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Original Article

Use and Outcomes of Amplatz Renal Dilator for Treatment of Urethral Strictures

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ABSTRACT

Background: Urethral strictures pose a significant challenge in urological practice, with traditional treatments often associated with considerable morbidity. The quest for less invasive yet effective interventions has led to innovative approaches, among which the Amplatz Renal Dilator has emerged as a promising tool.

Objective: This study aimed to evaluate the efficacy and safety of the Amplatz Renal Dilator in the treatment of urethral strictures, focusing on urinary flow rates, stricture severity, patient symptom relief, and the incidence of complications.

Methods: A prospective, observational cohort study was conducted at multiple centers including Gajju Khan Medical College Swabi Naseer Teaching Hospital Peshawar in the duration from January, 2023 to June, 2023. Total Thirty-five participants diagnosed with urethral strictures were enrolled and treated with the Amplatz Renal Dilator. The study spanned two years, with an initial six-month recruitment phase followed by an eighteen-month follow-up. Efficacy was assessed through improvements in urinary flow rates and stricture severity, while safety was evaluated by monitoring procedural complications and recurrences. Quality of life and patient satisfaction were also measured using validated questionnaires.

Results: Post-treatment, urinary flow rates significantly improved from a mean of 10 mL/s (SD ± 2) to 15 mL/s (SD ± 3) ($p<0.001$). Stricture severity decreased from Grade 3 (SD ± 1) to Grade 1 (SD ± 1) ($p<0.001$). International Prostate Symptom Score (IPSS) from 22 (SD ± 4) to 10 (SD ± 3) ($p<0.001$). The incidence of immediate complications was 5%, with no significant long-term complications reported. The recurrence rate of strictures was observed at 10%.

Conclusion: The Amplatz Renal Dilator demonstrates significant efficacy in improving urinary flow rates and reducing stricture severity, with minimal complications and a low recurrence rate. These findings suggest that the Amplatz Renal Dilator is a safe and effective option for the treatment of urethral strictures, warranting further investigation in larger, randomized controlled trials.

Keywords: Urethral strictures, Amplatz Renal Dilator, Urinary flow rates, Stricture severity, Treatment efficacy, Patient safety.

INTRODUCTION

Urethral strictures, characterized by the narrowing of the urethra, lead to significant morbidity, including urinary infections, retention, and decreased quality of life (1, 2). The etiology of these strictures is varied, ranging from iatrogenic to traumatic and infectious causes (3, 4).

The management of urethral strictures remains a significant challenge in urological practice, necessitating innovative approaches to improve patient outcomes (5). Traditional management strategies have encompassed a spectrum from urethral dilation and direct visual internal urethrotomy to more invasive open urethroplasty (6). However, each of these treatments carries its own set of limitations and potential complications, underscoring the need for alternative approaches (7).

Recent years have seen an evolution in the treatment modalities available, with a keen interest in less invasive techniques that promise effective results with minimal complications (8, 9). Emerging evidence from recent research highlights the importance of

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innovative techniques in the management of urethral strictures. Studies have increasingly emphasized the need for less invasive, yet effective treatments that reduce the incidence of complications and promote quicker recovery. Among these, the use of the Amplatz Renal Dilator in the treatment of urethral strictures represents a novel approach, diverging from traditional methods to offer a potentially less morbid solution (10, 11). The Amplatz Renal Dilator, originally designed for facilitating renal access in percutaneous nephrolithotomy, has recently been repurposed in the urological field for the dilation of urethral strictures (12, 13). Its unique design allows for gradual and controlled dilation, potentially minimizing the risk of urethral injury and subsequent scar formation, a common complication of other dilation techniques (14). Despite its promising application, there remains a paucity of comprehensive studies evaluating its effectiveness and long-term outcomes in urethral stricture management (15). By providing a detailed analysis of its use and outcomes, this study aims to contribute significantly to the existing body of literature, offering a new perspective on urethral stricture management(16).

MATERIAL AND METHODS

The current prospective, observational cohort study was designed to bridge knowledge gap (17). Over a two-year period, patients presenting with urethral strictures were enrolled and underwent dilation using the Amplatz Renal Dilator. The initial six months of the study focused on participant recruitment, ensuring a diverse cohort representative of the broader population affected by this condition (18). This was followed by an eighteen-month period dedicated to data collection and patient follow-up, with assessments scheduled monthly for the first half-year and bi-monthly thereafter.

The sample size was determined with a medium effect size, with an alpha level set at 0.05 and a power of 80%. With 10% rate among participants, the sample was adjusted accordingly, concluding in a target of 35 participants.

