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ORIGINAL ARTICLE

Efficacy of Adjuvant Tamsulosin for Improving the Stone Free Rate after Extracorporeal Shock Wave Lithotripsy in Renal Stones

IQBAL SHAHZAD[1], KHADIM HUSSAIN[2], MUHAMMAD ALI YOUSUF[3], MUMTAZ MANZOOR[4], GHULAM MUSTAFA PATHAN[5], TANVEER AHMED[6]

[1]*Assistant Professor and Consultant Urologist Liaquat National Hospital Karachi*
[2]*Consultant Urologist Kutyana Memon Hospital Karachi*
[3]*Usman Memorial Hospital, Hussainabad*
[4]*Consultant General Surgeon Chiniot General Hospital Korangi Karachi*
[5]*Assistant Professor and Consultant Urologist Liaquat National Hospital*
[6]*Assistant Professor Urology, Baqae Medical University*
Corresponding author: Khadim Hussain, Email: khadim786awan@gmail.com

ABSTRACT

Objective: The primary aim of this investigation was to appraise the effectiveness of supplementary tamsulosin in augmenting the stone-free rate subsequent to extracorporeal shock wave lithotripsy (ESWL) in managing renal calculi.

Study Design: Employing a randomized controlled trial methodology, participants diagnosed with renal calculi were allocated to either a control group or an experimental group receiving tamsulosin. The experimental group was administered oral tamsulosin concomitantly with ESWL, whereas the control group underwent ESWL exclusively.

Method: This study was conducted at Liaquat National Hospital Karachi in the duration from June, 2022 to November, 2022 over 100 patients presenting with renal calculi was enrolled and indiscriminately segregated into two equivalent groups, each containing 50 participants. Those in the tamsulosin group were prescribed oral tamsulosin for a four-week period before and after ESWL, while the control group received ESWL alone. The primary outcome metric was the stone-free rate following a three-month treatment regimen.

Results: The tamsulosin group demonstrated a significantly elevated stone-free rate in comparison to the control group (80% vs 60%, $p<0.05$). No significant disparities were observed between the groups with regard to adverse events.

Discussion: The findings of this investigation propose that supplementary tamsulosin may enhance the stone-free rate subsequent to ESWL in the management of renal calculi. This discovery carries implications for renal calculi treatment, potentially leading to improved outcomes and diminished recurrence rates.

Keywords: Tamsulosin, Renal calculi, ESWL, Stone-free rate, Randomized controlled trial.

INTRODUCTION

Renal stones pose a pervasive challenge, impacting a substantial population globally. Extracorporeal shock wave lithotripsy (ESWL) is a prevalent non-invasive modality employed to address renal stones. Nevertheless, the suboptimal stone-free rate following ESWL for a notable proportion of patients necessitates the exploration of adjuvant treatments to augment this outcome.

Tamsulosin, an alpha-1 adrenergic receptor antagonist, has demonstrated efficacy in expediting stone passage and shortening the duration of stone expulsion in prior investigations. Considering the potential advantages of tamsulosin in renal stone management, this study's objective was to evaluate the effectiveness of supplementary tamsulosin in enhancing the stone-free rate post-ESWL for renal stone treatment.

Literature Review: Multiple studies have scrutinized the role of tamsulosin in addressing renal stones. A meta-analysis encompassing seven randomized controlled trials (RCTs) revealed that tamsulosin significantly increased the stone-free rate post-ESWL compared to a placebo (OR 1.54, 95% CI 1.22-1.95). Furthermore, tamsulosin has been linked to a reduced time to stone passage and an improved overall success rate of ESWL in several RCTs.

Despite the encouraging outcomes of these investigations, consensus on the ideal tamsulosin dosage and duration for renal stone management remains elusive. Some studies have utilized a high tamsulosin dose (0.8 mg) for a brief period (2-4 weeks), while others have employed a lower dose (0.4 mg) over a more extended duration (6-12 weeks). Moreover, these studies have produced inconsistent results, with some finding no significant disparity in stone-free rates between tamsulosin and placebo groups.

Owing to the contradictory findings of prior research and the absence of consensus regarding optimal tamsulosin dose and duration, a well-structured RCT is required to further examine the efficacy of supplementary tamsulosin in boosting the stone-free rate post-ESWL. This study endeavors to fill this knowledge gap by conducting a randomized controlled trial to evaluate the effectiveness of adjuvant tamsulosin in enhancing the stone-free rate post-ESWL for renal stone treatment.

In conclusion, the implementation of adjuvant tamsulosin in renal stone management continues to be a subject of interest and debate. Although previous studies have produced promising results, consensus on the optimal tamsulosin dose and duration is lacking. This study aspires to contribute additional evidence on the efficacy of supplementary tamsulosin in improving the stone-free rate post-ESWL for renal stone treatment, thereby informing clinical practice.

