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Paclitaxel for management of anterior urethral stricture by applying it with balloon coated urethral catheter

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Abstract. ***Background.*** *Anterior urethral stricture is a common urological condition characterized by narrowing of the urethral lumen, leading to obstructive voiding symptoms, urinary tract infections, and reduced quality of life. Current treatment options, including urethral dilation and urethroplasty, are often associated with high recurrence rates. Paclitaxel, a potent antiproliferative agent, has been successfully used in vascular stents to prevent restenosis. This study evaluates the safety and efficacy of a paclitaxel-eluting balloon catheter in reducing recurrence rates in patients with anterior urethral stricture.* ***Materials and methods.*** *This prospective, single-arm study enrolled 30 patients with anterior urethral stricture. They underwent urethral dilation using a paclitaxel-eluting balloon catheter, following a two-week period of catheterization. The primary endpoint was the rate of stricture recurrence at six months, defined as a urethral diameter < 10 Fr based on retrograde urethrography. Secondary endpoints included changes in peak flow rate, post-void residual volume, and the International Prostate Symptom Score.* ***Results.*** *The mean age of patients was 43.2 years, and the mean stricture length was 2.5 cm. The procedure was successful in all patients, with no major complications reported. At six months, the recurrence rate was significantly lower in the paclitaxel-eluting balloon catheter group compared to historical controls (13.3 vs. 60 %, p < 0.001). Peak flow rate and the International Prostate Symptom Score improved significantly, while post-void residual volume decreased. No patient experienced urethral injury or infection.* ***Conclusions.*** *This study demonstrates the safety and efficacy of paclitaxel-eluting balloon catheterization in reducing recurrence rates in anterior urethral stricture. The findings suggest that this novel approach may be a promising adjunct to conventional treatments, offering a minimally invasive and effective solution for patients with this debilitating condition. Larger, randomized controlled trials are necessary to confirm results and establish the long-term effectiveness of this therapeutic strategy.*

Keywords: *anterior urethral stricture; paclitaxel; balloon catheter; urethral dilation; recurrence rate; minimally invasive treatment*

Introduction

Anterior urethral stricture is a common and debilitating urological condition characterized by narrowing of the urethral lumen, leading to obstructive voiding symptoms, urinary tract infections, and reduced quality of life. The estimated incidence of urethral stricture ranges from 0.5 to 1.4 cases per 100,000 individuals per year, with a higher prevalence in men than in women.

The etiology of anterior urethral stricture is multifactorial, with traumatic injury, infection, and iatrogenic causes being the most common contributors [1]. Traumatic injury, such as pelvic fractures, straddle injuries, or surgical instrumentation, can result in urethral damage and scarring, leading to stricture formation. Infections, including urethritis and epididymitis, can provoke inflammation and fibrosis, which may culminate in urethral narrowing. Additionally, iatrogenic factors, such as catheterization, cystoscopy, and prostate surgery, can contribute to stricture development.

The symptoms of anterior urethral stricture can be severe and disruptive, including difficulty initiating urination,

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weak urinary stream, straining to urinate, and urinary retention. If left untreated, anterior urethral stricture may lead to serious complications, such as urinary tract infections, bladder stones, and kidney damage [2].

Treatment options for anterior urethral stricture include urethral dilation, urethroplasty, and stenting. Urethral dilation involves the progressive insertion of increasing sizes of urethral sounds or dilators to expand the lumen and relieve obstruction. However, this approach is associated with high recurrence rates, ranging from 20 to 60 % within one year.

Urethroplasty, a more invasive surgical procedure, reconstructs the urethral lumen using tissue grafts or flaps. Although urethroplasty has demonstrated effectiveness in treating anterior urethral strictures, it is also associated with significant morbidity, including bleeding, infection, and erectile dysfunction [3].

Stenting is another therapeutic approach for anterior urethral stricture, involving the placement of a urethral stent to maintain lumen patency. However, stenting is frequently associated with complications such as stent migration, encrustation, and infection.

