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Uretroplastia con balón con Paclitaxel (UBP). 10 años de experiencia

Balloon urethroplasty with Paclitaxel. 10 years of experience

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RESUMEN

Al cumplirse los 10 años del que consideramos el caso 0 en el mundo de esta herramienta que está cambiando el paradigma del tratamiento de la estrechez de la uretra, iniciando el cambio hacia las plastias mínimamente invasivas sin uso de cateter, presentamos esta serie que, a nuestro criterio, es la primera y de mayor seguimiento hasta el momento. Nuestra serie no randomizada y aleatorizada incluye tanto pacientes con estrechez de la uretra anterior (35/69) (50,7%) como con estenosis de toda la uretra posterior (34/69) (49,2%), y se muestran datos de los casos con al menos un año de seguimiento (media 54 meses). El 82% de los pacientes no requirió otros procedimientos dentro del primer año y el 75% no lo requirieron en los 5 años o más. De los que requirieron otro procedimiento, 2 pasaron a cirugía reconstructiva, 2 a dilataciones periódicas, 3 a una segunda plastia con balón y 3 a una tercera plastia. El índice de aceptación fue alto (95%).

SUMMARY

On the 10th anniversary of what we consider the case 0 in the world of this tool that is changing the paradigm of the treatment of narrowing of the urethra, initiating the change towards minimally invasive plasties without the use of catheter, we present our series, which in our opinion is the first and most followed so far. Our series, non-randomized, randomized, includes both patients with narrowing of the anterior urethra (35/69) (50.7%), and with stenosis of the entire posterior urethra (34/69) (49.2%) and data are shown for cases with at least one year of follow-up (mean 54 months). 82% of patients did not require another procedure within the first year and 75% did not require it in the 5 years or more. Of those who required another procedure, 2 went to reconstructive surgery, 2 to periodic dilations, 3 a second balloon plasty and 3 a third plasty. The acceptance rate was high (95%).

INTRODUCCIÓN

Las estenosis uretrales masculinas tienen una incidencia estimada de 229-667 por cada 100.000 hombres y suponen una carga sustancial para los pacientes y los sistemas sanitarios. Las estenosis son una entidad diversa con diferentes topografías, etiologías variadas, modalidades diagnósticas limitadas y altas tasas de recurrencia, lo que plantea desafíos para los cirujanos en centros de bajo volumen en países de ingresos bajos y medios. Las opciones de tratamiento actuales a menudo requieren acceso a subespecialistas y tecnologías que pueden presentar un desafío para los centros de recursos limitados. Por esta razón, la adopción de tecnología que facilite procedimientos más asequibles para tratar las estenosis uretrales masculinas es crucial. En la búsqueda de tratamientos accesibles, investigamos la eficacia del uso de dispositivos médicos recubiertos con medicamentos quimioterapéuticos, específicamente Paclitaxel, para tratar las estenosis uretrales masculinas. El Paclitaxel es una potente droga antitumoral cuyo mecanismo de acción es inhibir la reproducción celular (antimitótico) por alteración de la reproducción de microtúbulos (antimicrotubular).¹ Desde fines de siglo pasado es de uso en tumores diversos, sobre todo, cáncer de mama. Desde 1999 se usa en recubrimiento de endoprótesis y balones de dilatación de arterias coronarias, recibiendo aprobación en 2014 por la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA, por sus siglas en inglés) para uso endoluminal arterial periférico.

No es casual, en nuestra casuística, que fuera que un hemodinamista motivado por la confianza y experiencia en el uso de dichos dispositivos en vasos coronarios (Dr. Fiandra) quien hiciera uso de balones de angioplastia en su propia uretra para tratar una estrechez que lo aquejaba. Motivados por la seguridad y eficacia de la prueba piloto, el Dr. Fiandra se contactó con colegas urólogos y, en el año 2013, se diseñó un protocolo de aplicación de estos balones en estrecheces y estenosis uretrales.

Presentamos aquí nuestra experiencia de 10 años con nuestra serie, en la que usamos balones de angioplastia periféricos recubiertos con Paclitaxel, úni-

cos disponibles en Latinoamérica hasta el momento del análisis.

MATERIALES Y MÉTODOS

La serie de 104 pacientes está compuesta en su integridad por casos no preseleccionados, y, salvo 4 individuos, el resto presentaba por lo menos un procedimiento previo luego de su diagnóstico. De los 104 casos hasta julio de 2023, 101 son de sexo masculino y 3 de sexo femenino. Presentaremos datos sobre los casos de sexo masculino con más de un año de seguimiento (n=69).

NUESTRA TÉCNICA

Excepto los portadores de sonda al momento del procedimiento, todos fueron evaluados con Uretrocistografía retrograda y miccional, IPSS, QoL y Uroflujometría.

A todos los pacientes se le realizó urocultivo y, en el caso de ser positivo, se le trató de acuerdo al antibiograma 3 días antes y continuaron 5 días después. Los pacientes anticoagulados suspendieron el tratamiento 3 días antes.

Los procedimientos se realizaron en sala de Hemodinamia, bajo sedo analgesia en condiciones de esterilidad quirúrgica.

1. Uretrografía retrograda para identificar sitio/s de estechez/estenosis.
2. Pasaje de guía a vejiga.
3. Predilatación con balón desnudo por 5 min a 10 Bar.
4. Dilatación con Balón con Paclitaxel 5 m. a 10 Bar.
5. Pasaje de contraste para documentar y verificar resultado.

Desde el inicio, el protocolo fue planificado para no dejar catéter uretral posterior; tras la recuperación y una vez que orina es dado de alta.

Ninguno requirió cateterismo inmediato por retención urinaria. Aquellos con vejiga neurogénica de bajo tono (alto residuo) requirieron un cateterismo transitorio posterior en domicilio (2 / 69) (2.9 %).

A todos los pacientes se les prescribió Prednisona 20 mg y cobertura ATB guiada por cultivo durante 7 días. No se requirió otros analgésicos u otra medicación adicional. El uso de prednisona lo comenzamos luego de los primeros 3 casos por síntomas irritativos y disuria. El uso de corticoides disminuyó significativamente los síntomas y mejoró la micción inicial por lo cual lo incorporamos al protocolo.

En los primeros 15 casos usamos balones de angioplastia periféricas Ranger™ (Boston Scientific, Marlborough, Massachusetts, EEUU) de 7 mm de diámetro. A medida que adquirimos experiencia y confianza, incrementamos el diámetro y desde el caso 15, usamos balones Elutax usamos balones Elutax (AR Baltic Medical, Vilna, LituaniaBaltic), de 8 y 10 mm de diámetro. Desde el 2023, los catéteres Elutax tienen aprobación HIFU de CE (Comunidad Europea).

ANÁLISIS DE SANGRE

La serie de 104 pacientes está compuesta en su integridad por casos no seleccionados. Salvo 4 individuos, el resto presentaba por lo menos un procedimiento previo luego de su diagnóstico. De los 104 casos hasta julio de 2023, 101 son de sexo masculino y 3 de sexo femenino. Presentaremos datos y comentarios sobre los casos de sexo masculino con más de un año de seguimiento (n=69). También hemos utilizado este procedimiento en uréter (6 casos) que son considerados en otro trabajo, pero con resultados similares y auspiciosos, por lo que en el futuro pensamos que, cuando la evidencia lo confirme, esta herramienta pasará a ser uroplastia (incluyendo toda la vía urinaria) con balón con drogas (puede que en futuro aparezcan otras drogas similares o mejores de transferencia con balón) (UBD).

El número de procedimientos fue aumentando luego del 2019 por lo que más de la mitad de los procedimientos fueron realizados en los últimos tres años (grafico 1). Para el seguimiento se consideran los pacientes masculinos con más de un año de se-

guimiento (n =69), por lo que el tiempo máximo es de 8 años. (Media 4 años). Quedan fuera de consideración los últimos 12 meses a julio del 2023 (n =26). La distribución por edad se muestra en grafico 2 tomada de auditoria externa de verificación de datos que encargamos en dos oportunidades con resultados similares en ambas (Figura 1).

Edad mínima de 37 y máxima de 87, con media de 62 años.

EL 94,2% (65/69) presentaban procedimientos previos y en sólo 4 pacientes este fue el primer tratamiento (de novo) (5,8%). Analizaremos por separado los pacientes tratados en uretra posterior por su interés especial dado lo complejo de su resolución y los resultados obtenidos (34/69) (Gráfico 1).

RESULTADOS

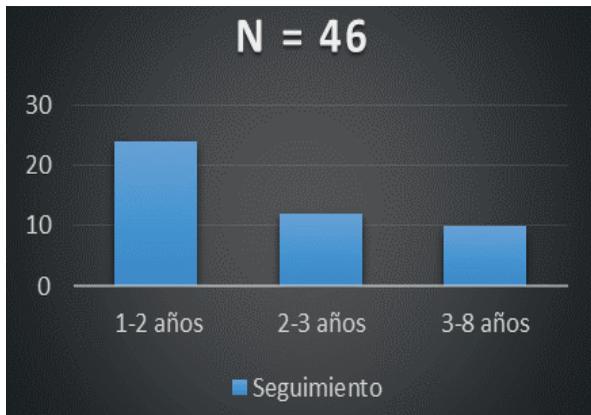
100% de los pacientes retornaron a domicilio con síntomas mínimos (disuria y sangrado leve) en las primeras 24 hs. La actividad normal, salvo ejercicios físicos, la retomaron en las primeras 36 horas.

El grado de aceptación, conformidad con el procedimiento y mejora de la calidad de vida (subjetivos) se muestran en los graficos tomados de la auditoria externa.

Todos los parametros por encima del 90%. De los 54 pacientes auditados en forma externa, se lograron confirmacion de datos en 46 (85,1%). Seguimiento entre 1 y 2 años, 24/46 (52,1%); seguimiento entre 2 y 3 años, 12/46 (26%); seguimiento entre 3 y 8 años, 10/46 (21,7%) (Figura 1).

- 8/46 requirieron otro procedimiento (17,3%).
- 2/8 pasaron a solución quirúrgica (25%).
- 3/8 recibieron UBP adicional antes de los 3 años (37,5%).
- 3/8 recibieron 2 UBP en los primeros 5 años (37,5%).

Figura 1. Número de casos según los años de seguimiento.



Los pacientes que repitieron UBP habían tenido procedimientos quirúrgicos o invasivos previos rechazando esa solución. El Q_{Mx} se midió previo al procedimiento, a la semana, al mes, a los tres meses, a los 6 meses y al año. Después, durante el primer año y, luego, anualmente.

Sólo 2 pacientes del total (2.9 %) presentaron signos de bacteriemia post procedimiento que requirió ATB i/v con buena evolución en 48 horas. Estos pacientes no habían recibido cobertura i/v.

Como la mayoría presentaba de inicio, flujos por debajo de 5 ml, e incluso algunos con 0 (pacientes con talla (3/69) (4.3%) o sonda vesical (2/69) (2.8%), el flujo de partida fue muy bajo.

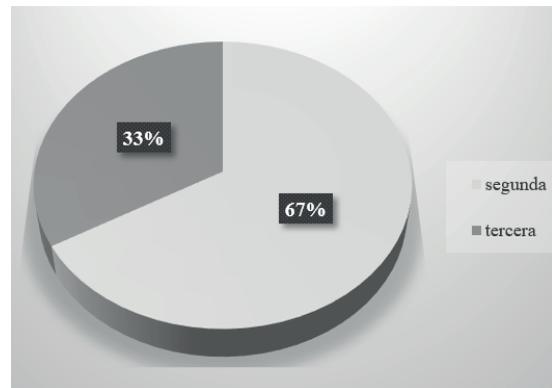
Podemos concluir que el 95% presentó flujo aceptable (mas de 12 ml/s). Destacamos que hay una disminución de aproximadamente un 20% entre el Q_{Mx} tomado a la semana y a los tres meses .

- 8/69 (11,5%) requirieron una segunda dilatación antes de los 12 meses.
- 4/69 (5,7%) requirieron un tercer procedimiento antes de los tres años (Figura 2).

SITUACIONES ESPECIALES

6/69 (8,6%) presentaron más de un sitio de estrechez en 4/69 (5,7%) usamos 2 balones sucesivos en el mismo procedimiento y en 2/69 (2,8%), 3 balones sucesivos (tratamiento de toda la uretra) (Figura 3 y 4).

Figura 2. Incidencia de segundo y tercer procedimiento (UBP).



Estos pacientes llevan tres años asintomáticos, con buena calidad de vida y flujos, y residuo aceptable sin otros procedimientos.

Figura 3. Imagen de plastia con dos balones escalonados (comienzo proximal).



