conversely, among the 30 (50%) patients receiving silodosin, eight (26.66%) individuals reported encountering side effects. This data underscores the importance of monitoring and assessing side effects associated with each medication, providing valuable insights into the tolerability and safety profile of tamsulosin and silodosin in the context of treating AUR with prostatomegaly Table 3.

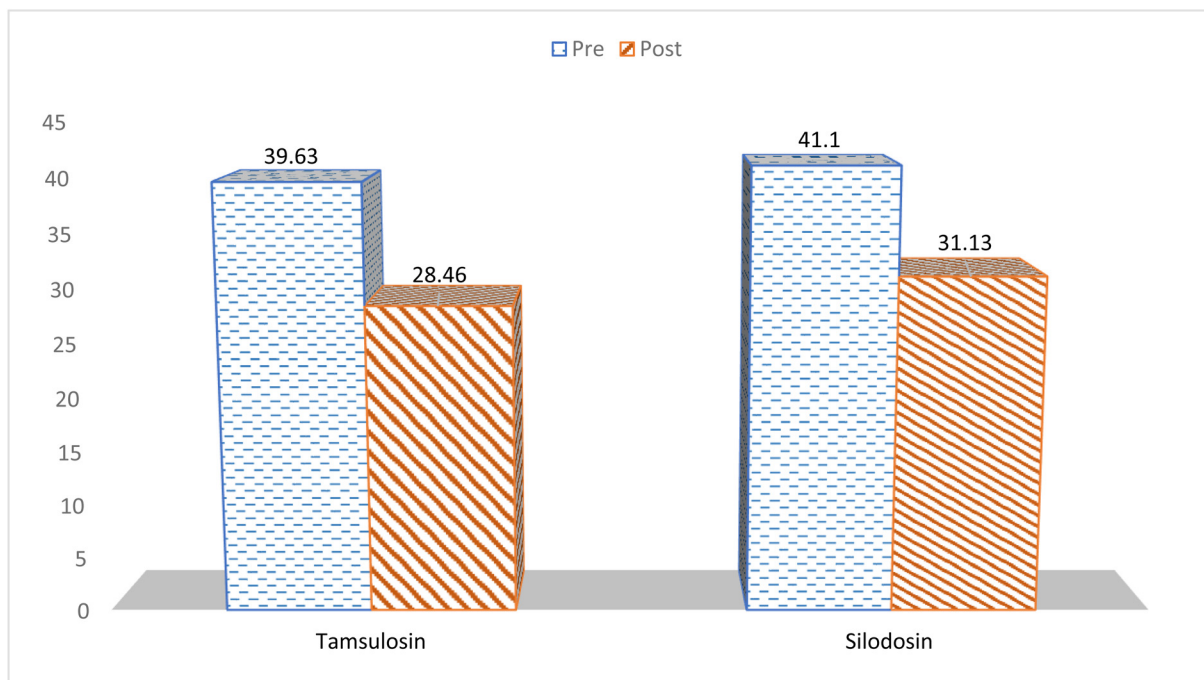
Discussion

The findings of this study, conducted at the Department of Urology, Dhiraj Hospital in Vadodara, shed light on several important aspects of BPH management and its associated factors.

Table 2 Comparison of ultrasound sonography (USG) size

	Tamsulosin pre- and post-treatment USG size		Silodosin pre- and post-treatment USG size	
	Pre	Post	Pre	Post
Mean \pm SD	39.63 ± 4.62	28.46 ± 2.17	41.1 ± 8.3	31.13 ± 2.28
Summarized effectiveness of drugs				
Treatment groups	Paired difference	Cohen's D		Effect Size
Tamsulosin	11.16	2.52		Large
Silodosin	9.96	1.49		Large