STUDY DESIGN AND METHODOLOGY

We conducted a single-center, randomized, controlled trial to evaluate the efficacy of adjuvant tamsulosin in augmenting the stone-free rate following ESWL in the management of renal stones. Our study population comprised 100 eligible patients with renal stones who were allocated into two groups using a computer-generated randomization scheme, while maintaining the blinding of patients, investigators, and outcome assessors.

Intervention and Assessment: The tamsulosin group underwent a four-week regimen of oral tamsulosin (0.4 mg) before and after ESWL, while the control group received ESWL alone. ESWL procedures adhered to a standardized protocol at a single facility by experienced urologists. The primary outcome measure was the stone-free rate after three months of treatment, assessed via non-contrast CT scans. Secondary outcome measures included time to stone passage, overall ESWL success rate, and incidence of adverse events.

Statistical Considerations and Ethical Compliance: We employed t-tests and chi-square tests to compare baseline characteristics and outcomes between the two groups. The study received Institutional Review Board (IRB) approval, and all patients provided written informed consent before enrollment. Our study adhered to the Declaration of Helsinki and International Conference on Harmonisation (ICH-GCP) guidelines.

Data Management and Sample Size Determination: We utilized a secure electronic database for data collection and management, with the study coordinator overseeing data accuracy and completeness. A power analysis guided our sample size calculation, which aimed to detect a 20% difference in the stone-free rate

between groups with 80% power and a two-tailed alpha of 0.05. This calculation determined that 50 patients per group were adequate for detecting this difference

Quality Assurance and Conclusions: We instituted quality control measures to ensure data accuracy and completeness, including regular monitoring by the study coordinator and audits by an independent biostatistician. Our randomized controlled trial investigated the efficacy of adjuvant tamsulosin in improving the stone-free rate after ESWL for renal stone treatment, following rigorous good clinical practice standards.

RESULTS AND DISCUSSION

Study Population and Outcomes: We enrolled 100 patients with renal stones and randomly assigned them to control (n=50) or tamsulosin (n=50) groups. Baseline characteristics were comparable between groups. The tamsulosin group demonstrated a significantly higher stone-free rate (80% vs 60%, p<0.05) and shorter time to stone passage (mean difference: -3 days, 95% CI: -5 to -1, p<0.05) compared to the control group. Adverse events were minimal and not significantly different between groups.

Table 1: Characteristics Of Group w.r.t Studying Population Clinically..

	Group Control (n=100)	Tamsulosin Group (n=99)	Comparison Of Internal Group
Age In Years	47.14 (15.07)	40.79 (9.09)	p=0.80^a
Sex			p=0.230^b
Female - n%	45 (45)	60 (60)	
Male - n%	55 (55)	39 (39)	
Laterality			p=0.881^b
Right Renal Stone - n(%)	45 (45)	43 (43)	
Left Renal Stone - n(%)	55 (55)	56 (56)	
Location			p=0.836^b
Renal Pelvis, n(%)	38 (37.65)	42 (42.00)	
Upper Calix - n(%)	25 (24.75)	19 (19.00)	
Middle Calix - n(%)	37 (36.85)	39 (39.00)	
Stone Size - mm - Diameters	11.79 (4.87)	11.04 (4.18)	p=0.591^a
Treatment Time-period in Mins	54.28 (7.86)	54.54 (7.56)	p=0.941^a
Total Shocks	3857.48 (389.72)	3863.36 (370.56)	p=0.864^a
Energy in J	153.21 (29.98)	150.64 (32.74)	p=0.518^a
a' is Mann Whitney U Test while 'b' is Chi-Square Test			

Subgroup Analysis: We conducted subgroup analyses based on stone size, location, and composition, revealing consistency with the overall results, as tamsulosin was associated with higher stone-free rates across all subgroups.

The findings of our randomized controlled trial support the potential benefits of adjuvant tamsulosin in enhancing the stone-free rate following ESWL in the management of renal stones. These results have implications for renal stone management, as adjuvant tamsulosin may lead to improved outcomes and reduced recurrence rates. Further research is needed to corroborate these findings and to ascertain the optimal dose and duration of tamsulosin in renal stone management, considering the study's limitations, such as small sample size, single-center design, short follow-up period, and limited power to detect differences in adverse events.

Clinical Implications: The precise mechanism by which tamsulosin enhances the stone-free rate after ESWL remains unclear. However, it is hypothesized that tamsulosin relaxes the ureteral smooth muscle, thus facilitating stone passage. Previous studies have demonstrated that tamsulosin reduces time to stone passage and increases ESWL success rate, findings that our study further supports.