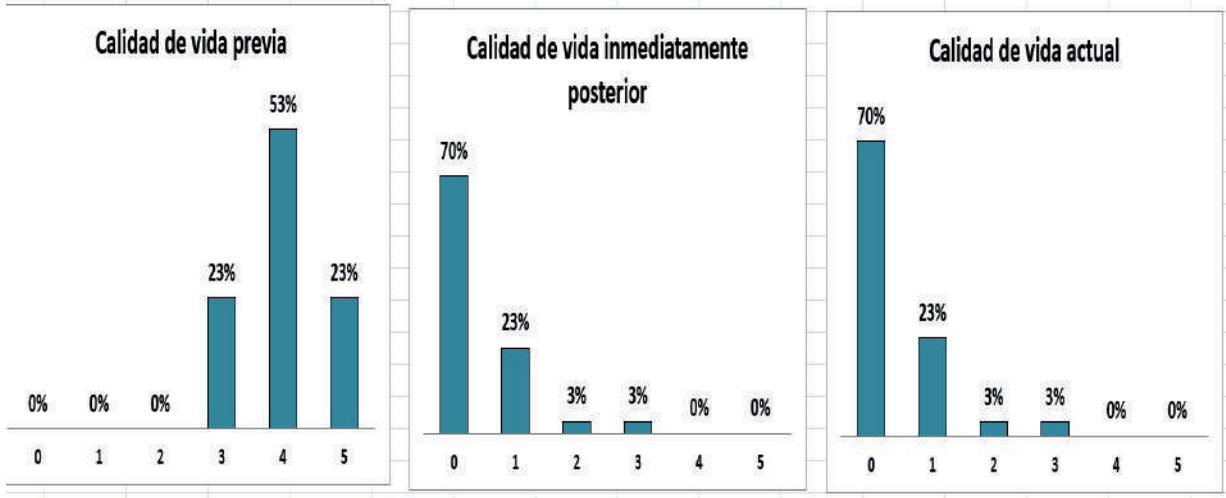
Figura 4. Imagen radiológica de plastia con tres balones escalonados (panuretral).



Calidad de vida

El grado de aceptación del procedimiento es alto (95%), así como su voluntad de tener que repetirlo o recomendarlo (95%) (Figura 5).

Figura 5. Calidad de vida previa (subjetiva) antes y posprocedimiento, inmediata y a 5 años.



UBP en cuello vesical

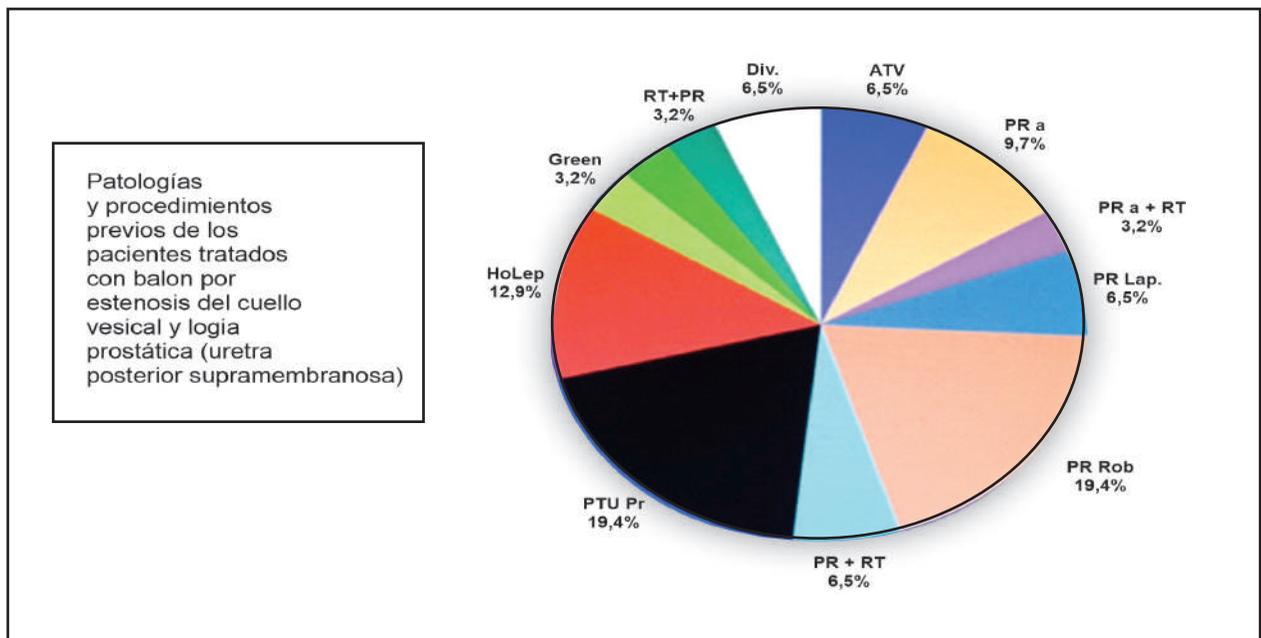
Trataremos en forma separada los casos de estenosis de cuello vesical. Se incluyen, en esta serie, los pacientes con estenosis de uretra prostática (próstata presente), ya que la técnica aplicada y los resultados son similares (Figura 7).

Excluimos los casos de estenosis de uretra membranosa única (3/46) (6,5%), cuya evolución es diferente. En cuello vesical (CV) y uretra prostática (Upar) (ambas: uretra posterior supra membranosa), de los

33 casos tratados hasta enero 2023, todos presentaban procedimientos quirúrgicos y endoscópicos diversos.

Secuelas de: adenomectomía transvesical (ATV) 2/33; prostatectomía radical abierta (PR a.) 3/33; PR a. mas RT (PR a + RT) 1 / 33; prostatectomía radical laparoscópica (PRL) 2/33; prostatectomía radical robótica (PR Rob.) 6/33; PR Rob. Mas RT (PR Rob.+RT) 2/33; RTU de próstata (RTU) 6/33; Pr R. Salvataje 1/33; diverticulectomía a cuello abierta (Div.) 2/33; HoLep 4/33; Green Vap. 1/33; RT Próstata 3/33; RT más PR Rob. 1/ 33.

Figura 6. Incidencia de patologías y procedimientos previos en estenosis cuello vesical.



- 4 / 33 (8.2%) eran portadores de gérmenes multiresistentes.
- 2/ 33 (6%) portadores de cateterismo vesical a permanencia.
- 3 / 33 (9%) catéter suprapúbico colocada en el último mes.

Todos los pacientes recibieron cobertura antibiótica según sensibilidad por cultivo, durante 7 días. En todos los casos se retiraron los drenajes (sonda o catéter supra púbico) una vez finalizado el procedimiento, salvo un paciente con drenaje suprapúbico con vejiga residual, en ese caso, cerrado durante 5 días.

Figura 7. Imagen inicial de estenosis filiforme en neocuello.



RESULTADOS EN CV

100% retomaron la micción espontáneamente. El incremento de Q_{Mx} fue notorio aunque se partía de casos con flujo 0 o por debajo de 5 ml/s.

3 /33 (9.1%) presentaron incontinencia de orina leve (1 pad diario) evidenciada al esfuerzo. De ellos, 2/3 quedaron continentales a los 3 meses (sobre todo nocturna), menor disuria y mayor independencia (subjetivamente una mejora significativa de su calidad de vida) (95%).

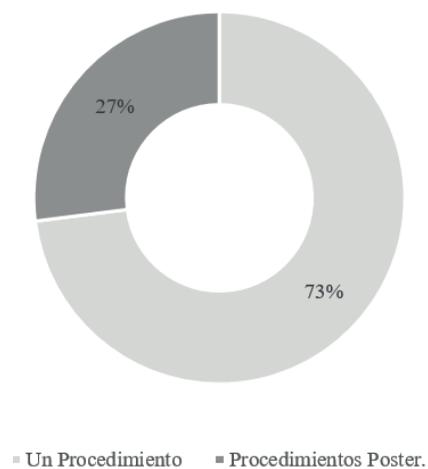
Otro fenómeno observado es la disminución de infecciones urinarias e, incluso, negativización de algunos cultivos con gérmenes persistentes.

Tomando todos los pacientes el seguimiento, fue entre 12 meses y 9 años (medios 54 meses).

- 3/33 tuvieron un segundo procedimiento al año.
- 2/33 un segundo procedimiento al segundo año.
- 2/33 tuvieron un tercer procedimiento quirúrgico al año.
- 2/33 necesitaron dilatación dentro del año y no repitieron plastia ni cirugía.
- 24/33 no requirieron procedimientos adicionales (73 %) (Figura 8).

Figura 8. Casos con y sin procedimientos posteriores a la UBP.

Procedimientos Posteriores CV (n=33)



Estenosis de uretra y liquen escleroso

4/69 (5,8%) presentaron liquen asociado en actividad (estenosis de meato y uretra distal). La tolerancia y resultados fueron similares a los pacientes sin liquen. El tiempo del procedimiento es mucho menor (15 min).

REACCIONES ADVERSAS

En ningún caso de la serie se presentaron complicaciones mayores ni de reacción sistémica hasta el momento. Todas las complicaciones (disuria y uretrorragia) fueron leves y en promedio con 36 horas de evolución controlados con AINES.

En los primeros casos no usamos corticoides que incorporamos luego del caso 10 al notar síntomas irritativos intensos con chorro fino en las primeras 24 h, síntomas que mejoraron notoriamente con el uso de Prednisona durante 7 días.

Algunos pacientes (sobre todo los que recibieron RT) en algún momento en los primeros 6 meses presentan un episodio agudo de disuria y disminución del calibre del chorro urinario. En estos casos, repetimos un ciclo de 5 días de Prednisona y el cuadro revierte rápidamente (24-36 h).

DISCUSIÓN

En el año 2016, presentamos el primer trabajo con nuestra serie preliminar de 10 casos con y 3 años de seguimiento en CAU Panamá. Esta experiencia ha permitido conectar dos especialidades que en principio no tenían mucho que comunicarse; sin embargo, ha potenciado el desarrollo de esta herramienta que difícilmente se le hubiera ocurrido a algún urólogo, ya que el desconocimiento de estos catéteres es absoluto en la especialidad.

Estos mismos balones ya se están probando en vía digestiva y vía Biliar con resultados prometedores. Creemos estar en el inicio de un cambio de paradigma en el tratamiento de la estenosis de la vía urinaria, es decir, no solamente de la uretra, sino también de la vía urinaria alta. Es impactante el resultado en uréter no neoplásico (trabajo de 25 pacientes publicado en Europa) (75% a tres años),⁵ así como en la unión pieloureteral.

Este cambio implica: menor uso de sala de operaciones, menor tiempo de aprendizaje por la simplicidad del procedimiento, mejora notoria de la calidad de vida de los pacientes (ambulatorio y sin sonda posterior), rápida re inserción a tareas habituales, menor costo y menos complicaciones.

Del análisis de la serie, destacamos los siguientes puntos de interés. El 90 % de los pacientes tenían uretrocistografía (UCG) como documentación de su patología; un 10 % tenía sólo como método diagnóstico una uretrocistoscopia, incluso en aquellos en

que se les había planteado un procedimiento quirúrgico planificado.

Sólo un paciente con larga historia de obstrucción tratado con dilataciones y con vejiga atona, residual de más de 1000 cc tenía un estudio urodinámico (paciente en cateterismo intermitente). De interés de este paciente, no diagnosticado ni tratado en tiempo y forma de su estenosis, es comprobar la repercusión irreparable sobre la vejiga sometida durante largo tiempo a vaciamiento a presión con residuo en aumento (vejiga atona con residuo alto). A este paciente que sumaba dificultad para el cateterismo por la estrechez se le dilató con balón, lo cual facilitó el cateterismo y aumento la autonomía con mejoría del vaciado vesical con pujo abdominal intercalado.

Se destaca de los estudios previos: a) aproximadamente el 20% de las UCG mostraban su diagnóstico al momento de realizar el procedimiento; b) 15 % de los pacientes se presentaban con cultivos portadores de distintos gérmenes gramnegativos multi-resistentes solo sensibles a ATB intravenosos; y c) en un trabajo de investigación presentado en conjunto con investigadores y microbiólogos del Instituto Clemente Estable, realizado con una muestra (10 casos), se detectaron gérmenes intracelulares (BIC) en uretra y en vejiga (diagnóstico por microscopia con focal y urocultivo estándar y extendido).

Este, presentado en CAU 2023, obtuvo el primer premio de ese evento. Este hallazgo permite abrir líneas de investigación sobre una microbiota normal y patológica en la uretra que pueda explicar la etiología y/o la persistencia o reiteración del fenómeno inflamatorio en la estrechez de uretra.