Figure 6



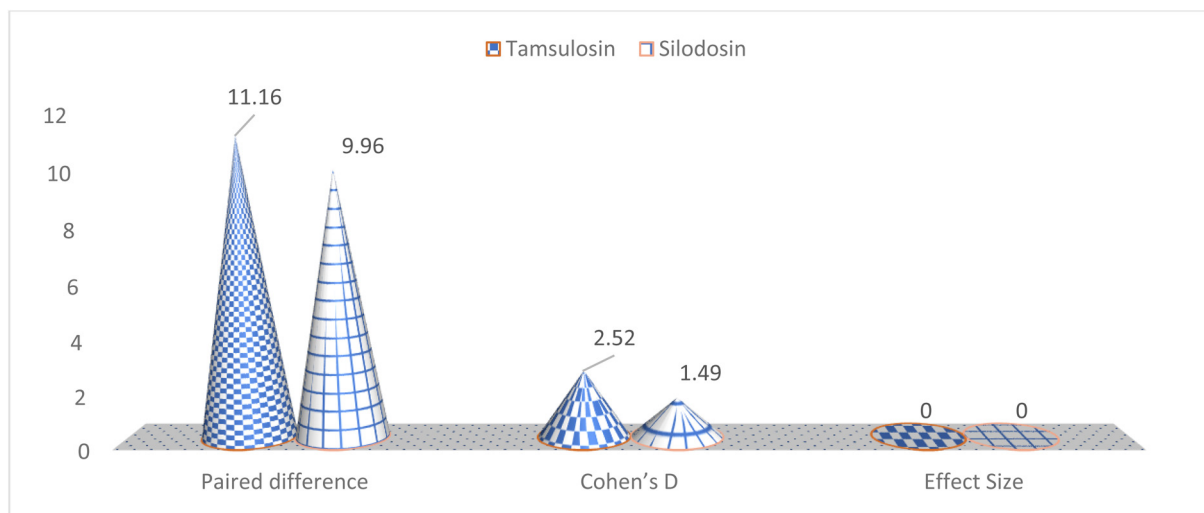
Tamsulosin and Silodosin Pre and Post-treatment ultrasonography size mean.

The current research focused on a cohort of patients aged between 50 and 80 years, providing valuable insights into the prevalence of certain lifestyle habits such as alcohol consumption, tobacco chewing, and smoking among this demographic. Notably, it was observed that a significant proportion of the study patient population indulged in habits such as smoking, with 28.3% identified as smokers. This observation is consistent with existing literature suggesting a potential link between smoking and the development or exacerbation of BPH-related symptoms.

In addition to lifestyle factors, the study also investigated urinary frequency patterns following the onset of symptoms. The findings indicated a wide range of urination frequencies, with a substantial number of patients reporting multiple voids per day.

Furthermore, this research examined the distribution of patients across different prostate grades, providing insights into disease severity within our study population. The majority of patients were classified as grade 1, indicating milder forms of BPH, while a

Figure 7



Effectiveness of drug: comparing both tamsulosin and silodosin.

Table 3 Safety profile

Tamsulosin			Silodosin		
Side effects	Frequency	% value	Side effects	Frequency	% value
Dizziness	1	3.33	Dizziness	2	6.66
Somnolence	1	3.33	Light headedness	1	3.33
Weakness	3	10	Headache	3	10
			Dark urine	2	6.66
Total	5	16.66	Total	8	26.66

smaller proportion fell into grade 2, suggestive of more advanced disease. These findings contribute for understanding of BPH progression and may inform clinical decision-making regarding treatment strategies. Studies conducted by Ozan Efesoy and Baris Saylam, as well as Yong Nam Gwon, have provided valuable insights into the efficacy of alpha-blockers in managing BPH symptoms, particularly in patients with larger prostate volumes. Moving forward, further research is warranted to validate our findings and explore novel therapeutic strategies aimed at improving outcomes for patients with BPH [11,12].

The study presented in this research paper adds significant insights into the efficacy of tamsulosin in the management of BPH-related AUR. One investigation involved 149 male patients, with 75 individuals receiving tamsulosin treatment and 74 assigned to the placebo group. Notably, in this analysis exclude eight patients due to incomplete evaluation, ensuring the robustness of the findings. The primary outcome measure of this study was need for re-catheterization following initial treatment for AUR, along with the achievement of successful post-voiding outcomes and the occurrence of adverse effects. The results revealed a clear advantage for the tamsulosin group, with a significantly higher proportion of patients (34 men) not requiring re-catheterization compared with those in the placebo group (18 patients). Overall, this study underscores the importance of evidence-based medicine in guiding clinical practice and improving outcomes for patients with BPH [13].

