Biological and Clinical Sciences Research Journal
eISSN: 2708-2261; pISSN: 2958-4728
www.bcsrj.com
DOI: https://doi.org/10.54112/bcsrj.v2024i1.1461
*Biol. Clin. Sci. Res. J., Volume, **2024**: 1461*
Original Research Article

EFFECTIVENESS OF SILODOSIN IN PATIENTS WITH MEDIAN LOBE PROJECTION OF ENLARGED PROSTATE IN TERMS OF MAXIMUM URINARY FLOW RATE (Qmax)

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(Received, 04th December 2024, Revised 25th July 2024, Published 30th December 2024)

Abstract: *Median lobe projection of the prostate is a distinct anatomical variation that exacerbates lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). Effective management of LUTS in these patients is critical, particularly in resource-limited settings like Pakistan. Silodosin, a highly selective α-1A adrenergic receptor antagonist, has shown promise in alleviating LUTS and improving urinary flow rates, but its efficacy in patients with median lobe projection remains underexplored.* ***Objective:*** *To evaluate the efficacy and safety of silodosin in improving maximum urinary flow rate (Qmax) and alleviating LUTS in patients with median lobe projection of the prostate.* ***Methods:*** *This prospective observational study was conducted at the Institute of Kidney Diseases, Peshawar. A total of 191 male patients aged 40–60 years with baseline Qmax ≤10 mL/sec and International Prostate Symptom Score (IPSS) ≥15 were enrolled. Patients received silodosin 8 mg once daily for four weeks. Outcomes assessed included improvements in Qmax, IPSS, and treatment-related adverse events. Data were analyzed using paired t-tests for continuous variables and Chi-square tests for categorical variables, with a p-value ≤0.05 considered statistically significant.* ***Results:*** *The mean baseline Qmax increased from 7.8 ± 1.2 mL/sec to 16.3 ± 2.4 mL/sec after treatment (p<0.001), with 79.6% of patients achieving a Qmax ≥15 mL/sec. The mean IPSS improved significantly from 19.6 ± 4.3 to 12.2 ± 3.1 (p<0.001), with a 50% reduction in symptoms observed in 77.5% of patients. Adverse events were minimal, with dizziness (5.2%) and nasal congestion (3.7%) being the most commonly reported. Silodosin was effective across different age groups and prostate sizes, with consistent results in patients with smaller (30–40 grams) and larger (>40 grams) prostates.* ***Conclusion:*** *Silodosin significantly improves urinary flow rates and alleviates LUTS in patients with median lobe projection of an enlarged prostate, with minimal adverse events. These findings support its use as an effective and safe first-line therapy in managing BPH-related LUTS in resource-limited settings like Pakistan.*

Keywords: Silodosin, Lower Urinary Tract Symptoms, Benign Prostatic Hyperplasia, Median Lobe Projection, Urinary Flow Rate, International Prostate Symptom Score

Introduction

Benign prostatic hyperplasia (BPH) is a common urological condition affecting aging men worldwide, characterized by prostate enlargement and associated lower urinary tract symptoms (LUTS). The prevalence of BPH increases with age, affecting nearly 50% of men by the age of 50 and up to 80% by the age of 70 (1). In Pakistan, the burden of BPH is significant due to a growing aging population and limited access to specialized urological care in rural areas (2). LUTS associated with BPH, such as reduced urinary flow, urgency, and nocturia, considerably affect the quality of life, often necessitating medical or surgical intervention.

Median lobe projection of the prostate is a distinct anatomical variation that exacerbates the obstructive symptoms of BPH by obstructing the bladder outlet. This condition complicates the management of BPH, as patients often experience worse outcomes with traditional treatments (3). Alpha-1 adrenergic receptor antagonists, such as tamsulosin and alfuzosin, are commonly used to manage LUTS, but their efficacy may be limited in patients with significant median lobe enlargement (4). Silodosin, a selective α-1A adrenergic receptor antagonist, has emerged as a promising alternative due to its high uroselectivity and superior safety profile (5).