Agradecimiento

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Anterograde placement of drug-coated balloon for ureteroileal anastomosis stricture

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SUMMARY

We describe a case of ureteral stricture after radical cystectomy with orthotopic neobladder. The patient presented 4 months after laparoscopic radical cystectomy with intracorporeal orthotopic ileal neobladder, with fever and left lower back pain.

Laboratory analysis showed leucocytosis and elevated C reactive protein and creatine levels. CT scan showed left hydronephrosis and slow excretion of the intravenous contrast medium with a narrowing at the left ureteroileal anastomosis.

A nephrostomy was placed and, 6 weeks later, the anterograde placement of a drug-coated balloon with paclitaxel was placed. Inflation to rated burst pressure occurred for 3–5 min, the drug-coated balloon was removed and a new nephrostomy tube was placed without ureteral stent placement. We performed a kidney ultrasound 30 days after the drug-coated balloon placement with the nephrostomy tube closed showing no left hydronephrosis and the nephrostomy tube was removed.

BACKGROUND

A ureteral stricture (US) after radical cystectomy with orthotopic neobladder is caused by distal ureteral ischaemia in the ureteroileal anastomosis. The ischaemia is secondary to the transposition of the left ureter, periureteral urine leak and fibrosis of the new anastomosis.¹ The incidence of this postoperative complication has been reported to be 1%–30% and the management remains a challenge for the urologist. Surgical revision was considered the gold standard for the US treatment; however, due to high postoperative morbidity, endourological management is often the first choice in minimally invasive treatment.² The balloon dilatation was reported many years ago; but recently, the drug-coated balloon with paclitaxel has emerged as a promising treatment in the urethral and USs with excellent results.^{3 4}

CASE PRESENTATION

A man in his mid 50s who had undergone a laparoscopic radical cystectomy with intracorporeal orthotopic ileal neobladder (Studer's neobladder) for muscle-invasive bladder cancer 4 months earlier presented to the emergency with fever and left low back pain. Previously, we have already performed a routine flexible cystoscopy of the neobladder with a urinary cytology that was negative for tumour cells in the third postoperative month. Until the visit,

the patient voided spontaneously, with a Valsalva manoeuvre of about 200 mL per episode and intermittent catheterisation.

INVESTIGATIONS

Laboratory analysis showed a leucocytosis (15.75 million/mm³), C reactive protein of 197.1 mg/L and an elevated creatine level of 1.76 mg/dL. The CT scan showed left hydronephrosis and slow excretion of the intravenous contrast medium with a narrowing at the left ureteroileal anastomosis ([figure 1](#)). No images or tumour lesions were found in the upper urinary tract in this CT scan. Urinalysis of a neobladder sample found the presence of leucocytes and bacteria. A multidrug-resistant *Klebsiella Oxytoca* grew in the urine culture and 2 g of Cefepime every 12 hours was initiated.

TREATMENT

We decided to offer our patient an off-label treatment of ureteral dilatation with a drug-coated balloon. The patient was notified about the advantages and possible complications of this new surgical technique.

The patient was positioned according to Giusti's position. The supine position facilitates simultaneous manipulation of anterograde and retrograde of the neobladder and the upper urinary tract.⁵ A left nephrostomy was placed and an anterograde placement of a guidewire into the neobladder was performed. An anterograde pyelography showed a 1 cm US in the left ureteral-ileal anastomosis. A secure and working guidewires were then placed in an anterograde fashion. An 8 Fr double-J stent was placed to dilate the US and a Foley catheter was inserted in the neobladder. 6 weeks after the procedure, we performed the anterograde placement of drug-coated balloon. We used paclitaxel+dextran-coated balloon elutax '3' PTA-catheher-OTW (AR Baltic Medical) that combines mechanical dilatation of the stricture with the circumferential delivery of the drug. Previously, the negotiation of the stricture could be done by the 'rendezvous technique' and predilatation was performed using a 5–7 mm high-pressure balloon catheter. A 6×60 mm (almost 18 Fr) balloon was selected for this patient according to the stricture characteristics. Inflation to rated burst pressure (10 Bar) occurred for 3–5 min to allow the dilatation and the drug delivery based on the manufacturer's recommendations ([figure 2](#)). Finally, the



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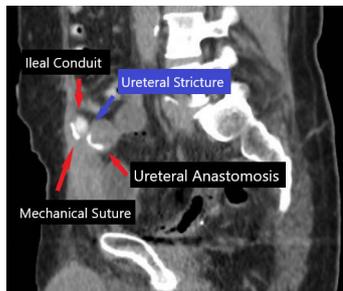


Figure 1 Sagittal CT scan demonstrates the US (blue arrow). US, ureteral stricture.

drug-coated balloon was removed and a new nephrostomy tube was placed without a ureteral stent placement (online supplemental video 1).

OUTCOME AND FOLLOW-UP

The patient was discharged 24 hours after the procedure. No immediate and late postoperative complication occurred during the 1-month follow-up according to Clavien–Dindo classification. We measured the left renal function by performing a creatine clearance of the left nephrostomy tube. The total urine of 24 hours was measured and sent for urine creatine estimation, which was normal (1564 mg/day). We performed a bilateral kidney ultrasound 30 days after the drug-coated balloon placement with the nephrostomy tube closed (figure 3). No left hydronephrosis was shown and the nephrostomy tube was removed. 12 months postoperatively, the patient continued to be asymptomatic with a normal renal function (creatinine level of 1.09 mg/dL).

DISCUSSION

The endourological options in the US management are usually the first treatment despite the long-term outcomes and the stricture's characteristics. Schöndorf *et al*² showed that the successful treatment for ureteroileal stricture depends primarily on stricture length. Endourological interventions have an acceptable success (50%) for short US (≤ 1 cm). Nevertheless, for greater USs, the success rate drops to 8%.

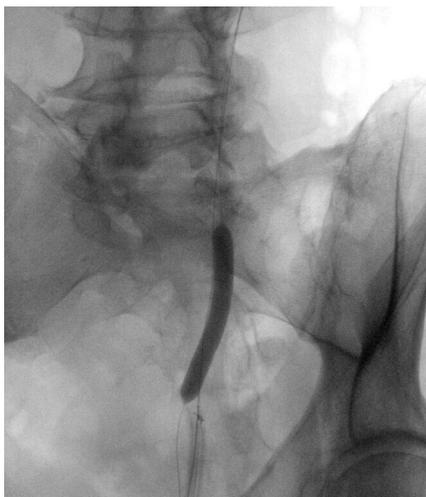


Figure 2 Rendezvous technique with the antegrade placement of the drug-coated ureteral balloon.



Figure 3 Follow-up kidney ultrasound at 1-month postoperative with the nephrostomy tube closed.

The ureteral fibrosis and the stenosis of the ureteral lumen are caused directly by an excess of type 3 collagen.⁶ This is an important issue because paclitaxel stabilises cellular microtubules and inhibits cell replication reducing the production of type 3 collagen. Furthermore, it inhibits fibroblast growth and scar formation preventing the fibrotic reaction in the ureteral stenosis.

Currently, there is only one study that describes the ureteral balloon dilatation with paclitaxel. Kallidonis *et al*⁴ described 25 patients with benign US, of which 13 had ureteroenteric stenosis diagnosis (52%). The overall success at 1-year follow-up was 88%; however, of the three cases that failed, two patients had ureteroileal strictures. Notably, in that study, most of the strictures exceeded 2 cm and the authors concluded that the ischaemic nature of the stenosis could be more important than the length.

Learning points

- ▶ The management and the treatment of ureteroileal anastomosis strictures represent a particular challenge for urologists.
- ▶ Endourological management of ureteral stenosis is usually the first treatment option despite the high rate of recurrence.
- ▶ Drug-coated ureteral balloons have emerged as a promising treatment, despite the fact that further clinical trials are needed to reaffirm these results.

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Contributors The following authors were responsible for drafting of the text, sourcing and editing of clinical images, investigation results, drawing original diagrams and algorithms, and critical revision for important intellectual content: LR and LB. LR collected the images and videos and clinical data for the case report. MM edited the images and videos. LR and LB drafted the manuscript. LR, MM, LB and PC supervised the final manuscript. LR acted as a guarantor. The following authors gave final approval of the manuscript: LR, MM, LB and PC.

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Case reports provide a valuable learning resource for the scientific community and can indicate areas of interest for future research. They should not be used in isolation to guide treatment choices or public health policy.

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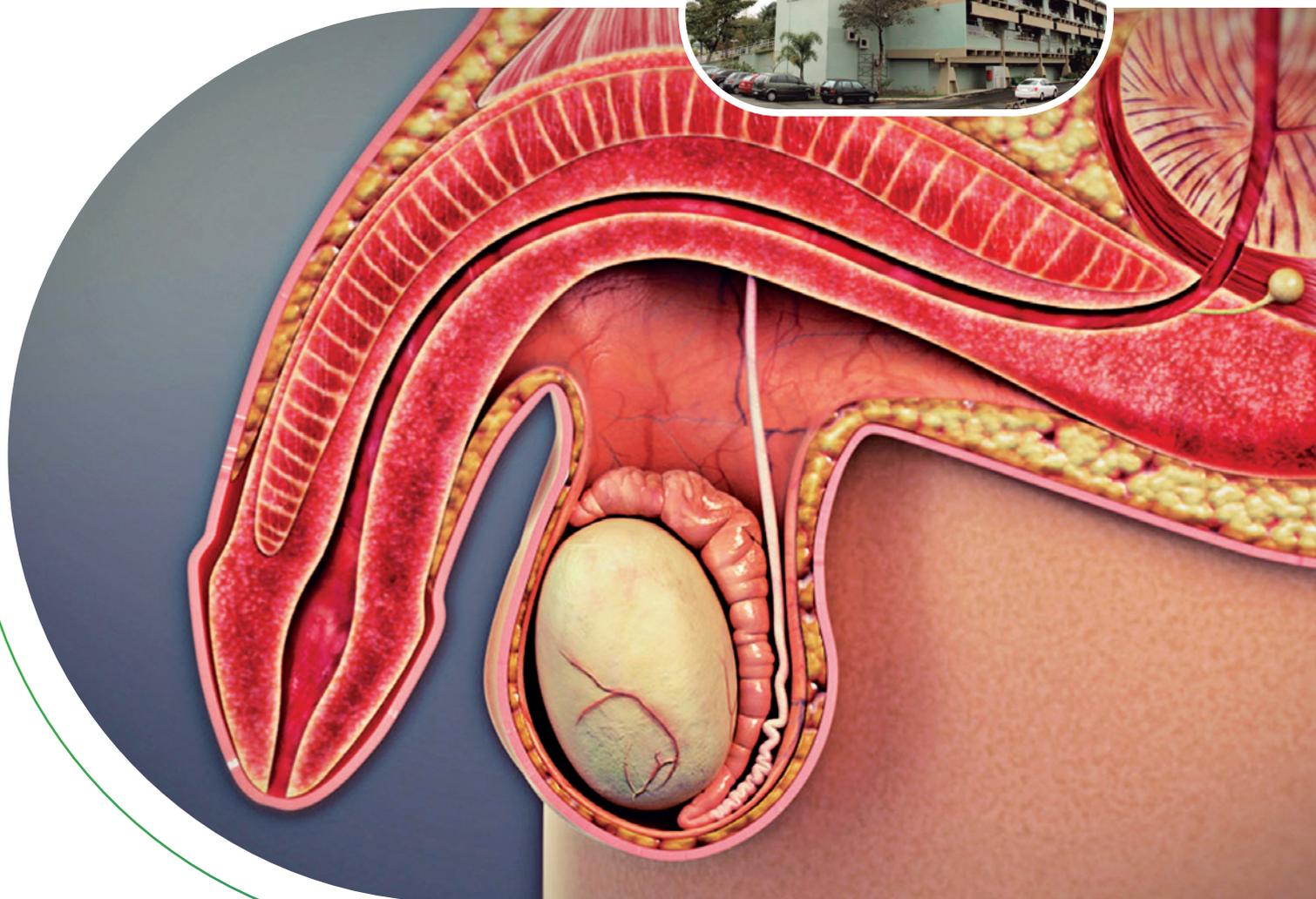
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| INOVAÇÃO/ENDOUROLOGIA
**TREATMENT AND PREVENTION OF POST OPERATIVE
URETERAL STRICTURES WITH PACLITAXEL +
DEXTRAN COATED BALLOON**



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Ureteral strictures (US) are becoming more frequent following endourologic or laparoscopic procedures. Even there are described endoscopic, laparoscopic, or open procedures to treat US, in general, the success rate is uncertain, and recurrences are frequent.

Paclitaxel, one the essential medicines by World Health Organization, is a natural chemotherapeutic compound with antiproliferative properties that inhibit smooth muscle cell proliferation and collagen production by impeding the disassembly or depolymerization of microtubules.