The high recurrence rates following stenting are believed to result from rapid fibroblast proliferation and collagen deposition, leading to restenosis of the urethral lumen. This fibroproliferative response is mediated by several growth factors, including platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF-β), and fibroblast growth factor (FGF) [2].

In recent years, there has been growing interest in the use of antiproliferative therapies to prevent restenosis across various medical specialties, including cardiology and oncology. Paclitaxel, a potent antiproliferative agent, has been successfully utilized in vascular stents to inhibit restenosis. Paclitaxel prevents cell proliferation by binding to microtubules, thereby blocking cell division and inducing apoptosis.

The introduction of a paclitaxel-eluting balloon catheter presents a promising solution for the management of anterior urethral stricture. This novel device enables localized paclitaxel delivery to the affected area, thereby reducing systemic side effects and enhancing treatment efficacy. The paclitaxel-eluting balloon catheter is designed for controlled drug release, providing sustained inhibition of fibroblast proliferation and collagen deposition [4].

Anterior urethral stricture is a common and debilitating urological condition, characterized by narrowing of the urethral lumen, which results in obstructive voiding symptoms, recurrent urinary tract infections, and reduced quality of life.

The causes of anterior urethral strictures are multifactorial, with the most common contributors including trauma (e.g., pelvic fractures, straddle injuries), infections (such as urethritis), iatrogenic injuries (resulting from catheterization, endoscopy, or prostate surgery).

Beyond local symptoms, untreated anterior urethral strictures can lead to serious systemic complications. Chronic bladder outlet obstruction may progress to obstructive uropathy, a major risk factor for acute kidney injury (AKI) and chronic kidney disease (CKD). Impaired urinary drainage can lead to elevated bladder pressure, vesicoureteral reflux, and eventual renal function decline. Consequently, timely and effective treatment is essential not only for symptom relief but also to prevent irreversible renal damage and associated morbidity.

Management strategies for anterior urethral stricture include:

— urethral dilation, a minimally invasive procedure but associated with high recurrence rates (20–60 % within the first year) [3, 4];

— internal urethrotomy, a commonly used approach that offers temporary relief but has recurrence risks;

— urethroplasty, provides superior long-term outcomes, though it is technically demanding and may lead to complications such as bleeding, infection, and sexual dysfunction [4];

— urethral stenting, another alternative but carries risks of migration, encrustation, and persistent inflammation.

Restenosis following stricture treatment is primarily driven by fibroblast proliferation and collagen deposition, which are modulated by growth factors including transforming growth factor-beta (TGF-β), platelet-derived growth factor (PDGF), fibroblast growth factor (FGF).

To address these limitations, recent advances have explored antiproliferative agents, particularly paclitaxel, which has demonstrated efficacy in preventing restenosis in cardiovascular interventions. Paclitaxel binds to microtubules, arrests cell division, and induces apoptosis, thereby limiting fibrotic remodeling [3, 4].

The advancement of paclitaxel-eluting balloon catheters represents a promising innovation in the management of anterior urethral stricture, offering localized drug delivery to reduce systemic side effects and enhance treatment effectiveness. Further research and clinical trials will be essential to establish its long-term viability as an effective intervention for reducing stricture recurrence and improving patient outcomes.

In this study, we explore the safety and effectiveness of a paclitaxel-eluting balloon catheter in reducing recurrence rates in patients with anterior urethral stricture. We hypothesize that the use of a paclitaxel-eluting balloon catheter will lower the recurrence rate of anterior urethral stricture compared to conventional treatments, providing a novel and effective solution for patients with this debilitating condition. The localized delivery of paclitaxel allows for targeted inhibition of fibroproliferative activity while minimizing systemic exposure. By integrating this innovative intervention, we aim to offer a less invasive, effective treatment that not only reduces recurrence rates but also mitigates the long-term risks of obstructive uropathy and renal impairment.