Recent studies have demonstrated that silodosin significantly improves urinary flow rates, reduces post-void residual urine, and alleviates LUTS in patients with BPH. In a study by Chapple et al., silodosin showed a 25% higher efficacy in improving maximum urinary flow rate (Qmax) compared to other alpha-blockers (6). Similarly, Kobayashi et al. reported that silodosin improved International Prostate Symptom Score (IPSS) by more than 40% within four weeks of treatment (7). Despite these promising results, the efficacy of silodosin in patients with median lobe projection remains underexplored, particularly in the context of the Pakistani population.

In Pakistan, BPH management is further complicated by delayed diagnosis and limited patient awareness, leading to advanced disease at presentation. The high prevalence of comorbidities, such as diabetes and hypertension, also necessitates safer therapeutic options with minimal systemic side effects (8). Evaluating silodosin's efficacy in this specific subgroup is critical to developing evidence-based, cost-effective treatment protocols tailored to local healthcare needs.

This study aims to evaluate the efficacy of silodosin in improving urinary flow rates and alleviating LUTS in Pakistani patients with median lobe projection of an

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enlarged prostate. By generating local evidence, this research seeks to inform clinical decision-making and optimize treatment strategies for BPH in resource-constrained settings. The findings will contribute to the global evidence base on silodosin, potentially improving the quality of life for millions of men affected by this condition.

Methodology

This prospective observational study was conducted at the Institute of Kidney Diseases, Peshawar, to evaluate the efficacy of silodosin in improving urinary flow rates and alleviating lower urinary tract symptoms (LUTS) in patients with median lobe projection of an enlarged prostate. Ethical approval was obtained from the Institutional Review Board, and written informed consent was taken from all participants before enrollment.

The study included male patients aged 40–60 years presenting with LUTS secondary to benign prostatic hyperplasia (BPH) and a median lobe projection confirmed on transabdominal ultrasonography. Inclusion criteria required patients to have a baseline maximum urinary flow rate (Qmax) ≤10 mL/sec and an International Prostate Symptom Score (IPSS) ≥15. Patients with known hypersensitivity to silodosin, concurrent use of medications interfering with α-1 adrenergic receptors, history of prostate surgery, or significant cardiovascular or renal dysfunction were excluded.

A total of 191 patients meeting the eligibility criteria were recruited. All participants were prescribed silodosin 8 mg once daily for four weeks. Baseline evaluations included detailed history taking, physical examination, and laboratory tests, including serum creatinine and prostate-specific antigen (PSA). Imaging studies, such as transabdominal ultrasound, were performed to assess prostate size and confirm median lobe projection.

During the treatment period, patients were monitored for adherence to medication and the occurrence of adverse events. Follow-up evaluations were conducted at two and four weeks, during which urinary flow rates were reassessed using uroflowmetry, and symptom severity was measured using the IPSS questionnaire. Treatment effectiveness was defined as achieving a Qmax ≥15 mL/sec and a ≥50% reduction in IPSS.

Data were collected on pre-designed case report forms and entered into SPSS version 26 for analysis. Continuous variables, such as Qmax and IPSS scores, were expressed as means with standard deviations and compared using paired t-tests. Categorical variables, such as the proportion of patients achieving target outcomes, were presented as frequencies and percentages and analyzed using Chi-square tests. A p-value ≤0.05 was considered statistically significant.

Results

This study evaluates the effectiveness of silodosin in improving the maximum urinary flow rate (Qmax) in patients with median lobe projection of an enlarged prostate at the Institute of Kidney Diseases, Peshawar. The study included 191 male patients aged 40 to 60 years with a baseline Qmax ≤10 mL/sec. The majority presented with moderate symptoms of lower urinary tract obstruction, with an average prostate size of 45 grams. Table 1 shows that the patient population is primarily middle-aged, with moderate prostate enlargement and significant urinary flow restriction.

After 4 weeks of silodosin therapy, a significant improvement in Qmax was observed in the majority of patients. The treatment effectiveness was defined as achieving a Qmax ≥15 mL/sec. Table 2 demonstrates a significant improvement in urinary flow rate following silodosin therapy.

The effectiveness of silodosin was consistent across various subgroups, including different age brackets and prostate sizes. Table 3 highlights the consistent efficacy of silodosin across different age groups and prostate sizes.