Our group, Uroplastia Uruguay (Montevideo, Uruguay) and Hospital Alemán (Buenos Aires, Argentina), did a study that is still under review. As a summary of our trial, we found a success rate was 90.5% and 80 % patients reach 12 months of follow-up with zero hydronephrosis.

In our study data from 21 consecutive patients were recorded. There were 11 women and 10 men. Mean age was of 54 years old. The median length of the US was 2.11 cm (1- 6). 11 had US in the abdominal part of the ureter (52,38%) and 10 (47.6%) in the pelvic part. The median follow-up was 14 months (58 - 4 months).

All patients were treated following the same protocol. Antibiotic prophylaxis was Cefazolin 2 grams during anesthesia induction. With the patient under general anesthesia in a RX table a retrograde pyelography was performed using a 5 French open-end catheter. Characterized the area of stenosis (AOE), the C arm was fix and two marks below and above the AOE were attached to the pyelography image on the monitor. Using a 0.018 wire, a 6 millimeters non coated drug balloon (IAR-RX Baltic Medical) was positioned covering the full length of the AOE and 3 centimeters bellow and above it. After that, 5 minutes non-drug coated balloon dilation was performed. The balloon used was 6 millimeters, insufflated with contrast solution at 10 atmospheres of pressure. After that, 5 minutes dilation with PDCB was performed (ELUTAX Baltic Medical) insufflated with contrast solution. The balloon used was a 6 millimeters one, at 10 atmospheres of pressure. The balloon's length was chosen depending on the length of the AOE + 6 cm. (4,6 12 cm). You can find an attachment video with the step by step procedure.

The complication rate was 19.5 % (Clavien 3b), pain in 3 of them and renal function impairment in 1 patient. The treatment for these 4 patients was a double J insertion.

In the literature the incidence of US following ureteroscopy is between 0,3 - 4,9 % of cases, that number seems to be increasing because retrograde intrarenal surgery is becoming more and more common every day. Smaller scopes, suction scopes, suction ureteral access sheath and laser with more power allow to treat high burden stones in retrograde fashion but unfortunately an increasing number of US after ureteroscopy have happened in this scenario.

Since 1993, LP became the treatment of choice for ureteropelvic junction obstruction. US following LP has been reported between 2,5 and 10 %. 5

Many treatment options have been described during the years for US. Open, laparoscopic and endoscopic treatments are part of the armamentarium, but procedures are complex, the average success rate is uncertain, recurrence are frequents and nephrectomies are the final outcome in certain cases.1234

The use of paclitaxel as inhibitor of ureteral smooth muscle cell proliferation and collagen production have been described in animal models more than 20 years ago, but there is only one

published clinical series of US using paclitaxel coated balloon dilation. Paclitaxel + Dextran coated balloon got CE approval to open up strictures of hollow organs as arteries, veins, urethra, ureter and biliar.

The use of dextran polymer as controller of the drug delivery has been studied in peripheral arteries showing a better release pattern compared with paclitaxel only coated balloons. To our knowledge, our study is the first one using PDCB dilation in the ureter. There is a paper published by one of our investigators using PDCB for urethral strictures showing a success rate of 82 % at 12 months. The Robust I using only paclitaxel coated balloon dilation for urethral strictures, showed a 70 % success rate at 12 months (8). If the use of dextran as vehicle could explain the zero re-treatment rate in our group is an hypothesis, but that hypothesis needs to be proven.

If you read the title of this manuscript, you may think, why is treatment mentioned before prevention?

The answer is that through experience, we found that PDCB is an excellent option for ureteral stricture treatment. This notion has made us come to the conclusion that the real focus should be put on the prevention of strictures and not only the treatment.

The most dangerous scenario for ureteral strictures are the impacted stones. Degree of hydronephrosis, ureteral wall thickness and hounsfiels units of the ureteral wall below the stone, had been described as a predictor of stone impactation. Ureteral strictures are a significant complication following laser lithotripsy for impacted stones, occurring in up to 25% of cases. These strictures lead to long-term patient morbidity, increased healthcare costs, and reduced quality of life.

In summary, today we know that PDCB is effective and safe to treat patients with post operative ureteral strictures and we believe that the adoption of paclitaxel-coated balloons for impacted stone cases could be a highly cost-effective preventive strategy, significantly reducing healthcare costs and enhancing patient outcomes. Given the economic and clinical benefits, this approach should be prioritized in urological practices.

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Grey Zone

Ureteral Stricture: Endoscopic Management

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1. Introduction

The prevalence and incidence of kidney stones are increasing worldwide. Ureterscopy procedures have shown exponential growth, and ureterscopy is now the most common endourological procedure. The relative incidence of ureteral stricture (UST) following ureterscopy procedures is between 0.3% and 25%, but the absolute number of UST cases seems to be growing because retrograde intrarenal surgery is increasingly common. Technological advances such as smaller scopes, suction scopes, suction ureteral access sheaths, and lasers with greater power allow retrograde treatment of cases with a high stone burden, but unfortunately this has led to an increase in the number of USTs after ureterscopy. UST can lead to long-term patient morbidity, lower quality of life, and higher health care costs.

2. UST causes

The most dangerous UST scenario is an impacted stone. The degree of hydronephrosis, the ureteral wall thickness below the stone, and the stone density (Hounsfield units) have been identified as predictors of stone impaction [1]. USTs are a significant complication following laser lithotripsy

for impacted stones, occurring in up to 25% of cases [2–4]. Thermal injuries caused inadequate laser settings, low irrigation flow, and prolonged laser time during treatment for an impacted stone represents the worst case scenario for potential UST incidence.

As described by Patel et al [5], mechanical damage during ureterscopy can be managed with placement of a double-J stent and time, but this approach is not applicable to thermal injuries.

Thermal injury can occur if the temperature around the tip of the laser fiber exceeds 43 °C. This can result in cell damage, protein coagulation, and tissue injury, with potential to progress to UST. At temperatures > 43 °C, the time required to cause cellular damage decreases by half. Thus, use of improper laser settings and/or low fluid irrigation for a few seconds strongly increases the risk of UST development.

Thermal injuries are intricately related to laser power, laser time, and fluid irrigation. High frequency and/or high energy settings increase the total power. Therefore, the total power should be kept below 12–15 W and low frequencies should be used to remain within safe limits.

Another cause of UST is failed pyeloplasty. Since 1993, laparoscopic pyeloplasty (LP) became the treatment of choice for ureteropelvic junction obstruction. The rate of UST incidence reported following LP ranges from 2.5% to 10%, but in comparison to UST after ureterscopy, this rates seem to be stable.

3. UST treatment

For the past 60 yr, incision and dilation have been the two major techniques used to treat UST.

Percutaneous endourerotomy with a standard urethrotome was described by Wickham in 1983 [6]. Since then, results for cold incision, electrocautery incision, and laser

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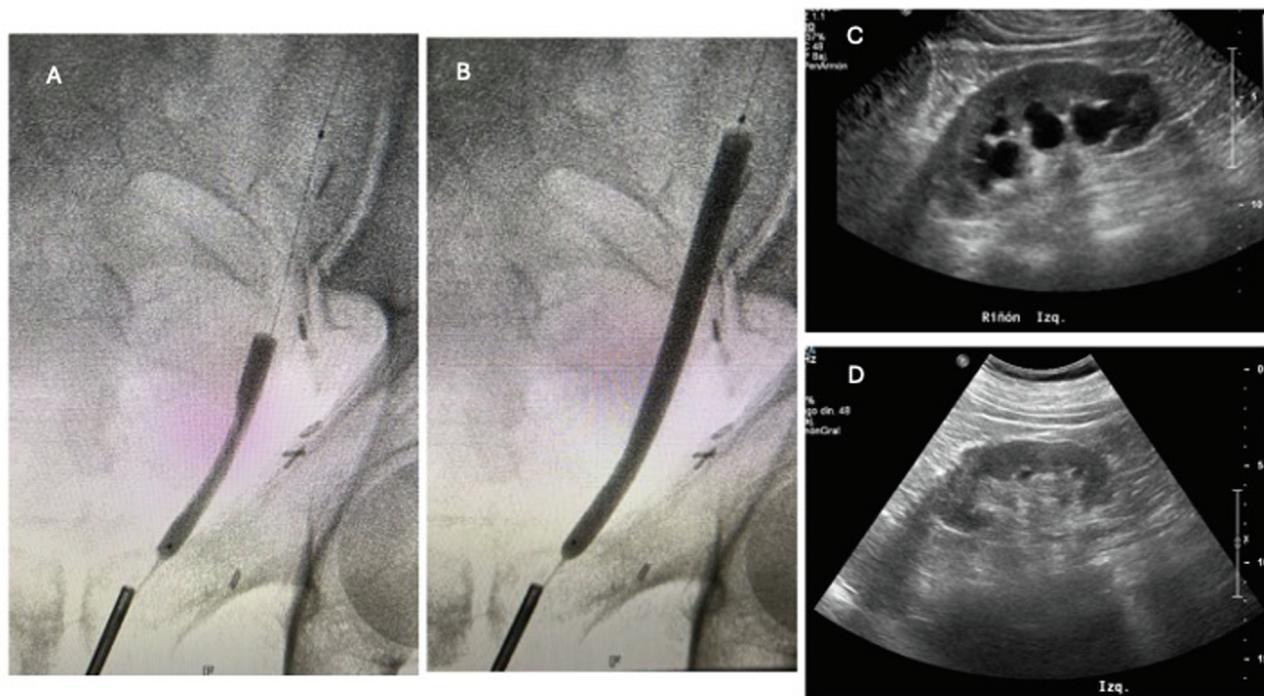


Fig. 1 – Imaging for a 67-yr-old patient with a 3-cm distal ureteral stricture. Dilation using a 6-mm balloon (A) without any coating and (B) with paclitaxel + dextran coating. (C) Preoperative ultrasound scan. (D) Follow-up ultrasound scan at 36 mo.

incision have been reported, with success rates ranging from 60% to 95% at median follow-up of 10 mo. Laser incision has the advantage of being suitable for use with semi-rigid or flexible scopes. Among the lasers available, thulium fiber laser produces a precise cut, has the shortest tissue penetration, can be used with smaller fibers, and has a broader coagulation zone.

The concept of self-healing after incision was described by Davis in 1948 [7]. One of the questions posed by the author is how the ureter, and the muscularis in particular, heals around the tube, which is key to understanding the mechanism of action of balloons coated with paclitaxel + dextran (P+D). Paclitaxel is an inhibitor of ureteral smooth-muscle cell proliferation and collagen production and thus regulates the healing process. Use of paclitaxel to inhibit ureteral smooth-muscle cell proliferation and collagen production in animal models was described more than 20 yr ago [8]. In addition, paclitaxel prevented hyperplastic proliferation of ureteral tissue in vitro [9].

Balloon dilation as a treatment for benign UST was described by Banner et al in 1983 [10]. The authors reported a success rate of 47% after 6 mo of follow-up. In 2019, Zeballos et al [11] reported results for UST dilation with a P+D-coated balloon after 1 yr of follow-up. Interestingly, dilation with coated balloons seems to add some benefits in relation to Davis's question regarding smooth-muscle cell proliferation. Paclitaxel-coated balloons received US Food and Drug Administration approval for UST treatment on the basis of results from a clinical trial by Virasoro et al [12].

Kallidonis et al [13] published results for UST treatment with paclitaxel-coated balloons in a cohort of 25 patients. The success rate at 1-yr follow-up was 88%.

In 2024, a balloon coated with P+D received Conformité Européenne approval for the treatment of fibrotic strictures. Use of this device in the ureter is supported by clinical data, but may require case-by-case clinical justification. A study on the use of dextran polymer to control drug delivery in peripheral arteries revealed a better release pattern in comparison to balloons coated with paclitaxel alone. In 2024 we reported results for 21 patients treated for UST following ureteroscopic or laparoscopic procedures with a P+D-coated balloon (2/1 ratio: 2.2 μ g paclitaxel and 0.7 μ g dextran). The success rate was 90% at median follow-up of 21 mo (Fig. 1) [14].

4. Conclusions

UST is a real problem in daily endourology practice and the incidence seems to be rising. As for any other iatrogenic event, prevention is the key.

Rapid treatment for impacted stones and proper laser, fluid, and time settings are unequivocal factors in strategies to prevent UST. The use of paclitaxel-coated balloons to prevent UST after ureteroscopy for impacted stones appears to be an interesting approach, but further research is needed to confirm the effectiveness of this strategy.

In our own daily practice, dilation with a P+D-coated balloon is the first-choice endoscopic treatment for UST. Time and further evidence will reveal whether we are on the right path.

Conflicts of interest: Pablo Contreras reports a consultant role for AR Baltic Medical. Javier Zeballos reports a speaker role for AR Baltic Medical. The remaining authors have nothing to disclose.