A meta-analysis, encompassing data from five randomized controlled trials involving 4348 patients, aimed to assess the efficacy and safety of tamsulosin plus dutasteride combination therapy compared with tamsulosin monotherapy in treating BPH over one year. Findings revealed that the combination therapy group exhibited significantly greater improvements in the international prostate symptoms score and maximum urine flow rate compared with the monotherapy group. The results underscore potential

of combination therapy as a preferred treatment approach for symptomatic BPH, providing clinicians with valuable insights for optimizing patient care [14].

The research study from Bangalore Medical College and Research Institute emphasized age as a risk factor for AUR in prostatomegaly patients. In China, tamsulosin treatment alongside catheterization improved urinary function, warranting further investigation into optimal treatment strategies. Moving forward, additional research is warranted to further elucidate the optimal treatment strategies and long-term outcomes in this patient population, ultimately guiding evidence-based clinical practice and improving patient care [15,16].

The results of two prospective studies evaluated alpha-blockers' effectiveness in managing AUR. Silodosin was found to be safe and effective, particularly in elderly individuals. Additionally, a prospective, randomized, placebo-controlled study was conducted and, in this study, 60 male patients aged 50 years and older with AUR were randomly assigned to receive either silodosin or placebo. The results demonstrated that silodosin treatment was both safe and effective in facilitating urinary function in patients with AUR, including elderly individuals. The efficacy of alpha-blockers and silodosin in promoting successful voiding and relieving UR symptoms highlights the importance of pharmacological interventions in the management of this condition. Furthermore, the safety profile of these medications, particularly in elderly patients, underscores their feasibility as treatment options for a diverse patient population. Moving forward, additional research is warranted to further elucidate optimal treatment strategies and long-term outcomes, ultimately guiding evidence-based clinical practice and improving patient care in the management of AUR associated with prostatomegaly [17,18].

The research conducted in a Dutch medical centre aimed to compare the efficacy of doxazosin and alfuzosin in patients with moderate to severe LUTS suggestive of bladder outlet obstruction. This

randomized trial enrolled 210 patients who were treated with either doxazosin (1–8 mg once daily) or alfuzosin (5–10 mg divided into two or three daily doses) for a duration of 14 weeks. The mean doses administered were 6.1 mg/day for doxazosin and 8.8 mg/day for alfuzosin. The study findings demonstrated that both medications resulted in improvements in urinary flow rate and the management of AUR. Additionally, an observational study conducted by S. Alan McNeill in the UK sought to investigate the role of alpha-blockers in managing AUR caused by benign prostatic obstruction. Further research, including randomized controlled trials and long-term follow-up studies, is warranted to validate and extend these findings, ultimately guiding evidence-based clinical practice in the management of LUTS and AUR [19,20].

The randomized, double-blind study was conducted in London aimed to evaluate the efficacy of tamsulosin compared with placebo in catheterized patients experiencing AUR due to prostatomegaly. This study enrolled 149 men, with 34 patients receiving tamsulosin and 18 receiving placebo treatment. The findings revealed that men catheterized for AUR demonstrated improved urinary function after catheter removal when treated with tamsulosin compared with placebo, with a reduced likelihood of requiring re-catheterization. Additionally, the study noted that the side effects associated with tamsulosin, an alpha-blocker drug, were minimal [13].

The observational, prospective, randomized study conducted in Gujarat aimed to compare the efficacy of tamsulosin, silodosin, and alfuzosin in catheterized patients following AUR due to prostatomegaly. The study enrolled 49 male patients who were randomly assigned to receive treatment with tamsulosin, silodosin, or alfuzosin for 3 days. After catheter removal, the study assessed the effects of alpha-blockers on urinary function restoration. The findings indicated an overall success rate of 62.5% in patients treated with alpha-blockers. This study contributes valuable insights into the therapeutic equivalence of different alpha-blockers in managing AUR. Further research, including larger-scale randomized controlled trials and long-term follow-up studies, is warranted to validate these findings and refine treatment algorithms for AUR management in patients with prostatomegaly [21].