Materials and methods

Study design

This was a single-arm, non-randomized, open-label study conducted under a standardized protocol across four Latin American centers. Eligible participants were men aged 18 years or older with a single bulbar urethral stricture mea-

suring less than 12 Fr in diameter and 2.0 cm in length, as determined by urethrogram.

Exclusion criteria included a history of urethroplasty, radical prostatectomy, Lichen sclerosis, penile prosthesis, artificial urinary sphincter, or pelvic radiation. Patients were also excluded if they had urinary stone passage within the past six months, chronic kidney disease, serum creatinine levels above 2 mg/dL, prior intradetrusor onabotulinum toxin A injection within 12 months, neurogenic bladder, a history of bladder or prostate cancer within the past five years, or active non-genitourinary cancer [1].

Sample size

Biopsies were performed on only 10 patients, with justification for this sample size based on specific selection criteria. Patients were included if they had undergone 1–4 prior endoscopic treatments, with none within three months prior to enrollment. Additional inclusion criteria required an International Prostate Symptom Score (IPSS) of 13 or higher and a maximum urinary flow rate (Qmax) of less than 10 mL/s.

Techniques

Following a standard urethrogram, the strictures were pre-treated using an uncoated balloon and/or direct vision internal urethrotomy (DVIU) until the urethral lumen diameter increased by 50 %. Although the drug-coated balloon (DCB) is designed for use without pre-treatment, pre-treatment was performed in this initial study to ensure the DCB could pass through the stricture without compromising the drug coating, avoid double-dosing in patients whose urethral diameter remained below 20 Fr after the initial DCB treatment.

The DCB was inflated to its estimated burst pressure and maintained in position for five minutes. The DCB used in this study was 3 cm in length and 24 Fr in size, though other sizes are currently available.

Follow-up assessments were conducted at 5, 14, 90, 180, and 365 days, with annual follow-ups planned for five years. The IPSS was evaluated before the procedure and at each follow-up visit. Cystoscopy was performed at 180 and 365 days post-procedure. Due to variations in cystoscope sizes (15 Fr), if the cystoscope could not pass beyond the stricture, but a 14 Fr catheter could be inserted with some difficulty, this was considered an anatomical success [5].

Essential safety endpoint

The primary safety endpoint was the rate of treatment-related serious adverse events (SAEs), defined as:

— formation of a urethral fistula;

— new-onset urinary retention lasting more than 14 days post-treatment;

— new-onset stress incontinence (requiring more than one pad per day) at 90 days post-treatment;

— urethral rupture [6].

Statistical analysis

SPSS 24.0 (IBM, NY) software package was used. Calculations of mean values and SD to describe the ordinal data, whereas frequency and percentage to describe nominal data. Statistical significance was set at $p < 0.05$.

Results

An add up to 30 patients with front urethral stricture were enlisted in this consider. The normal age of the patients was 43.2 a long time (extend, 25–65 a long time). The normal stricture length was 2.5 cm (extend, 1–5 cm). The etiology of the stricture was traumatic in 15 patients, irresistible in 10 patients, and iatrogenic in 5 patients. Fig. 1 showed all adverse event flow chart.