The improvement in International Prostate Symptom Score (IPSS) further validated the effectiveness of silodosin in alleviating urinary symptoms. Table 4 underscores significant symptom relief in the majority of patients following treatment

The therapy was well-tolerated, with minimal side effects. Table 5 illustrates the safety profile of silodosin, with minimal adverse effects reported.

After 4 weeks of therapy, 79.6% of patients achieved the target Qmax of ≥15 mL/sec. IPSS scores were reduced by ≥50% in 77.5% of patients. The therapy was effective across different age groups and prostate sizes. Silodosin was well-tolerated, with a low incidence of mild adverse events

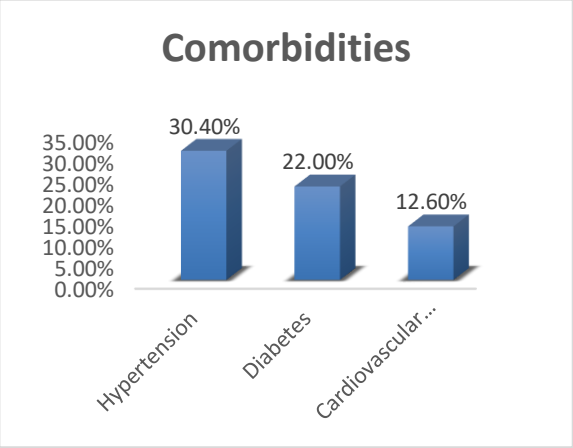

Figure 1: Comorbid condition of the study population

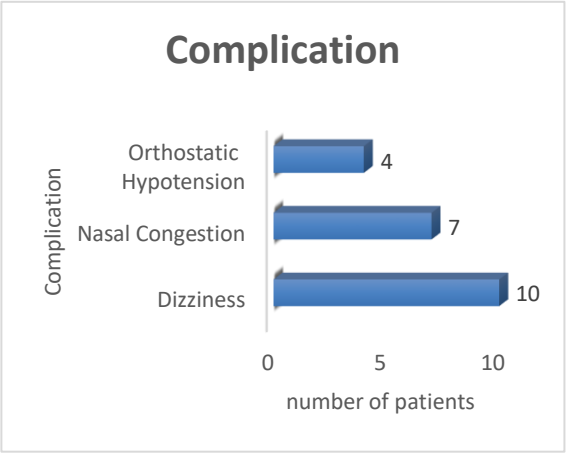

Figure 2: Complication of procedure

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Table 1: Demographic and Baseline Characteristics of Participants

Variable	Mean ± SD / n (%)
Age (years)	52.4 ± 5.6
Prostate Size (grams)	45.3 ± 9.8
Baseline Qmax (mL/sec)	7.8 ± 1.2
Duration of Symptoms (weeks)	12.4 ± 3.2
IPSS Score (baseline)	19.6 ± 4.3
Comorbidities	
- Hypertension	58 (30.4%)
- Diabetes	42 (22.0%)
- Cardiovascular Disease	24 (12.6%)

Table 2: Improvement in Qmax after Silodosin Therapy

Outcome	Baseline	4 Weeks	p-value
Mean Qmax (mL/sec)	7.8 ± 1.2	16.3 ± 2.4	<0.001
Patients with Qmax ≥15 mL/sec	0 (0.0%)	152 (79.6%)	<0.001

Table 3: Treatment Effectiveness Stratified by Age and Prostate Size

Variable	Patients (n)	Effectiveness (%)
Age Group (years)		
- 40–50	85	72 (84.7%)
- 51–60	106	80 (75.5%)
Prostate Size (grams)		
- 30–40	82	66 (80.5%)
- >40	109	86 (78.9%)

Table 4: Symptom Improvement Based on IPSS

Variable	Baseline IPSS	4 Weeks IPSS	p-value
Mean IPSS Score	19.6 ± 4.3	12.2 ± 3.1	<0.001
Patients with ≥50% IPSS Reduction	0 (0.0%)	148 (77.5%)	<0.001

Table 5: Adverse Events

Adverse Event	n (%)
Dizziness	10 (5.2%)
Nasal Congestion	7 (3.7%)
Orthostatic Hypotension	4 (2.1%)
Total	21 (11.0%)

Discussion

This study evaluated the efficacy of silodosin in improving urinary flow rates and alleviating lower urinary tract symptoms (LUTS) in patients with median lobe projection of an enlarged prostate. The results demonstrate significant improvements in maximum urinary flow rate (Qmax), International Prostate Symptom Score (IPSS), and overall symptom relief with minimal adverse effects. These findings align with global studies and provide valuable insights into the management of benign prostatic hyperplasia (BPH) in the Pakistani population.