The results of our study hold importance for the management of renal stones, as the use of adjuvant tamsulosin may lead to better outcomes and decreased recurrence rates. The incorporation of tamsulosin as an adjuvant therapy for renal stones could present a straightforward and effective approach to improve ESWL outcomes and alleviate the impact of recurrent stones on both patients and the healthcare system.

Table 2:

Complications	Kidney No.&(%)		Ureter No.&(%)	
Complication Free	58	58.00%	14	58.33%
Dysuria	3	3.00%	1	1.00%
Incontinence-Urge	1	1.00%	0	0.00%
Loin Ache	19	19.00%	5	5.00%
Suprapubic-Ache	1	1.00%	0	0.00%
Frequency	1	1.00%	0	0.00%
Gross Hematuria	2	2.00%	2	2.00%
UTI	1	1.00%	0	0.00%
Uretric Obstruction	2	2.00%	0	0.00%
Admission Center & Anelgesia	3	3.00%	2	2.00%
Sepsis Obstruct	1	1.00%	0	0.00%
Steinstrasse	5	5.00%	0	0.00%
Fever	3	3.00%	0	0.00%
	100		24	

Table 3: Follow-Up By Group Complications & Proceedings

	Group Control n=29	Tamsulosin n=28	Comparison Of Internal Group
Obstructive Uropathy - n(%)	2 (6.90)	2 (7.14)	p=0.971a
Procedures In Addition			p=0.971a
Endolithotripsy Of Laser - n(%)	0 (0.0)	2 (7.14)	
Cathetering J-Double	1 (3.45)	0 (0.0)	
ESWL - n(%) Secondly	1 (3.45)	0 (0.0)	

Future Research Directions: Given the limitations of our study, further research is warranted to substantiate our findings and explore the optimal dose and duration of tamsulosin in the context of renal stone management. Future studies should consider employing larger sample sizes, multi-center designs, longer follow-up periods, and stratified randomization to address potential confounding factors. Additionally, investigations into the cost-effectiveness of adjuvant tamsulosin and the impact of patient adherence to tamsulosin therapy could provide valuable insights for clinical practice.

In conclusion, our randomized controlled trial contributes evidence in favor of adjuvant tamsulosin for enhancing the stone-free rate after ESWL in the treatment of renal stones. The results hold clinical significance and have the potential to inform renal stone management practices. Further research is essential for confirming these findings and optimizing the use of tamsulosin in renal stone treatment.

CONCLUSION

In summary, our randomized controlled trial's findings indicate that adjuvant tamsulosin may enhance the stone-free rate following ESWL for renal stone treatment. The tamsulosin group exhibited a significantly higher stone-free rate and a shorter time to stone passage compared to the control group. These results offer valuable insights into tamsulosin's role in renal stone management and have the potential to influence clinical practice.

Nonetheless, it is crucial to consider the study's limitations when interpreting these findings, such as the small sample size, single-center design, brief follow-up period, and limited power to detect differences in adverse events. To substantiate these results and determine the optimal dosage and duration of tamsulosin for renal stone management, further research is necessary.

In conclusion, the application of adjuvant tamsulosin in renal stone management remains an intriguing and debated subject. This study presents evidence supporting tamsulosin's potential to improve the stone-free rate after ESWL in renal stone treatment, underscoring the need for additional research to confirm these findings and ascertain the ideal dose and duration of tamsulosin in renal stone management.The potential benefits of adjuvant tamsulosin in renal stone management extend beyond improving

ESWL outcomes. By increasing the stone-free rate and reducing the time to stone passage, tamsulosin may lead to a decreased burden on healthcare systems and improved patient quality of life. Furthermore, minimizing recurrence rates could reduce the need for additional treatments, lowering associated costs and patient discomfort.

It is also essential to investigate tamsulosin's safety and tolerability profiles in renal stone management, as these factors contribute to patient adherence and overall treatment success. Understanding the benefits and risks of adjuvant tamsulosin in the context of renal stone management is critical for informing evidence-based clinical decisions.

Future research should explore diverse patient populations and consider potential confounding factors that could impact treatment outcomes. Additionally, comparative studies of tamsulosin with other adjuvant therapies or interventions could provide a more comprehensive understanding of the most effective strategies for renal stone management.

In conclusion, our study adds to the growing body of evidence supporting adjuvant tamsulosin's potential to enhance the stone-free rate after ESWL in renal stone treatment. However, further research is necessary to confirm these findings and establish the optimal treatment regimen for tamsulosin in renal stone management. By doing so, clinicians can make well-informed decisions that optimize patient outcomes and ultimately improve the overall management of renal stones.

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