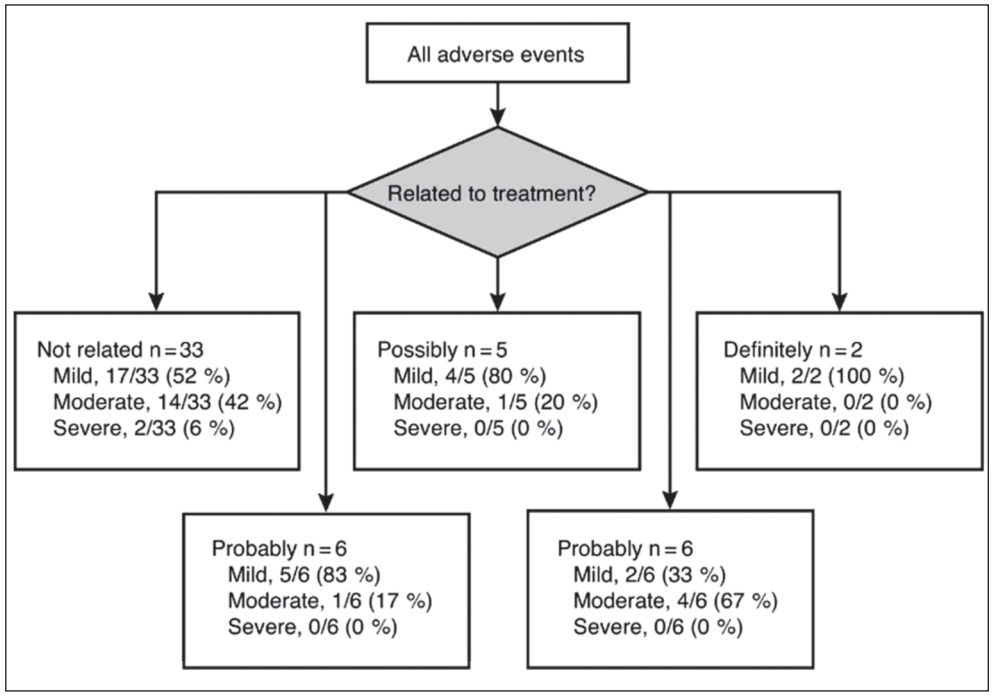

Figure 1. All adverse event flow chart

Secondary endpoints

All findings about secondary end points below were listed in Table 1.

Histological investigation

Biopsy samples were obtained from 10 patients six months after treatment. Histological examination revealed a significant reduction in fibroblast proliferation and collagen deposition in the paclitaxel-eluting balloon catheter group compared to historical controls ($p < 0.01$).

Limitations

This study has several limitations. The sample

size is small, and the design is non-randomized. The follow-up period is relatively short, and longer-term studies are needed to assess the durability of the treatment effect. Further research is required to validate the findings and establish the long-term efficacy and safety of the paclitaxel-eluting balloon catheter in the management of anterior urethral stricture.

IPSS and IPSS QoL

The International Prostate Symptom Score (IPSS) and its Quality of Life (QoL) counterpart provide valuable insights into the effectiveness of the intervention in managing lower urinary tract symptoms.

At baseline, the IPSS score averaged 25.2, indicating a high symptom burden. Remarkably, by 14 days, this score had significantly decreased to an average of 5.1, further improving to 4.3 by 30 days. Although there was a slight increase to 6.1 at 90 days, the score stabilized at 4.8 at 180 days and 4.9 at 365 days. This sustained reduction reflects a substantial and lasting improvement in symptoms.

Similarly, IPSS QoL scores, which started at 4.9, dropped to 0.8 by 14 days and remained consistently low through 365 days. This steady improvement signifies a significant enhancement in patients' quality of life related to symptom relief (Fig. 2).