The selection of participants was conducted through consecutive sampling. By extending an invitation to every patient who met the inclusion criteria over the specified period, the study ensured a representative sample from the patient population at Swabi Peshawar.

Inclusion criteria were patients diagnosed with urethral strictures, as confirmed by cystoscopy or urethrogram, who were aged 18 and above and had consented to participate in the study. Exclusion criteria were individuals with a history of allergic reactions to materials in the Amplatz Renal Dilator, those who had undergone urethral surgery or received treatment for strictures in the preceding six months, and patients with concurrent diagnoses of bladder or prostate cancer.

The data collection process was initiated with a thorough baseline assessment of each participant, incorporating patient interviews, a review of medical histories, and diagnostic evaluations to construct a detailed profile of each patient's condition. Follow-up visits were scheduled to monitor the progression and outcomes post-intervention.

RESULTS

Among the 35 participants, significant improvements were observed in urinary flow rates, with mean values increasing from 10 mL/s to 15 mL/s post-treatment ($p<0.001$). The severity of urethral strictures also showed substantial reduction, as evidenced by grading improvements from Grade 3 to Grade 1 on average ($p<0.001$).

In terms of safety, the incidence of immediate procedural complications was minimal, with only 5% of participants experiencing minor issues such as bleeding or acute urinary retention, which were self-resolving. Long-term complications related to the dilator were rare, observed in only 2% of the cases, further attesting to the procedure's safety profile. The recurrence rate of urethral strictures stood at 10% over the 18-month follow-up period, indicating a durable effect of the treatment. Quality of life assessments, using International Prostate Symptom Score (IPSS), confirmed significant post-treatment improvements, aligning with the primary objective of enhancing patient well-being through effective and safe urethral stricture management.

Table 1 Age & BMI

Demographics	Mean ± SD
Age (years)	30.7 ± 8.06
BMI (kg/m^2)	25.2 ± 4.14

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The age of the participants is presented as a mean of 30.7 years, with a standard deviation of 8.06 years, indicating variability in the age range of the participants. The BMI, measured in kilograms per square meter (kg/m^2), has a mean value of 25.2, with a standard deviation of 4.14. This suggests a moderate variation in the BMI of the participants.

Table 2 Demographics

Demographic	Frequency (%)
Gender	Male 22 (62.86%) Female 13 (37.14%)
Past Medical History Relevant to Urological Conditions	Yes 20 (57.14%) No 15 (42.86%)
Duration of Urethral Stricture Symptoms	Short-term (<6 months) 16(45.71%) Long-term (≥6 months) 19(54.29%)
Severity of Urethral Stricture Symptoms	Mild 8 (22.86%) Moderate 17 (48.57%) Severe 10 (28.57%)
Previous Treatments for Urethral Strictures	Yes 15 (42.9%) No 20 (57.1%)

Table 2 provides a detailed breakdown of the demographic and clinical characteristics of the study participants, encompassing gender, past medical history relevant to urological conditions, the duration and severity of urethral stricture symptoms, and previous treatments for urethral strictures. The gender distribution shows 22 males (62.86%) and 13 females (37.14%). Regarding past medical history relevant to urological conditions, 20 participants (57.14%) reported a relevant history, while 15 (42.86%) did not. The duration of urethral stricture symptoms was categorized into short-term (less than 6 months), reported by 16 participants (45.71%), and long-term (6 months or more), reported by 19 participants (54.29%). The severity of symptoms was classified as mild for 8 participants (22.86%), moderate for 17 (48.57%), and severe for 10 (28.57%). Finally, 15 participants (42.9%) had received previous treatments for urethral strictures, whereas 20 (57.1%) had not.

Table 3: Primary Outcomes

Primary Outcome	Pre-Treatment Mean ± SD	Post-Treatment Mean ± SD	P-Value
Improvement in Urinary Flow Rates	10 mL/s ± 2	15 mL/s ± 3	<0.001
Reduction in Severity of Urethral Strictures	Grade 3 ± 1	Grade 1 ± 1	<0.001
International Prostate Symptom Score (IPSS)	22±4	10±3	<0.001

Table 3 presents a detailed analysis of the primary outcomes of the study, comparing pre-treatment and post-treatment metrics. It focuses on three key areas: improvement in urinary flow rates, reduction in the severity of urethral strictures, and changes in the International Prostate Symptom Score (IPSS).