As further research continues to elucidate the nuances of AUR management, including the optimal selection and dosing of alpha-blockers, these medications

remain a cornerstone in the armamentarium against prostatomegaly-related UR, providing hope for improved patient care and symptom management [14].

Sustained-release alfuzosin in Scotland showed promise in improving urinary outcomes post-AUR, emphasizing individualized treatment approaches. This observation underscores the importance of considering patient demographics and individualized treatment approaches in the management of AUR. While sustained-release alfuzosin shows promise in improving urinary outcomes post-AUR, further research is needed to elucidate the factors contributing to treatment response variability, ultimately guiding tailored therapeutic strategies to optimize patient outcomes in this challenging clinical scenario [22].

Even with the small sample size the findings have demonstrated significant variation in treatment outcome. Though their still need of study on larger population the current findings are applicable on similar population group.

Conclusion

Both tamsulosin and silodosin were effective in reducing prostate size and alleviating symptoms of AUR. Tamsulosin demonstrated a greater reduction in prostate size and a higher effect size (Cohen's D value of 2.52) compared with silodosin (Cohen's D value of 1.49). This indicates that tamsulosin is more effective in treating AUR in prostatomegaly patients. Tamsulosin was associated with fewer side effects, with only five out of 30 (16.66%) patients reporting adverse effects, compared with eight out of 30 (26.66%) patients for silodosin. This suggests that tamsulosin not only is more effective but also has a better safety profile. The study identified higher risks of AUR among patients aged 61–70 and smokers. These demographic factors could be critical in tailoring prevention and treatment strategies for AUR in prostatomegaly patients. This information is invaluable for clinicians in optimizing AUR management strategies in prostatomegaly patients.

Limitation

- (a) The current study had a relatively small sample size thus it may be difficult to generalize the results, and comparison between two widely used alpha-blocker drugs, Tamsulosin and Silodosin required a large sample size to get a better comparative outcome. Due to the limited period, we cannot achieve a large sample size.

- (b) Some specific diagnostic tests, such as cystoscopy, electromyography, and prostate-specific antigen, were not done due to availability and feasibility issues.
- (c) Patients who are already suffering from this disease are deprived of awareness and knowledge about future complications or related circumstances; therefore, this becomes a barrier to the treatment outcome.

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Nil.

Conflicts of interest

The authors declare there are no conflicts of interest.

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Ethical considerations: Ethical approval was taken from the Sumandeep Vidyapeeth Institutional Ethics Committee. The approval number is SVIENCE/NO/Phar/BNPG21/Nov/22/13 which was approved on November 5, 2022. Consent from the participants for both data collection and publication were obtained.

Previous presentation in conferences: Not Presented in any conferences.

IRB number: SVIENCE/NO/Phar/BNPG21/Nov/22/13.

Ethical Approval and Consent to Participate: Yes.

Consent to publish: Consent for the publication of the data has been obtained from all study participants.

Patient Consent: Yes.

Authors' contribution: N.S.: contributed to title selection, clinically reviewed all patients for enrollment in the study, and contributed to the study design. H.S.R.: assisted in title selection, obtained ethics committee approval documentation, provided writing assistance, assisted in questionnaire selection, made intellectual contributions to revision, reviewed the final manuscript for publication, and conducted proofreading. K.M., J.P., J.P.: contributed to proposal development, data collection, data analysis, drafting the manuscript, designing the manuscript, data interpretation, and manuscript editing. R.H.: assisted in obtaining ethics committee approval documentation, provided writing assistance, and reviewed the final manuscript for publication, conducting proofreading.

Conflicts of interest

Regarding the content of this manuscript, the authors state that they have no conflicts of interest. All affiliations and interests, both financial and nonfinancial, that can be viewed as possible sources of bias have been declared. This covers any associations, sources of financing, or personal ties that could have an impact on the study, interpretation, or analysis of the data in this journal article.

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