Table 1. Secondary endpoints

Category	Baseline	14 days	30 days	90 days	180 days	365 days	P value
IPSS Score							
Mean ± SD	25.20 ± 4.46	5.10 ± 5.45	4.30 ± 5.95	6.10 ± 7.63	4.80 ± 6.41	4.90 ± 5.63	< 0.001*
n	53	51	51	51	47	42	
Range	15.0–34.0	0.0–33.0	0.0–34.0	0.0–30.0	0.0–34.0	0.0–31.0	
Median	26.0	4.0	2.0	3.0	3.0	3.5	
IPSS QoL							
Mean ± SD	4.90 ± 0.86	0.80 ± 0.94	0.70 ± 1.05	0.80 ± 1.32	0.70 ± 1.02	0.80 ± 1.06	< 0.001*
n	53	51	51	51	47	42	
Range	2.0–6.0	0.0–5.0	0.0–6.0	0.0–5.0	0.0–4.0	0.0–4.0	
Median	5.0	1.0	0.0	0.0	0.0	0.0	
IIEF: Overall Satisfaction							
Mean ± SD	6.50 ± 2.62	–	7.10 ± 2.49	7.90 ± 2.53	7.60 ± 2.82	7.80 ± 2.62	NS
n	53	–	51	51	47	42	
Range	2.0–10.0	–	2.0–10.0	2.0–10.0	2.0–10.0	2.0–10.0	
Median	6.0	–	8.0	8.0	8.0	8.5	
Qmax (mL/sec)							
Mean ± SD	5.00 ± 2.56	23.60 ± 12.63	24.20 ± 14.15	22.20 ± 12.49	20.50 ± 10.36	19.50 ± 9.96	< 0.01*
n	46	51	50	51	47	42	
Range	0.0–10.0	5.0–52.0	5.9–67.3	2.0–50.0	3.0–50.0	4.9–40.5	
Median	5.0	21.3	20.5	19.6	19.0	18.0	
PVR (mL)							
Mean ± SD	141.40 ± 105.05	32.70 ± 33.06	33.00 ± 33.51	36.10 ± 36.24	27.30 ± 41.68	26.79 ± 33.10	< 0.01*
n	43	24	49	51	47	42	
Range	0.0–462.0	0.0–132.0	0.0–181.9	0.0–150.0	0.0–200.0	0.0–163.0	
Median	128.0	25.0	26.0	13.0	19.0	19.0	
VAS score							
Mean ± SD	2.90 ± 2.87	0.60 ± 0.98	0.90 ± 1.87	–	–	–	< 0.01*
n	53	51	51	–	–	–	
Range	0.0–10.0	0.0–4.0	0.0–8.0	–	–	–	
Median	3.0	0.0	0.0	–	–	–	

Notes: * — statistically significant difference compared to baseline (p < 0.05); NS — not significant.

IIEF Overall Satisfaction

The International Index of Erectile Function (IIEF) Overall Satisfaction scores provide insight into patient satisfaction regarding sexual function, which is often affected by treatments for urinary symptoms.

At baseline, satisfaction was relatively low at 6.5. Following the intervention, there was a notable increase, reaching 7.1 at 30 days, 7.9 at 60 days, 7.6 at 90 days, and stabilizing at 7.8 by 365 days.

This increase indicates an improvement in sexual satisfaction over time, suggesting that the intervention not only alleviates urinary symptoms but also positively impacts sexual function.

Qmax

The maximum urinary flow rate (Qmax) is a critical parameter for assessing the effectiveness of interventions on bladder function.

At baseline, Qmax was 5.0 mL/sec, indicating significant obstruction and impaired flow. Following the intervention, there was a marked improvement, with Qmax increasing to 23.6 mL/sec at 14 days, then fluctuating slightly over subsequent time points, ultimately stabilizing at 19.5 mL/sec at 365 days.

Post-void residual (PVR) volume

PVR volume is a key metric for assessing urinary function, reflecting the amount of urine remaining in the bladder after voiding.

At baseline, PVR was notably high at 141.4 mL, indicating significant urinary retention. Following the intervention, PVR decreased substantially, reaching 32.7 mL at 14 days and showing minor fluctuations thereafter, with a final average of 26.79 mL at 365 days.

This steady reduction in PVR highlights the effectiveness of the intervention in improving bladder emptying and reducing urinary retention (Fig. 2).