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Paclitaxel-Coated Balloon for Ureteral Strictures

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In 2025, stone disease prevalence and incidence are increasing worldwide, and a retrograde approach is the most common endourologic procedure.

Smaller scopes, suction scopes, suction ureteral access sheaths, and lasers with more power allow treatment of high-burden stones in a retrograde fashion, but unfortunately, after these retrograde procedures, an increasing number of ureteral strictures have occurred. These strictures lead to long-term patient morbidity, increased health care costs, and reduced quality of life.¹

The most dangerous scenario for ureteral strictures is impacted ureteral stones. The degree of hydronephrosis, ureteral wall thickness, and number of Hounsfield units of the ureteral wall below the stone have been described as predictors of stone impaction. Ureteral stricture is a significant complication following laser treatment for impacted stones and occurs in up to 25% of cases. If we add damages caused by the stone and thermal injuries, the combination of impacted stone, inadequate laser setting, low irrigation, and prolonged laser time can be “the sum of all fears.”²

As described by the Ralph Clayman group in 2016, mechanical damage occurring during a ureteroscopy can be managed with double-J stent placement and time, but thermal injuries are different. Boiled or burned ureters cannot be resolved with a double-J stent and time.³

Thermal injuries are caused by the rising temperature around the tip of the laser fiber. When temperature exceeds 43 °C, cell damage, protein coagulation, and

tissue injury occur, subsequently progressing to a ureteral stricture. Above 43 °C, the time required to cause cellular damage decreases by half. This means that, after a few seconds of using inadequate settings and/or low fluid irrigation, the probability of ureteral stricture development strongly increases.

Thermal injuries are intricately related to laser power, laser time, and fluid irrigation. High-frequency and/or high-energy settings will increase total power; therefore, the safety limit has been described as total power less than 12 to 15 watts and the use of low frequencies.

Other causes of ureteral strictures are failed pyeloplasty procedures. Since 1993, laparoscopic pyeloplasty became the treatment of choice for ureteropelvic junction obstructions. Ureteral stricture following laparoscopic pyeloplasty has been reported in between 2.5% and 10% of procedures, but compared with ureteral stricture after ureteroscopy, these numbers seem stable.

For the past 60 years, incision and dilation have been the 2 major techniques used to treat ureteral strictures.

Endoureterotomy with a standard urethrotome was described

by John Edward Wickham from St Bartholomew’s Hospital in London in 1983 using a percutaneous approach.⁴ After Wickham’s reported cold incision, electrocautery incision or laser incision was described with similar results, with a 60% to 95% success rate and a median follow-up of 10 months. Laser incision has the advantage of being used with semirigid to flexible scopes and, comparing different lasers, a thulium fiber laser produces a precise cut, has the shortest tissue penetration, and can be used with smaller fibers.

The concept of incision and self-healing was described by David M. Davis from Jefferson Medical College in Philadelphia in 1948.⁵ Among the questions Dr Davis asks in his paper, “How does the ureter and particularly its muscularis heal around the tube?” is the key to understanding the target of paclitaxel-coated balloons. Paclitaxel is an inhibitor of ureteral smooth muscle cell proliferation and collagen production, which regulates the healing process.

Balloon dilation was described by Marc Banner from Pennsylvania University in 1983 and had a success rate of 47%.⁶ In 2019, Javier Zeballos from Uruguay showed

the first use of a paclitaxel and dextran-coated balloon to treat a ureteral stricture.⁷ Interestingly, balloon dilation with coated balloons seems to add some benefits, answering Davis’s question related to smooth muscle cell proliferation.

The use of paclitaxel as an inhibitor of ureteral smooth muscle cell proliferation and collagen production was described in animal models more than 20 years ago. Also, prevention in hyperplastic proliferation of ureteral tissue was found in vitro. Paclitaxel-coated balloons received Food and Drug Administration approval for urethral strictures after the clinical trial published by Ramon Virasoro from Eastern Virginia Medical School in 2020.⁸

In 2022, Panagiotis Kallidonis from the University of Patras published the results of 25 patients with ureteral strictures treated with a paclitaxel-coated balloon, with a success rate of 88% after 1 year of follow-up.⁹

A paclitaxel and dextran-coated balloon received CE (conformité européenne) marking for the treatment of fibrotic strictures. Its use in the ureter is supported by clinical data but may require case-by-case clinical justification. The use of dextran polymer as

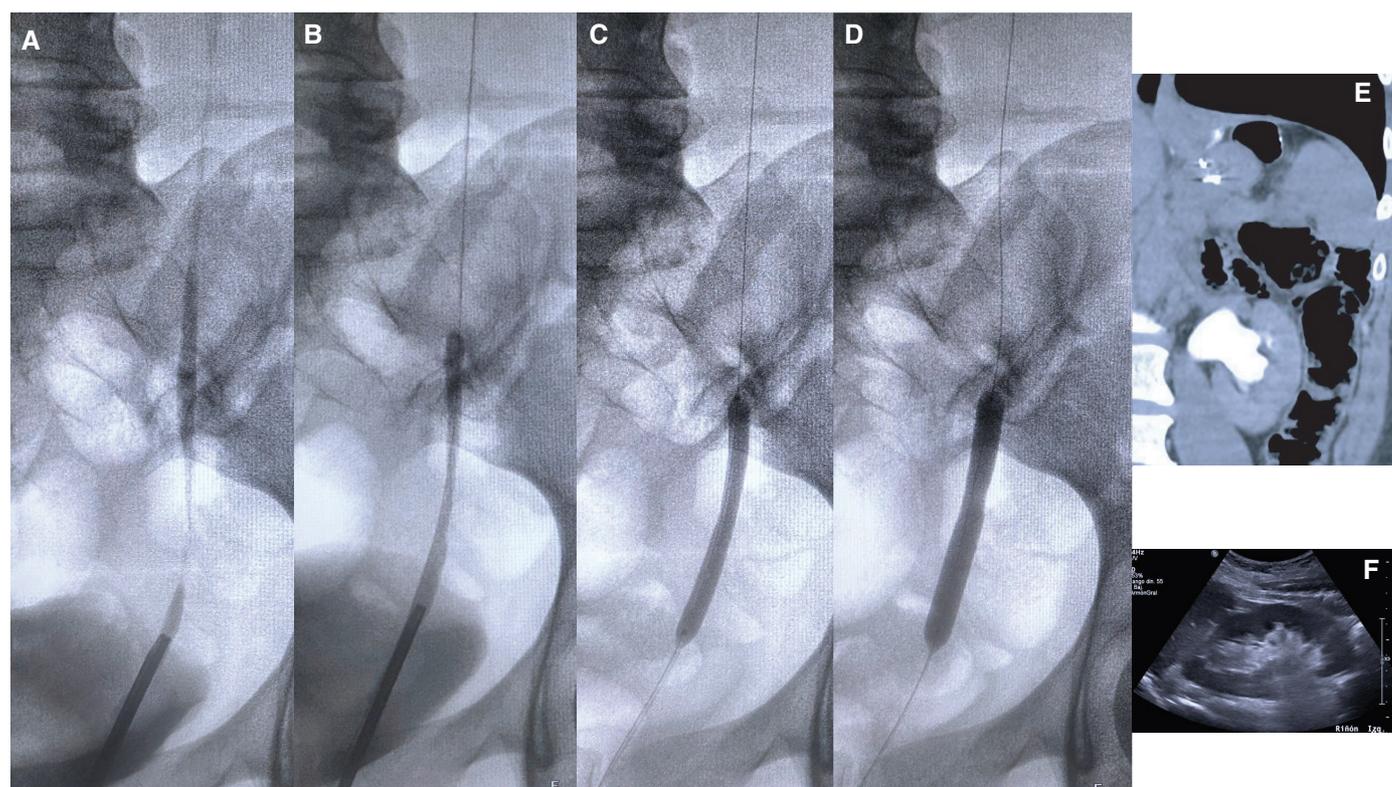


Figure. A 47-year-old patient with a left 3-cm distal ureteral stricture. A, Retrograde pyelography. B, Retrograde pyelography to determine the length of the ureteral stricture. C, Six-millimeter nondrug balloon dilation. D, Six-millimeter paclitaxel + dextran balloon dilation. E, Preoperative CT scan with moderate hydronephrosis. F, Follow-up ultrasound at 14 months.

the controller of drug delivery has been studied in peripheral arteries and showed a better release pattern compared with paclitaxel-only-coated balloons. In 2024, at the 41st World Congress of Endourology, our group from Uruguay and Argentina showed the results of 21 patients with ureteral strictures following ureteroscopic or laparoscopic procedures using a paclitaxel and dextran (2/1 ratio: 2.2 µg paclitaxel and 0.7 µg dextran)-coated balloon with a success rate of 90% and a median follow-up of 21 months (Figure).¹⁰

In summary, ureteral strictures are a real problem in our daily endourologic practice, and their incidence seems to be increasing.

As with any other iatrogenic event, prevention is the key.

Quick treatment for impacted stones and proper laser, fluid, and time settings are unequivocal parts of the strategies to prevent ureteral strictures. The use of paclitaxel-coated balloons to prevent strictures after ureteroscopy in impacted stones needs to be proven but appears to be an interesting idea.

There are proven benefits of using paclitaxel and dextran-coated balloons to perform dilation of a ureteral stricture. They act in the pathogenesis of the stricture by inducing fibrosis and recurrence.

In summary, paclitaxel-coated balloons provide added value to an old practice. ■

Conflicts of Interest: Dr Contreras is a consultant for AR Baltic Medical. Dr Zeballos is a speaker for AR Baltic Medical.

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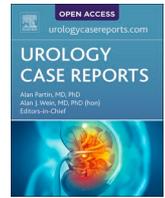
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“Ureteral stricture is a significant complication following laser treatment for impacted stones and occurs in up to 25% of cases. If we add damages caused by the stone and thermal injuries, the combination of impacted stone, inadequate laser setting, low irrigation, and prolonged laser time can be “the sum of all fears.”²”

“Paclitaxel is an inhibitor of ureteral smooth muscle cell proliferation and collagen production, which regulates the healing process.”

“Quick treatment for impacted stones and proper laser, fluid, and time settings are unequivocal parts of the strategies to prevent ureteral strictures.”

“There are proven benefits of using paclitaxel and dextran-coated balloons to perform dilation of a ureteral stricture. They act in the pathogenesis of the stricture by inducing fibrosis and recurrence.”



Endourology

Multimodal treatment for failed pyeloplasty: Description of a new technique

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ABSTRACT

In cases of failure after pyeloplasty, redo pyeloplasty remains the most definitive procedure, although it demands high technical expertise. In this context, we present a new multimodal surgical technique that combines laser endopyelotomy, dilation with a paclitaxel–dextran drug-coated balloon, and placement of a self-expandable ureteral stent for 3 months. Through 4 cases of failed pyeloplasty, we show resolution of ureteropelvic junction strictures after undergoing this multimodal procedure. The results of this series demonstrate a new treatment option in the challenging setting of pyeloplasty failure.

1. Introduction

Dismembered pyeloplasty remains the technique of choice for the surgical treatment of ureteropelvic junction (UPJ) obstruction, with success rates over 90 % regardless of the surgical approach.¹ Failure of this surgery is a serious complication that has been described in around 5 % of pyeloplasties.²

There are numerous series describing management after failure, with various techniques proposed. Some procedures with more modest success rates are balloon dilation (38.5 % in pediatric patients)³ and endopyelotomy (widely variable success rates between 37 and 87.5 %).^{4,5} Conversely, the procedure that has shown the highest effectiveness is redo pyeloplasty, with success percentages around 83–100 %.^{6,7}

As described, endourological techniques have lower success rates than redo pyeloplasty, while the latter has been reported as a technically demanding operation.⁸ Aiming to identify a new, safe, and effective procedure in this scenario, we present a multimodal technique combining three endourological procedures: laser endopyelotomy, drug-coated balloon dilation with paclitaxel, and placement of a self-expandable ureteral stent. We report outcomes through four clinical cases.

2. Case presentation and surgical technique

We present the case of a 52-year-old man with a history of right ureteropelvic junction obstruction who underwent laparoscopic

pyeloplasty. On the same day as the removal of the double-J stent (one month after the pyeloplasty), the patient presented to the emergency department with severe right lower quadrant renal colic. At that time, the patient exhibited more pronounced dilation of the right kidney than preoperatively (51 mm renal pelvis dilation versus 43 mm preoperatively) and impaired renal function (serum creatinine before pyeloplasty was 0.9 mg/dL and 1.4 mg/dL at the time of the renal colic). Suspecting pyeloplasty failure, a new double-J stent was urgently placed. Intraoperative retrograde pyelography was performed, revealing difficulty in contrast passage through the ureteropelvic junction obstruction, raising suspicion of restenosis. Following placement of the double-J stent, the pain episode resolved, and the patient was discharged 48 hours later with oral analgesia. The patient was then scheduled for surgery using the new surgical technique described in this paper, which is detailed below.