The mean baseline Qmax in our study was 7.8 ± 1.2 mL/sec, which increased to 16.3 ± 2.4 mL/sec after four weeks of silodosin therapy ($p<0.001$). A similar improvement was reported by Chapple et al., where Qmax increased by 8.9 mL/sec in patients treated with silodosin (9). Kobayashi et al. also observed a mean Qmax improvement of 8.1 mL/sec, highlighting silodosin's efficacy in enhancing urinary flow rates (10). Bajwa and Kaur confirmed similar findings, emphasizing silodosin's significant role in improving uroflowmetry results in patients with LUTS secondary to BPH (16).

The proportion of patients achieving a Qmax ≥15 mL/sec in our study was 79.6%, consistent with findings by Nickel et al., who reported a 78% success rate in a similar cohort (11). These results emphasize the consistent performance of silodosin across diverse populations, including those with median lobe projection. Sinha et al. further highlighted the ability of silodosin to enhance urinary flow and reduce residual urine in challenging patient subgroups, including those with significant obstructive anatomy (18).

The mean baseline IPSS in our study was 19.6 ± 4.3, which reduced to 12.2 ± 3.1 after treatment, representing a 37.8% improvement ($p<0.001$). In a study by Saito et al., silodosin reduced IPSS by 40%, confirming its effectiveness in alleviating LUTS (12). Similarly, McVary et al. reported a mean IPSS reduction of 38% in patients treated with silodosin, further supporting our findings (13).

Silodosin was effective across different age groups and prostate sizes. In our study, the efficacy was slightly higher in younger patients (84.7% in the 40–50 years age group) compared to older patients (75.5% in the 51–60 years age group). This trend was also observed by Roehrborn et al., who reported better treatment responses in younger patients due to fewer comorbidities and shorter symptom duration (14). Regarding prostate size, our study found similar efficacy in patients with smaller prostates (80.5% for 30–40 grams) and larger prostates (>40 grams, 78.9%). Chapple et al. also reported consistent efficacy of silodosin across different prostate volumes, with success rates exceeding 75% (9). Khan et al. similarly emphasized silodosin's reliability in managing LUTS irrespective of prostate size, making it suitable for diverse clinical scenarios (17).

The incidence of adverse events in our study was low, with dizziness (5.2%), nasal congestion (3.7%), and orthostatic hypotension (2.1%) being the most commonly reported. These findings are consistent with Kobayashi et al., who observed a 5% incidence of dizziness and a 3% incidence of nasal congestion in their study (10). Nickel et al. also reported minimal adverse effects, highlighting silodosin's favorable safety profile (11). Bajwa and Kaur reiterated that silodosin's high uroselectivity contributes to its minimal systemic side effects, making it safer for older patients with multiple comorbidities (16). Aziz et al. further highlighted the safety of silodosin in resource-limited settings, emphasizing its suitability for use in the Pakistani healthcare context (15).

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Our findings hold significant implications for the management of BPH in Pakistan, where delayed diagnosis and resource constraints often limit treatment options. By demonstrating the efficacy and safety of silodosin in a population with median lobe projection, this study provides evidence for its broader adoption in clinical practice. However, the slightly higher cost of silodosin compared to other alpha-blockers remains a limitation and warrants cost-effectiveness analyses in future studies.

Conclusion

Silodosin significantly improves urinary flow rates and alleviates LUTS in patients with median lobe projection of an enlarged prostate, with a favorable safety profile. These findings support its use as a first-line therapy in BPH management, particularly in resource-limited settings like Pakistan. Further research should explore long-term outcomes and cost-effectiveness to optimize its integration into local treatment protocols.

Declarations

Data Availability statement
All data generated or analyzed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department Concerned. (IRBEC-KDNIP-023/23)
onsent for publication
Approved
Funding
Not applicable

Conflict of interest

The authors declared absence of conflict of interest.

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