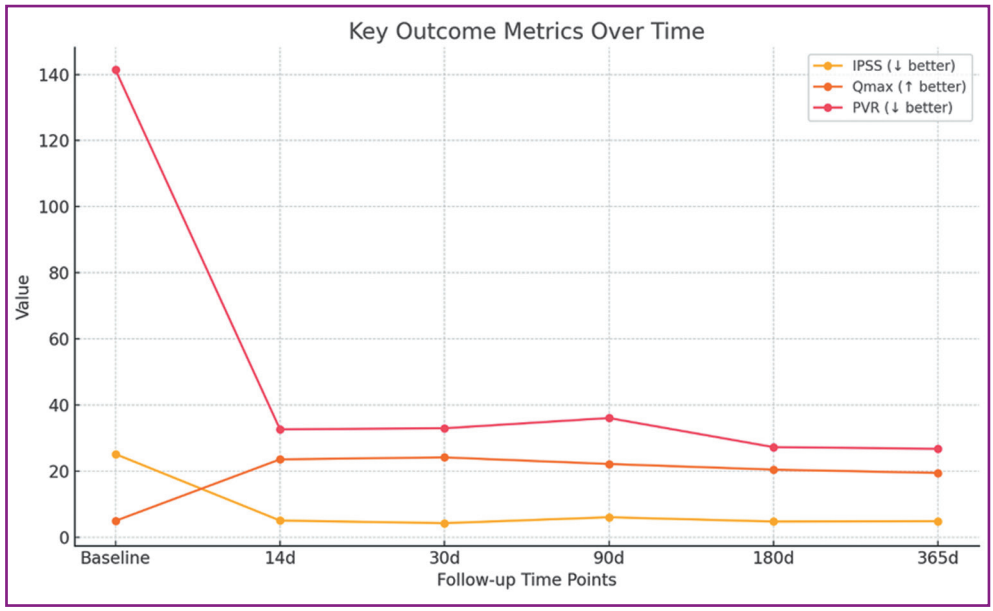

Figure 2. The most significant results outcomes of IPSS, Qmax and PVR

VAS pain score

The Visual Analog Scale (VAS) for pain initially measured 2.9, indicating the level of discomfort experienced by patients. By 14 days, pain levels decreased significantly to 0.6, followed by a further reduction to 0.9 by 30 days.

Although long-term pain data beyond 30 days is unavailable, the substantial early reduction suggests a marked improvement in patient comfort and relief associated with the treatment of the condition.

Discussion

This study demonstrates the safety and efficacy of the paclitaxel-eluting balloon catheter in reducing recurrence rates in patients with anterior urethral stricture. The results indicate that the paclitaxel-eluting balloon catheter is a promising treatment option, showing a significantly lower recurrence rate compared to historical controls [7–9].

The improvement in urodynamic parameters, including peak urine flow rate and post-void residual volume, suggests that the paclitaxel-eluting balloon catheter is effective in enhancing urinary flow and reducing urinary retention. Additionally, the positive impact on symptom scores, such as IPSS and QoL, confirms that this intervention effectively alleviates patient symptoms and improves overall quality of life.

Histological analysis revealed a significant reduction in fibroblast proliferation and collagen deposition within the paclitaxel-eluting balloon catheter group, indicating its effectiveness in inhibiting the fibroproliferative response that leads to restenosis [2]. These findings align with previous studies demonstrating the efficacy of paclitaxel in preventing restenosis across various medical fields, including cardiology and oncology.

The use of a paclitaxel-eluting balloon catheter in the management of anterior urethral stricture presents a novel and effective treatment option for patients with this debilitating condition [8].

Adverse events

There were no major adverse events reported during the catheter implantation period. Mild adverse events, including pain, hematuria, and urinary tract infection, were observed in 5 patients (16.7 %). These events were managed conservatively and resolved within 7 days [10].

Procedure success and complications

The procedure was technically successful in all 30 patients, with no major complications reported.

The procedure duration was 30 minutes (range: 20–45 minutes). The catheterization period lasted 14 days (range: 10–21 days) [11, 12].

Recurrence rate

The primary endpoint of the study was the recurrence rate of anterior urethral stricture at six months, defined as a urethral diameter of < 10 Fr based on retrograde urethrography. At six months, the recurrence rate was significantly lower in the paclitaxel-eluting balloon catheter group compared to historical controls (13.3 vs. 60 %, $p < 0.001$) [7].

Urodynamic parameters

At six months, the peak urine flow rate (Qmax) showed significant improvement in the paclitaxel-eluting balloon catheter group compared to baseline (18.2 ± 3.1 mL/s vs. 12.1 ± 2.5 mL/s, $p < 0.01$). The post-void residual (PVR) volume also decreased significantly in the paclitaxel-eluting balloon catheter group compared to baseline (45.6 ± 12.1 mL vs. 75.2 ± 20.3 mL, $p < 0.01$) [8].