In all cases using this new technique, a prior computed tomography (CT) angiogram is requested to check for the presence of a polar vessel that could compromise the safety of the procedure. In the patient presented here, the presence of a polar vessel was ruled out. The procedure began with the patient in the lithotomy position. To access the ureter with the affected ureteropelvic junction (UPJ), a 9.5Ch semirigid ureterorenoscope was used. After passing a safety ureteral guidewire, it was advanced to the area of the UPJ stenosis, allowing for its evaluation under direct vision and fluoroscopy (Fig. 1).

Subsequently, endopyelotomy was performed, in our cases using a holmium laser with a 550- μ m fiber and laser parameters of 1J-10Hz. The incision was made at 7–8 o'clock in the clockwise position for the right

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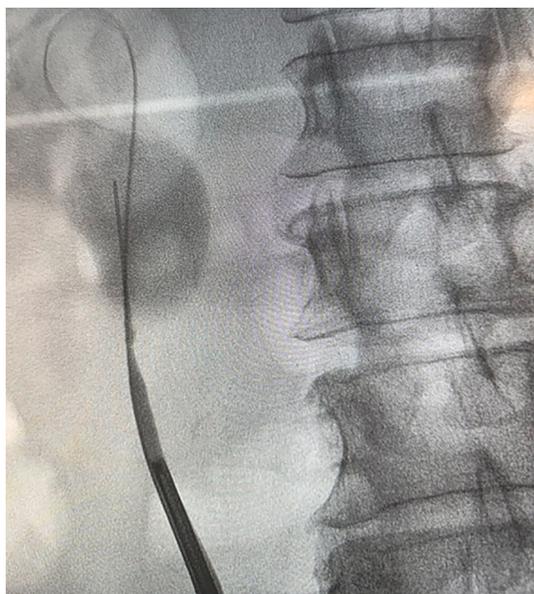


Fig. 1. Intraoperative retrograde pyelogram. Contrast is instilled through the ureterorenoscope, delineating the UPJ stricture. A safety guidewire and an additional wire used to facilitate scope advancement are also visible.

kidney, whereas it would have been made at 4–5 o'clock in the clockwise position for the left kidney (Fig. 2), always taking into account the possible presence of a polar vessel visualized on the previous CT angiography.⁹ Following removal of the ureterorenoscope, under fluoroscopic guidance, a paclitaxel-dextran balloon (Elutax-3, Baltic Medical®), in our case measuring 6 cm in length and 16 Ch, was retrogradely introduced. For the use of these balloons, a 0.018" ureteral guidewire is required beforehand. Once it was confirmed that the balloon was positioned over the incised area, it was dilated at 10 atm of pressure for 5 minutes (Fig. 3). Finally, after balloon removal, a self-expanding stent (Allium, Cardioliink®) was retrogradely placed over the treated area. In our case, the stent was 20 cm long and 9 mm in diameter (Fig. 4). The procedure concluded with the placement of a urinary catheter for 24 hours. Stent removal was performed surgically via retrograde ureteroscopy with semi-rigid instrument 3 months after placement. A table showing the characteristics of the patient described (case 1) and three other patients who underwent multimodal treatment is presented in Table 1. All cases were considered successful, as all showed improvement in dilation during the tests. Imaging studies showed almost complete resolution of hydronephrosis, and the mean elimination time on the renogram improved. Furthermore, in the three cases that had renal colic before surgery, the pain disappeared

afterward. It is worth noting that in all cases, hospitalization was only for one day. Regarding the complication in one patient, she developed a urinoma postoperatively. She presented to the emergency department with pain after hospital discharge and was diagnosed via CT scan with a urinary leak in the treated area of the urinary tract, with a 3 cm urinoma. The patient required placement of a double-J stent through an existing self-expanding stent, thus resolving both the pain and the urinary leak. The double-J stent was removed three months later, at the same time as the self-expanding stent.

Follow-up was one year in all cases, during which time there was no significant dilation of the treated kidney, nor any symptoms of pain.

3. Discussion

Pyeloplasty failure, although infrequent, poses a surgical challenge due to the inherent difficulty of redo pyeloplasty procedures, which are perceived by urologists as high-complexity surgeries with complication rates up to 20%.¹⁰ The procedure we present is attractive owing to its minimally invasive nature, the ability to perform it with basic endourological equipment, its technical simplicity, and the preliminary outcomes we observed in the 4 patients.

Reviewing the largest redo pyeloplasty series, success rates vary between 78% and 100%.^{8,10–13} Comparisons among series are difficult because cohorts include heterogeneous patients and approaches (open, robotic, or laparoscopic). Although our technique achieved success in all 4 cases, a clearly differentiating factor compared with redo pyeloplasty is operative time. For example, Swearingen et al. report operative times around 200 minutes for redo pyeloplasty,¹² and similar times are reported by Davis et al. in pediatric patients.¹¹ In our series, operative times ranged from 30 to 45 minutes—substantially shorter.

Specifically for endopyelotomy as a treatment for failed pyeloplasty, the technique offers moderate success (~34%) and is notably inferior to redo pyeloplasty (up to 100%).¹² Regardless of antegrade vs. retrograde access or energy source, endopyelotomy is well described and reproducible, technically easier than redo pyeloplasty, associated with low complication rates (~12%), and typically entails a short hospital stay of 1 day.¹⁴ In our technique we used holmium laser at 1 J/10 Hz, although other energy sources may also be suitable.

With respect to the paclitaxel-dextran balloon, experience in ureteral strictures is limited. In 2015, a basic research study in a porcine model concluded that paclitaxel reduced scarring markers in the ureter and diffused easily across all ureteral layers.¹⁵ The largest cohort of ureteral dilation with a paclitaxel-coated balloon was published in 2022 (25 patients; 88% success).¹⁶ Given its local anti-fibrotic mechanism and technical simplicity, the balloon appears to be an appealing option—particularly for selected patients like ours—although comparative studies with longer follow-up are needed to confirm durability and refine indications and protocols.



Fig. 2. Intraoperative endoscopic image. Laser endopyelotomy in a right-sided UPJ obstruction. Left panel (L): before incision. Right panel (R): after incision; the green laser fiber is visible.



Fig. 3. Intraoperative fluoroscopic image. Dilation with a paclitaxel–dextran drug-coated balloon passed over a 0.018" guidewire. Contrast extravasation outside the urinary tract is visible after the prior endopyelotomy.

Regarding self-expandable stents, evidence supporting their efficacy and safety in ureteral disease is increasing. Some recent studies support their use in specific profiles, such as ureteral urinary leaks or patients intolerant to double-J catheters.¹⁷ For strictures, reported success rates vary widely (34–80 %).^{18,19} In UPJ obstruction specifically, covered metallic stents have demonstrated adequate renal drainage (~85 %) and improved quality of life, generally as a medium-term control strategy rather than a definitive cure when the stent is left in place permanently.²⁰ The stent used in our series consists of a nitinol mesh embedded between two biocompatible membranes.¹⁷ This sandwich design prevents the metallic component from becoming embedded in the urothelium after deployment, while also reducing urinary leakage at the previously incised UPJ. A particularly useful feature in the present multimodal technique is the large diameter (9 mm), which we believe may favor healing with a wider caliber at the incised segment. Stent

length is another consideration: using long stents (20 cm in our series) facilitates subsequent removal by enabling distal access in the pelvic ureter.

Overall, we consider the described technique to be a promising option in the difficult context of pyeloplasty failure. While our series enables knowledge sharing and reproducibility of the technique, future series should address open questions: results when used as primary therapy for UPJ obstruction; outcomes in pediatric failure cases (not represented here); and the relative contribution of the balloon vs. the stent to overall success (whether either could be omitted). In our view, each component has a distinct role: the balloon delivers an anti-fibrotic drug locally, and the stent provides a wide-caliber scaffold. It would also be useful to assess whether factors such as stricture length or the presence of a crossing vessel affect the safety and efficacy of the multimodal treatment, these two characteristics are possibly factors that may limit the success of multimodal treatment. Therefore, proper patient selection is crucial. Preoperative examinations such as CT angiography or pyelography can provide valuable information to rule out long strictures or the presence of polar vessels that may compromise the success of multimodal treatment. Further studies with larger samples will be needed to confirm the success and safety of this new procedure.

4. Conclusion

The multimodal approach combining laser endopyelotomy, dilation with a paclitaxel–dextran drug-coated balloon, and temporary placement of a self-expandable ureteral stent appears to be an effective treatment option for cases of failed pyeloplasty. If its success is confirmed in larger series and across different patient profiles, it could represent a viable alternative in a scenario where redo pyeloplasty has thus far proven the most effective surgery.

CRediT authorship contribution statement

Jorge Panach-Navarrete: Writing – original draft, Investigation, Funding acquisition, Conceptualization. **Lorena Valls-González:** Methodology, Investigation. **Marcos Antonio Lloret-Durà:** Software, Conceptualization. **Ana Denia-Jàvega:** Data curation, Conceptualization. **José María Martínez Jabaloyas:** Supervision.

Declaration of competing interest

The authors declare that they have no conflict of interest.

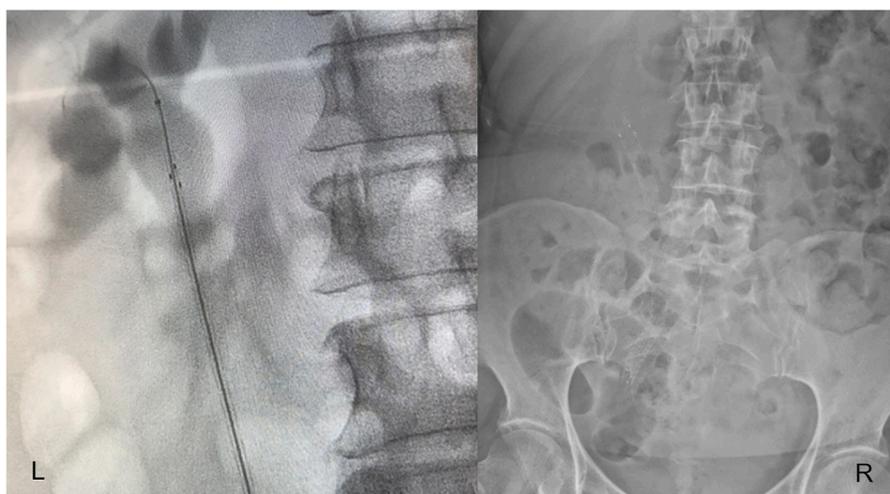


Fig. 4. Left panel (L): intraoperative fluoroscopic image showing placement of the self-expandable stent across the treated segment. The three adjacent radiopaque markers indicate the proximal end, which rests a few millimeters within the renal pelvis. Right panel (R): postoperative radiograph confirming the full stent length.

Table 1
Sample characteristics.

Patient	Sex	Age (years)	Side	Months since pyeloplasty	Pre-op serum creatinine (mg/dL)	Post-op serum creatinine (mg/dL)	Pelvic dilation pre (mm)	Pelvic dilation post (mm)	Renogram pre: Differential function (%)	Renogram post: T½ (min)	Renogram post: Differential function (%)	Pre-op pain	Post-op pain	OR time (min)	LOS (days)/Complications
1	Male	75	Left	120	1.11	1.03	30	16	38	19	38	No	No	45	1/None
2	Male	52	Right	3	1.37	1.19	51	10	49	9	49	Yes	No	35	1/None
3	Female	56	Right	24	0.74	0.70	3.6	0.3	37	35	38	Yes	No	30	1/Urinary leak
4	Female	65	Right	30	0.86	0.66	2.1	0.8	40	8	41	Yes	No	30	requiring double-J 1/None

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Title

Paclitaxel-Coated Balloon Urethroplasty (UBP) for Bladder Neck Stenosis: 9-Year Single-Centre Experience in 45 Patients with 60-Month Mean Follow-up

Authors

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Abstract

Balloon urethroplasty with paclitaxel (UBP) has been proposed as a minimally invasive alternative to repeat endoscopic incision or open reconstruction for post-surgical bladder neck (BN) stenosis. This abstract summarizes a single-centre experience using peripheral paclitaxel-coated angioplasty balloons, including ELUTAX, in BN strictures.

Between 2013 and 2024, 45 patients with BN stenosis, predominantly after prostate surgery (procedures for BPH 42%, radical prostatectomy 36%, radical prostatectomy plus radiotherapy 12%), were treated with UBP at a specialized centre in Uruguay. Mean age was 72 years (range 52–84) with a mean of two prior procedures. Only one case was de novo stenosis; the remainder occurred after urologic surgery, including cases with prior radiotherapy. The standardized four-step technique consisted of retrograde urethrocytography, guidewire placement, 5-minute predilatation with a non-coated balloon (7–12 mm), followed by 5-minute dilatation with a paclitaxel-coated balloon (8–10–12 mm), without post-procedural bladder catheterization.