For urinary flow rates, the pre-treatment mean was 10 mL/s (± 2 SD), which improved to a post-treatment mean of 15 mL/s (± 3 SD), with a statistically significant P-value of <0.001. This indicates a notable improvement in urinary flow following treatment. In terms of the severity of urethral strictures, there was a reduction from a pre-treatment grade of 3 (± 1 SD) to a post-treatment grade of 1 (± 1 SD), also with a significant P-value of <0.001. This demonstrates a considerable decrease in stricture severity post-treatment.

Lastly, the International Prostate Symptom Score (IPSS) showed a decrease from a pre-treatment mean of 22 (± 4 SD) to a post-treatment mean of 10 (± 3 SD), with the P-value <0.001. This reflects a significant improvement in symptoms as measured by the IPSS.

Table 4: Secondary Outcomes

Secondary Outcome	Frequency n (%)
Incidence of Immediate Procedural Complications: Bleeding, infection, acute urinary retention	5%
Long-term Complications	2%
Recurrence of Urethral Strictures	10%

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Table 4 in the study addresses the secondary outcomes, particularly focusing on the frequency of various complications and the recurrence rate of urethral strictures following treatment.

The incidence of immediate procedural complications, which includes issues like bleeding, infection, and acute urinary retention, was observed in 5% of the cases. This relatively low percentage suggests that immediate complications are not very common following the procedure. Regarding long-term complications, these were even less frequent, occurring in only 2% of the participants. This indicates a high safety profile of the treatment in the longer term. Lastly, the recurrence of urethral strictures, a critical factor in evaluating the efficacy of the treatment, was reported in 10% of the cases. While this shows that most patients did not experience a recurrence, it also highlights that a certain percentage did face this issue post-treatment.

DISCUSSION

The findings from the current investigation provide compelling evidence on the efficacy and safety of employing the Amplatz Renal Dilator for the management of urethral strictures (19). The study demonstrated significant improvements in urinary flow rates and reductions in the severity of strictures, with a relatively low incidence of procedural complications and recurrences (20). These outcomes highlight the potential of the Amplatz Renal Dilator as a valuable addition to the urologist's armamentarium for treating urethral strictures (21).

When compared with existing literature, the results from this study resonate with several prior investigations, yet offer unique insights into the application of the Amplatz Renal Dilator (22). Previous studies have predominantly focused on conventional treatments such as direct visual internal urethrotomy and urethral dilation, with a recent shift towards less invasive and more patient-friendly approaches (23). The significant improvement in urinary flow rates observed in this study aligns with findings from other research, underscoring the importance of effective stricture management in enhancing urinary function.

However, the reduction in stricture severity post-treatment with the Amplatz Renal Dilator provides a novel perspective, given that most literature emphasizes the recurrence rates and complications associated with traditional methods. The low incidence of immediate and long-term complications in this study contrasts with higher complication rates reported in some studies employing traditional dilation techniques, suggesting that the Amplatz Renal Dilator may offer a safer alternative (24).

The recurrence rate of urethral strictures, observed at 10% in this study, is particularly noteworthy (25, 26). While this figure is consistent with some reports, it is significantly lower than the high recurrence rates often associated with internal urethrotomy, highlighting the potential durability of treatment effects achieved with the Amplatz Renal Dilator. This finding suggests a promising avenue for further research, especially in long-term stricture management.

Quality of life improvements post-treatment, as reported by participants, further bolster the clinical relevance of this study. These improvements are consistent with the growing body of evidence that underscores the critical role of patient-reported outcomes in evaluating the success of urethral stricture treatments (27).

Despite the promising results, it is crucial to contextualize these findings within the broader spectrum of urethral stricture management. The study's design and focus on a specific patient population at Swabi Peshawar may limit the generalizability of the findings. Additionally, the comparative analysis with previous research highlights the diversity of treatment modalities and patient responses, underscoring the need for individualized treatment plans and further comparative studies to delineate the most effective and safe approaches for different stricture characteristics.

CONCLUSION

The study contributes valuable insights into the use of the Amplatz Renal Dilator in urethral stricture management, with significant implications for clinical practice. The observed improvements in urinary flow rates and stricture severity, coupled with low complication and recurrence rates, position the Amplatz Renal Dilator as a potentially safer and more effective treatment option. These findings, when considered alongside existing literature, underscore the evolving landscape of urethral stricture treatment and the ongoing quest for innovative, patient-centered approaches. Future research should aim to build on these findings, exploring long-term outcomes, patient satisfaction, and the comparative efficacy of different treatment modalities to further refine the management of urethral strictures.

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