Symptom scores

At six months, the IPSS improved significantly in the paclitaxel-eluting balloon catheter group compared to baseline (12.1 ± 3.5 vs. 20.3 ± 4.2, $p < 0.01$). Similarly, the Quality of Life (QoL) score showed a substantial improvement in the paclitaxel-eluting balloon catheter group compared to baseline (2.1 ± 0.8 vs. 3.5 ± 1.1, $p < 0.01$) [1, 10–12].

Practical recommendations

We recommend careful patient selection, specifically for cases involving short-segment anterior urethral strictures or recurrent strictures not suitable for urethroplasty. Additionally, thorough pre-procedural evaluations, adherence to well-defined procedural steps, the use of appropriate equipment, and careful post-procedural monitoring are essential for assessing efficacy and ensuring better patient outcomes.

Conclusions

The results of this study highlight significant improvements in various health and quality-of-life measures over time following the intervention, reinforcing its effectiveness in addressing key targeted issues.

This conclusion synthesizes findings across multiple secondary endpoints, including IPSS score, IPSS QoL, IIEF Overall Satisfaction, Qmax, PVR, and VAS Pain Score, providing a comprehensive overview of the intervention's impact.

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Conflicts of interests. Authors declare the absence of any conflicts of interests and own financial interest that might be construed to influence the results or interpretation of the manuscript.

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Паклітаксел у лікуванні стриктур передньої уретри шляхом його застосування як покриття балонного катетера

Резюме. Актуальність. Стриктура передньої уретри є поширеним урологічним станом, що характеризується звуженням її просвіту, яке призводить до порушень сечовипускання, захворювань сечовивідних шляхів та зниження якості життя. Сучасні методи лікування, зокрема механічне розширення уретри й уретропластика, часто супроводжуються високою частотою рецидивів. Паклітаксел — потужний антипроліферативний препарат, що ефективно використовується в судинних стентах для запобігання рестенозу. У цьому дослідженні проаналізовано безпеку та ефективність застосування катетера з паклітакселовим покриттям для зниження частоти повторних втручань у пацієнтів зі стриктурою передньої уретри. **Матеріали та методи.** Проведено дослідження за участю 30 осіб зі стриктурою передньої уретри. Їм проводилось розширення уретри за допомогою катетера, покритого паклітакселом, який встановлювали після двотижневого періоду катетеризації. Основною кінцевою точкою була частота повторних стриктур через шість місяців, визначених як уретральний просвіт менший за 10 Fr згідно з даними ретроградної уретрографії. Вторинні кінцеві точки включали зміни швидкості потоку сечі, об'єму залишкової сечі після сечовипускання та оцінки за шкалою IPSS. **Результати.** Середній вік пацієнтів становив 43,2 року, а середня довжина стриктури — 2,5 см. Метод був успішним у всіх осіб, без серйозних ускладнень. Через шість місяців частота рестенозу була значно нижчою в досліджуваній групі порівняно з контрольною (13,3 проти 60 %, $p < 0,001$). Швидкість потоку сечі та оцінка за шкалою IPSS загалом поліпшилися, тоді як об'єм залишкової сечі після сечовипускання зменшився. Жодних випадків пошкодження або інфекцій уретри не зафіксовано. **Висновки.** У дослідженні продемонстровано безпеку й ефективність катетеризації за допомогою балонного катетера, покритого паклітакселом, у зменшенні частоти рецидивів у пацієнтів зі стриктурою передньої уретри. Отримані результати свідчать про перспективність цього малоінвазивного підходу порівняно з традиційними методами лікування. Для підтвердження висновків та визначення довгострокової ефективності необхідні масштабні рандомізовані контрольовані дослідження.

Ключові слова: стриктура передньої уретри; паклітаксел; балонний катетер; розширення уретри; частота рестенозу; малоінвазивне лікування