Follow-up ranged from 12 months to 9 years (mean 60 months). Freedom from further invasive procedures at 5 years was 68% (30/45 patients). Failures occurred mainly within the first 2 years after treatment. Patient-

reported outcomes showed 95% overall satisfaction (external audit), with preservation of continence in 99% and improvement in quality of life in 99%. One case of complete incontinence (after radiotherapy + TUR) and one case of urinary retention related to low bladder tone were reported. The procedure was ambulatory, associated with mild, self-limited bleeding and discomfort, and did not preclude subsequent reconstructive surgery.

These data support that UBP using paclitaxel-coated balloons offers a clinically relevant, repeatable, and tissue-sparing option for BN stenosis, with acceptable long-term efficacy and a favourable safety and continence profile in an elderly, heavily pre-treated population.

Title

Minimally Invasive Combined Treatment: Mini Internal Urethrotomy (mUI) Plus Paclitaxel-Coated Balloon Uroplasty (UBP) for Recurrent Urethral Strictures

Authors

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Abstract

The available clinical evidence on a minimally invasive combined technique consisting of mini internal urethrotomy (mUI) followed by Paclitaxel-coated balloon uroplasty (UBP) for the treatment of recurrent urethral strictures, and reviews broader experience with Paclitaxel-coated dilation balloons in the urinary tract. The index case is a 46-year-old male on hemodialysis with a long history of urethral stricture disease, prior internal urethrotomy, self-dilatation, and two previous UBPs (durability 12 and 6 months, respectively), who achieved 36-month recurrence-free follow-up after the combined mUI+UBP procedure, with improved urinary flow, reduced pain, and rapid postoperative recovery. Building on this experience, a prospective randomized series of 33 male patients (30–80 years) with recurrent anterior and posterior urethral strictures and 2–4 prior endoscopic procedures was treated between June 2023 and May 2025 using a standardized two-step technique: mechanical incision/dilatation with a larger conventional or cutting balloon followed by Paclitaxel-coated balloon application. At 2–24 months of follow-up (mean 13 months), all 33 patients resumed spontaneous voiding immediately post-procedure; patients undergoing repeat procedures showed an approximate 20% improvement in initial flow, with systematically reduced bleeding, pain, dysuria, and need for analgesics. Early recurrence was observed in 3/33 patients within 14 months, predominantly in those with prior radiotherapy, and one patient developed complete obstruction in the context of previous transurethral resections of the bladder neck. Across more than 120 recent cases using peripheral angioplasty Paclitaxel-coated balloons (ELUTAX Baltic) in the urinary tract, no tissue necrosis or fistulae have been

reported. These data support the safety and promising mid-term effectiveness of mUI+UBP as a minimally invasive option for complex, recurrent urethral strictures and provide a clinical basis for defining the role of Paclitaxel-coated balloons in future urological practice.

Dextran / Paclitaxel-Coated Balloons for Urethral Strictures: Promising Short- and Mid-Term Outcomes

Presenters / Authors

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L. Blas, L. Rico, P. Contreras, N. Villasante

Abstract

Background:

Urethral stricture disease presents persistent clinical challenges due to dense fibrotic remodeling, high recurrence rates, and limited durability of minimally invasive therapies. Drug-coated balloons (DCBs) that deliver paclitaxel reduce fibroblast proliferation and may enhance long-term patency. This study evaluates the safety and performance of a dextran/paclitaxel-coated balloon (Elutax, AR Baltic Medical) for urethral strictures.

Methods:

A prospective study (Sept 2022–Feb 2024) enrolled 60 patients, of whom 37 completed full follow-up. Strictures ≤ 12 Fr and ≤ 3 cm were included, covering naïve strictures, recurrent strictures after DVIU, post-BMG, radiotherapy-induced strictures, and post-radical prostatectomy stenosis. All urethral anatomical segments were treated. Outcomes (IPSS, Qmax, PVR) were assessed at 4 and 12 months. No postoperative catheter was applied. Primary endpoints included symptom improvement, absence of urinary diversion, and freedom from re-intervention.

Results:

Overall clinical success was 80.4% at a median follow-up of 8.7 months. Success by location: bulbar 81.8%, penile 66.6%. In challenging subgroups: radiotherapy 50%, post-RP 66.6%, prior BMG urethroplasty 100% (n=2). Functional parameters improved substantially:

- Qmax: 7 → 16.4 mL/s (early); 14 mL/s (late)

- IPSS: 23 → 7 (early and late)

- PVR: 44% → 12% (early); 21% (late)

Results aligned with 12-month outcomes from the ROBUST I trial.

Conclusions:

Dextran/paclitaxel-coated balloons offer an effective, minimally invasive option for urethral strictures, particularly short bulbar lesions. Reduced success was observed after radiotherapy and prostatectomy. The catheter-free postoperative approach enhances patient comfort. Further comparative and long-term studies are recommended.

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Post Operative Ureteral Strictures Treated with Paclitaxel + Dextran Coated Balloon.

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Keyword:	Ureteroscopy, Stents
Manuscript Keywords (Search Terms):	coated balloon, ureteral stricture, paclitaxel
Abstract:	<p>Introduction: Post Operative Ureteral Strictures Treated with Paclitaxel + Dextran Coated Balloon. Ureteral strictures (US) are becoming more frequent following endourologic and laparoscopic procedures. In 2018, our group did the first communication of a female patient with US after laparoscopic pyeloplasty (LP) treated with a Paclitaxel + Dextran coated balloon (PDCB) with promising results.</p> <p>The aim of our study was to assess the safety and efficacy of PDCB dilation for endoscopic treatment of post-operative US.</p> <p>Materials and Methods: Between January 2018 and January 2024, a prospective non-randomized trial was carried out. All patients had post-operative US, 7 post laparoscopic pyeloplasty and 14 post ureteroscopy. Step 1 was a retrograde pyelography. Step 2 was a dilation with a 6 mm. non coated drug balloon (VIAR-OTW Baltic Medical) during 5 minutes non-drug coated balloon dilation was performed at 10 atmospheres of pressure. Step 3 was 5 minutes dilation with PDCB was performed (ELUTAX Baltic Medical). No ureteral stents or open end stents were used after the procedure. Success was defined as the absence of hydronephrosis in ultrasound or contrasted CT scan at 3 months of the procedure.</p> <p>Results There were 11 women and 10 men. Mean age was 54 years old. The median length of the US was 2.11 cm (1- 6). 11 (52.4%) patients had US in the abdominal part of the ureter and 10 (47.6%) in the pelvic part. Median follow-up was 22 months (4 – 58 months). The success rate was 90.5%. There were two failures (10%). Complication rate was 19.5 %, with pain in 3 patients and renal function impairment in 1 patient. The treatment for these four patients was a double-J stent insertion.</p> <p>Conclusion Post operative US treated with PDCB dilation had a high success rate and low-grade complications. Larger studies and longer</p>

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5 AOE=area of stenosis
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7 LP=laparoscopic pyeloplasty
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9 PDCB=Paclitaxel + Dextran coated balloon
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11 US= Ureteral strictures
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5 Post Operative Ureteral Strictures Treated with Paclitaxel + Dextran Coated Balloon.
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Post Operative Ureteral Strictures Treated with Paclitaxel + Dextran Coated Balloon.

Introduction

Ureteral strictures (US) are becoming more frequent following endourologic and laparoscopic procedures [1]. Despite the described endoscopic, laparoscopic, robotic-assisted and open procedures to the US treatment [2], the success is generally uncertain, and recurrences are frequent [3-5].

Paclitaxel, one of the essential medicines by the World Health Organization, is a natural chemotherapeutic compound with antiproliferative properties that inhibit smooth muscle cell proliferation and collagen production by impeding the disassembly or depolymerization of microtubules [6,7].

The safety and efficacy of Paclitaxel-Coated Balloon have been described for urethral strictures in 2020 and approved by the FDA in 2021 for the treatment of bulbar urethral strictures [8]. In 2018, our group did the first communication of a female patient with US after laparoscopic pyeloplasty (LP) treated with a Paclitaxel + Dextran coated balloon (PDCB) with promising results [9]. Due to that encouraging experience, we ran a prospective non-randomized trial for post-operative US using a PDCB. PDCB use in the ureter is supported by clinical data but may require case-by-case clinical justification.

The aim of our study was to assess the safety and efficacy of PDCB dilation for endoscopic treatment of post-operative US.

Materials and Methods

Between January 2018 and January 2024, a prospective non-randomized trial was carried out.

Data from two centers: Uroplastia Uruguay (Montevideo, Uruguay) and Hospital Alemán (Buenos Aires, Argentina) were recorded.

All patients had post-operative US, 7 post laparoscopic pyeloplasty and 14 post ureteroscopy. Patients with malignant ureteral obstructions were not eligible for this trial. All patients were treated following the same protocol. Antibiotic prophylaxis was Cefazolin 2 grams during anesthesia induction. With the patient under general anesthesia in an RX table, a retrograde pyelography was performed using a 5 French open-end catheter (Figure 1 and Supplementary video) Characterized the area of stenosis (AOE), the C arm was fixed and two marks below and above the AOE were attached to the pyelography image on the monitor. Using a 0.018 wire, a 6 millimeters non coated drug balloon (VIAR-OTW Baltic Medical) was positioned covering the full length of the AOE and 2 centimeters below and above it. After that, 5 minutes non-drug coated balloon dilation was performed. The balloon used was 6 millimeters, insufflated with contrast solution at 10 atmospheres of pressure. After that, 5 minutes dilation with PDCB was performed (ELUTAX Baltic Medical) insufflated with contrast solution. The balloon used was 6 millimeters one, at 10 atmospheres of pressure. The balloon's length was chosen depending on the length of the AOE + 4 cm. (2 above + 2 below)

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3 All the patients with previous pyeloplasty had a nephrostomy tube at the time of the
4 procedure. The nephrostomy was removed a week after the procedure after an
5 antegrade pyelography showing adequate passage of contrast through the US. No
6 ureteral stents or open-end stents were used after the procedure in the group of
7 patients with US following ureteroscopies. Success was defined as the absence of
8 hydronephrosis in ultrasound or contrasted CT scan at 3 months of the procedure.
9 Complications were recorded according to Clavien-Dindo classification.
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12 13 Results

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15 Data from 21 consecutive patients were recorded. Demographic data can be found in
16 Table 1. There were 11 women and 10 men. The mean age was 54 years old. The
17 median length of the US was 2.11 cm (1- 6). 11 (52.4%) patients had US in the
18 abdominal part of the ureter and 10 (47.6%) in the pelvic part. The median follow-up
19 was 22 months (4 – 58 months). The success rate was 90.5%, and 95 % of patients
20 reached 12 months of follow-up with zero hydronephrosis. There were two failures
21 (10%), one was a patient with the background of more than 20 ureteroscopies in the
22 same ureter treated with a long-term JJ.
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26 The complication rate of Clavien 3b or higher was 19.5 %, with pain in three of them
27 and renal function impairment in one patient. The treatment for these four patients
28 was a double-J stent insertion. Results are summarized in table 2.
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31 Discussion

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33 In our group of 21 patients, PDCB was effective and safe to treat patients with post-
34 operative US.

