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Original Research Paper

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SAFETY AND TOLERABILITY OF ALPHA-BLOCKERS IN MEDICAL EXPULSIVE THERAPY FOR DISTAL URETERIC CALCULI: A PROSPECTIVE COMPARATIVE STUDY

Dr.Anupam Nanda* Associate Professor, Department of Surgery Dr.RKGMC, Hamirpur *Corresponding Author

Dr.Kavita Nanda Associate Professor, Department of Anatomy, Dr.RKGMC, Hamirpur

ABSTRACT

Background: Medical expulsive therapy (MET) using alpha-blockers is widely employed for distal ureteric calculi. While efficacy is well established, comparative safety data between tamsulosin and silodosin in the Indian population remain limited.**Objective:** To evaluate and compare the safety and tolerability of tamsulosin and silodosin in patients undergoing MET for distal ureteric calculi.**Methods:** A prospective, randomized, single-center study was conducted on 200 patients with distal ureteric calculi (4–10 mm). Patients received either tamsulosin (0.4 mg) or silodosin (8 mg) once daily for up to 28 days. Adverse drug events (ADEs) were recorded and analyzed.**Results:** Both groups demonstrated comparable safety profiles. Retrograde ejaculation occurred in 1% of patients in each group. Other adverse events such as dizziness, headache, and gastrointestinal symptoms were minimal and statistically insignificant. Only two patients discontinued treatment due to side effects.**Conclusion:** Tamsulosin and silodosin exhibit excellent safety and tolerability profiles with minimal adverse effects. Both drugs can be safely used as first-line agents in MET for distal ureteric calculi.

KEYWORDS : Medical expulsive therapy, tamsulosin, silodosin, ureteric calculi, safety, tolerability.

INTRODUCTION

The management of distal ureteric calculi (stones) has evolved with the growing use of medical expulsive therapy (MET), which utilizes alpha-adrenergic blockers to augment the rate of spontaneous stone passage and minimize intervention needs. Tamsulosin and silodosin are two widely used alpha blockers, favored for their selective affinity to ureteral adrenergic receptors, which induces smooth muscle relaxation, reduces intraureteric pressure, and facilitates calculus expulsion.

Despite their recognized efficacy, alpha-blockers are associated with adverse effects, most notably ejaculatory disturbances and, to a lesser extent, hypotension or dizziness. These side effects can influence patient adherence and therapeutic selection, but direct prospective data comparing the safety and tolerability of Tamsulosin and Silodosin in the Indian population remain scant. This study evaluates and compares the adverse event profiles of both drugs in patients undergoing MET for distal ureteric calculi.

Objectives

- To evaluate the overall safety and tolerability of Tamsulosin and Silodosin in patients treated for distal ureteric stones.
- To compare the incidence and type of adverse drug events (ADEs), with special focus on ejaculatory dysfunction and other significant complaints.

Materials and Methods

Study Design and Setting

The analysis draws on a prospective, randomized, single-center clinical study performed at Dr. Radhakrishnan Government Medical College, Hamirpur, Himachal Pradesh, between August 2020 and December 2021.

Study Population

Eligibility Criteria:

- Inclusion: Adults (≥18 years), single distal ureteric calculus (4–10 mm), normal renal function, no prior ureteral interventions, written informed consent.
- Exclusion: Pregnancy, nursing, major renal or systemic comorbidities, intolerance to alpha-blockers, withdrawal, or non-compliance.

Interventions

200 patients, randomized evenly, received either Tamsulosin 0.4 mg or Silodosin 8 mg, once daily for up to 28 days or until stone passage. Concomitant supportive therapy (analgesics, antispasmodics) followed clinical protocols. All participants were advised to maintain adequate oral hydration and report adverse events at follow-up visits or whenever noted.

Data Collection and Follow-up

Patients were systematically assessed at baseline and weekly for up to four weeks. All adverse events were directly queried using a standardized proforma, with specific attention to:

- Abnormal ejaculation or other sexual side effects
- Symptoms of orthostatic hypotension (dizziness, syncope)
- Headache or gastrointestinal complaints
- Treatment discontinuation due to side effects

Statistical Methods

Descriptive statistics summarized adverse event frequencies and proportions within and between groups. Comparative analysis of event rates used the chi-square or Fisher's exact test. Statistical significance was considered at $p<0.05$.

Observations and Results

Patient Demographics

Among the 200 patients (121 male, 79 female; mean age 37.9 ± 14.6 years), 100 received tamsulosin and 100 received silodosin. Both groups were similar in baseline characteristics including stone size, site, and sex ratio.

Nature and Incidence of Adverse Events

Abnormal Ejaculation (retrograde ejaculation):

- Tamsulosin group: 1 patient (1%)
- Silodosin group: 1 patient (1%)
- No patient elected to stop treatment for this side effect.

Other Adverse Events:

- No significant difference was noted for headache, dizziness, gastrointestinal upset, or hypotension between groups.
- Two patients (1 from each group) discontinued study participation due to drug side effects, though specific symptoms (other than ejaculation disorders) were not recorded in the primary proforma.

No patient required hospitalization or additional medical intervention for drug-related complications

Tabulated Adverse Events:

Side Effect	Tamsulosin (N=100)	Silodosin (N=100)
Retrograde ejaculation	1	1

Treatment dropout (ADE)	1	1
Others (headache, dizziness)	Rare, no excess over control	Rare, no excess over control

Comparison with Literature

The observed incidence of sexual side effects (1% for both groups) was much lower than internationally reported rates (up to 10-23% for ejaculatory dysfunction, especially with Silodosin). Rates of other adverse effects remained minimal and did not impact overall treatment adherence.

DISCUSSION

This real-world, prospective study demonstrates an excellent overall safety and tolerability profile for both Tamsulosin and Silodosin in the Indian setting. The minimal incidence of abnormal ejaculation, dizziness, and other adverse events contributed to high treatment completion rates, aligning with the findings of Imparatore et al. and most other international studies.

Contrary to some prior reports (e.g., Dell'Atti et al., who noted rates of abnormal ejaculation exceeding 10% for Tamsulosin and 22% for Silodosin), the current study found virtually no difference in the frequency of side effects, likely reflecting the younger age demographic, proactive counseling, or population-based variables. Importantly, no patient was compelled to discontinue therapy strictly due to ejaculatory dysfunction, unlike certain Western cohorts.

It is worth noting, as a limitation, that detailed sub tabbing of other minor or transient side effects (especially postural or gastrointestinal complaints) was not performed, and that the relatively brief follow-up window may under recognize delayed events. Future work could benefit from even more granular patient-reported outcomes.

CONCLUSION

Both Tamsulosin and Silodosin are highly safe and well-tolerated for MET in distal ureteric calculi, with very low and comparable adverse event rates.Abnormal ejaculation occurred infrequently, at only 1% in each group, and was not a significant cause for dropout or morbidity.Adverse profiles should not be a major barrier to agent selection in routine clinical practice.

Summary

Alpha-blockers Tamsulosin and Silodosin demonstrate exemplary safety in this large, single-center cohort.The main recognized side effect, abnormal ejaculation, was rare, and both drugs were otherwise well tolerated. Both should be considered effective and safe first-line options for medical expulsive therapy of distal ureteric calculi.

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