35 The incidence of US following ureteroscopy is between 0,3 – 4,9 % of cases [9]. That
36 number seems to be increasing because retrograde intrarenal surgery is becoming
37 more and more common every day. Smaller scopes, suction scopes, suction ureteral
38 access sheath and laser with more power allow to treat high burden stones in
39 retrograde fashion but unfortunately an increasing number of US after ureteroscopy
40 have happened in this scenario [1-4].
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44 Since 1993, the laparoscopic approach became the treatment of choice for
45 ureteropelvic junction obstruction. US following this treatment has been reported
46 between 2,5 and 10 % [5].
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49 Many treatment options have been described during the years for US. Open,
50 laparoscopic and endoscopic treatments are part of the armamentarium, but
51 procedures are complex, the average success rate is uncertain, recurrence are
52 frequent, and nephrectomies are the final outcome in certain cases [1-4].
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55 The use of paclitaxel as inhibitor of ureteral smooth muscle cell proliferation and
56 collagen production have been described in animal models more than 20 years ago
57 [6,7], but there is only one published clinical series of US using PCBD. Kallidonis et al.
58 published in 2022 a cohort of 25 patients with 88 % of radiologic success rate with 1
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3 year of follow-up [10]. In our study, we checked hydronephrosis with ultrasound every
4 3 months, the first patient was treated in 2018 and the last one in 2023. The median
5 follow-up was 22 months.
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8 Our success rate was similar to the Kallidonis group (90% vs 88%), and there were no
9 needs of retreatment in our group compared with 30 % in the Kallidonis series [10].
10 The use of dextran polymer as controller of the drug delivery has been studied in
11 peripheral arteries showing a better release pattern compared with paclitaxel only
12 coated balloons. To our knowledge, our study is the first one using PDCB dilation in the
13 ureter. There is an experience published by one of our investigators using PDCB for
14 urethral strictures showing a success rate of 82 % at 12 months. The Robust I using
15 only paclitaxel coated balloon dilation for urethral strictures, showed a 70 % success
16 rate at 12 months (8). If the use of dextran as vehicle could explain the zero re-
17 treatment rate in our group is an hypothesis, but that hypothesis needs to be proven.
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21 Regarding complications, four of 21 patients returned to the emergency room. Three
22 of them complaining about back pain and 1 due to impairment of renal function. Two
23 patients had pain the first week after dilation and the renal impairment was check 3
24 days after the procedure. The last one patient had pain 3 years after the procedure.
25 The 3 patients with back pain were treated with JJ insertion. In two of them, the JJ was
26 removed after 4 and no hydronephrosis or back pain was observed in the follow-up.
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30 About the failures, the first one was the first patient of the series, who after 3 years of
31 follow-up had a stricture recurrence and preferred a long-term JJ insertion. The second
32 one was a patient with renal function impairment (creatinine level 3.9 mg/dl). She did
33 not have hydronephrosis but we decided, with the nephrologist, to insert a long-term
34 double J because the patient had a borderline pre operative creatinine (2.07 mg/dl)
35 level and a contralateral non-functional kidney. The patient decided to keep inserted
36 the JJ. Even the patient had less hydronephrosis after the balloon dilation, it was
37 considered as a failure.
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41 We believe that the back pain was due to edema in the AOE, because all the 3 patients
42 solved the US after removing the JJ.
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45 About the follow-up, it was similar to Kallidonis's trial [10], but we understand that
46 PDBC change an obstructive scar for and open scar. Due that we performed ultrasound
47 every 3 months the first year and every 6 months after that. Closed follow-up is
48 needed to be sure that the results are sustainable during the time.
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51 It is interesting to remember that endouretotomy with a standard urethrotome was
52 described by John Edward Wickham from St Bartholomew's Hospital in London in 1983
53 using a percutaneous approach. After Wickham's report cold incision [12], electrocautery
54 incision or laser incision have been described with similar results between 60 to 95 %
55 of success with a median follow-up of 10 months. The concept of incision and self-
56 healing was described by David M. Davis from Jefferson Medical College in Philadelphia in
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3 1948 [13]. Amongst the questions Dr. Davis enlists in his study, “How does the ureter
4 and particularly its muscularis heal around the tube?” is the key to understand the
5 target of Paclitaxel + Dextran coated balloons. Paclitaxel is an inhibitor of ureteral
6 smooth muscle cell proliferation and collagen production which regulates said healing
7 process. Balloon dilation was described by Marc Banner from Pennsylvania University in
8 1983 [14] with a success rate of 47% after 6 months of follow-up. Interestingly, balloon
9 dilation with coated balloons seems to add some benefits answering Davis’s question related
10 with smooth muscle cell proliferation.
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16 Finally, there were some limitations of our trial. Despite we added the initial
17 experience of this novel treatment for two institutions, the small sample and the lower
18 follow up to define the success of this treatment are the most important bias of the
19 present study. Another important limitation was the absence of randomization and the
20 lack of a control group.
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23 Conclusion

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26 Post operative US treated with PDCB dilation had a high success rate and low-grade
27 complications. Larger studies and longer follow-up are needed to confirm these
28 results.
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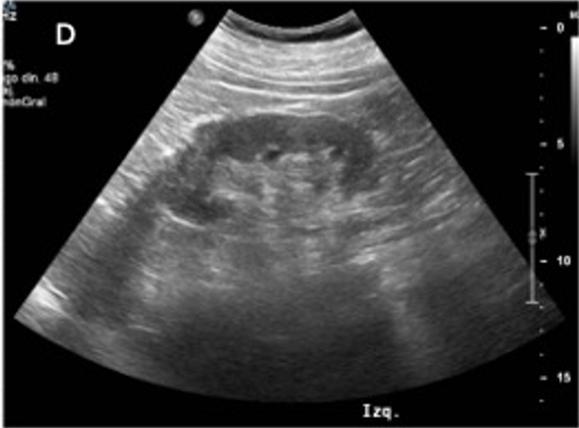
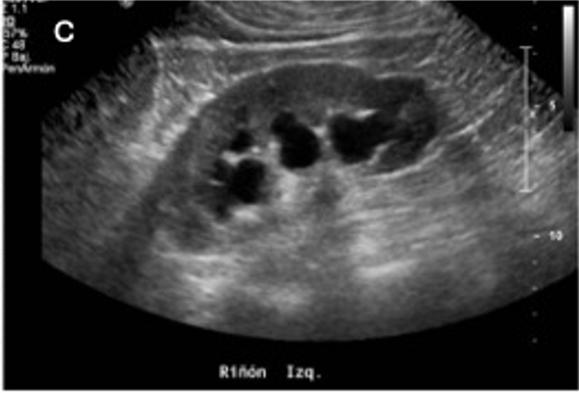
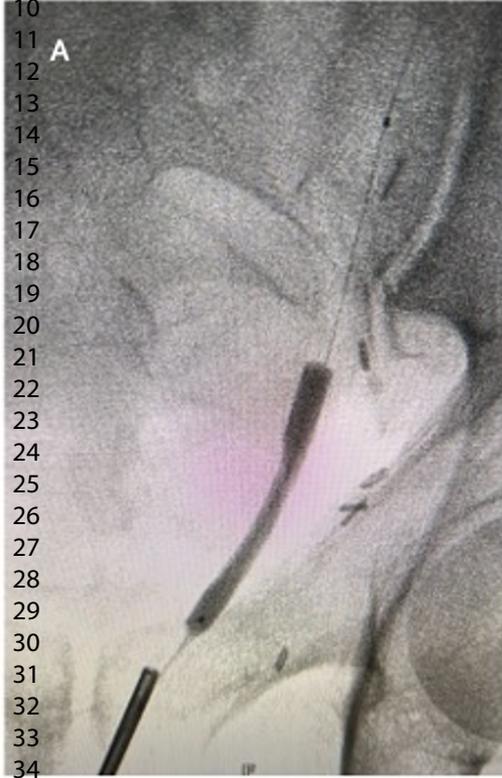
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Pte	Age	Gender	Location	Length	Side	Previous URS/Lap
1	49	female	pelvic	4 cm.	left	urs
2	35	male	abdominal	1.5 cm.	right	urs
3	74	female	abdominal	2 cm.	left	urs
4	69	male	pelvic	1 cm.	right	urs
5	66	male	pelvic	3 cm.	left	urs
6	61	female	pelvic	1 cm	right	lap
7	63	female	pelvis	1,5 cm	left	urs
8	56	female	abdominal	1 cm.	left	urs
9	65	female	pelvic	2 cm	right	urs
10	54	male	pelvic	2 cm.	right	urs
11	75	female	pelvic	6 cm.	right	urs
12	54	male	pelvic	1 cm	right	urs
13	49	male	pelvic	1 cm	left	urs
14	32	female	abdominal	2 cm.	right	lap
15	52	female	abdominal	2 cm.	left	lap
16	65	female	abdominal	2 cm.	right	lap
17	54	male	abdominal	4 cm.	left	urs
18	75	female	pelvic	1 cm.	right	urs
19	23	male	abdominal	3 cm.	right	lap
20	26	male	abdominal	2,5 cm.	right	lap
21	45	male	abdominal	1 cm.	left	lap

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Pte	Success	Clavien-Dindo	Nephrostomy	JJ pre	JJ post	Followup
1	no	3b	no	yes	yes	36 months
2	yes	0	no	yes	No	21 months
3	yes	3b	no	yes	yes	20 months
4	yes	0	no	yes	No	36 months
5	yes	0	no	yes	No	36 months
6	yes	0	no	yes	No	22 months
7	no	3b	no	yes	yes	1 months
8	yes	0	no	yes	No	16 months
9	yes	0	no	yes	No	18 months
10	yes	0	no	yes	No	14 months
11	yes	0	no	yes	yes	29 months
12	yes	0	no	yes	yes	40 months
13	yes	0	no	yes	yes	18 months
14	yes	0	no	yes	no	26 months
15	yes	0	no	yes	yes	30 months
16	yes	0	yes	no	no	30 months
17	yes	0	no	yes	no	13 months
18	yes	0	no	yes	no	13 months
19	yes	0	yes	no	no	12 months
20	yes	0	yes	no	no	12 months
21	yes	0	yes	no	no	14 months

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Figure 1: 67 year old patient with 3 cm distal US. A 6 mm non drug balloon dilation. B 6 mm Paclitaxel Dextran coated balloon. C Pre operative ultrasound. D 36 months follow-up ultrasound



The role of paclitaxel-coated balloons in treating ureteral or anastomotic strictures: current evidence and future directions from EAU endourology

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Abstract

Background This review aims to summarize the current literature on the use of paclitaxel-coated balloons (PCB) for the management of ureteral strictures (US), an area where minimally invasive alternatives to reconstructive surgery remains limited.

Methods A comprehensive search of the literature was conducted through September 2025. Case reports and case series published as full texts were included. The review protocol was prospectively specified and registered on the PROSPERO database (CRD420251126296). Additional references were identified from bibliographies of relevant articles. The review followed PRISMA guidelines, and a flowchart was constructed to illustrate the study selection process. Risk of bias was assessed.

Results Eight studies met the inclusion criteria: four clinical reports/series and four animal studies. Among 58 reported cases, the mean age at intervention was 62 years, with a male-to-female ratio of 34:24. The main etiologies of stricture included ureteroenteric anastomosis (n=25), post-ureteroscopy for urolithiasis treatment (n=19), post-laparoscopic pyeloplasty (n=7), iatrogenic surgical complications (n=5), transplanted kidney (n=1), and post-radiotherapy changes (n=1). The mean stricture length was 27.9 mm. Anatomical distribution comprised upper ureter (n=3), lower ureter (n=8), ureterovesical anastomosis (n=1), ureteroenteric anastomosis (n=25), abdominal ureter (n=11), and pelvic ureter (n=10). Mean follow-up was 20.7 months. Success criteria varied across series but generally included absence or improvement of hydronephrosis at 1–12 months. The overall success rate was 86.2% (50/58). Complications occurred in 5 patients (10.6%), most of which were minor and managed conservatively with stenting or antibiotics. The methodological quality of available studies revealed moderate risk of bias.

Conclusion PCB appears to be a promising, safe, and effective endourological option for the treatment of ureteral strictures, particularly in patients unsuitable for major reconstruction. However, current evidence is limited to small case series and animal models. Prospective, multicenter studies with standardized outcome measures and longer follow-up are essential to validate these encouraging early results and to define the role of PCB in future clinical practice.

Keywords Ureteral stenosis · Ureteral balloon · Paclitaxel · Drug-coated balloon

Abbreviations

PCB	Paclitaxel-coated balloons
US	Ureteral stricture

Introduction

The prevalence of urolithiasis is increasing worldwide, with rates varying by geographic location, reaching up to 20% [1]. This has led to a revolution in the endoscopic treatment of stone disease, with important technological advances. The minimally invasive management as the flexible and semirigid ureteroscopy, has shown an exponential growth and currently is one of the most frequent surgical options chosen by endourologists for ureteral and kidney stones treatment [2].

Despite all the advantages of these endoscopic surgeries and the international guidelines recommendations, there are intraoperative and postoperative complications, such as the ureteral strictures (US). The incidence of this much-feared complication is fortunately very low (0.7%), but ranges from 0.30% to 23.81% [3]. Furthermore, this can rise to 34% in patients with impacted ureteral stones [4]. The increase in the prevalence and endoscopic management of stone disease, the real incidence of US after ureteroscopy could be underreported. Reported risk factors for US include preoperative hydronephrosis, ureteral perforation, and stone impaction [5]. Recently, concern has been placed in the thermal effect of the different lasers on the ureteral wall during the endoscopic lithotripsy, especially with the widespread use of the high-power lasers [6].

However, not all US are of iatrogenic etiology. There are congenital factors (pelvic ureteric junction obstruction) or secondary factors, such as ischemic cause (post radiotherapy) or ureteroenteric strictures after radical cystectomy with urinary diversion. US are a real healthcare concern, and postoperative management is challenging and often an endourological nightmare, significantly affecting the quality of life if not properly treated. The gold standard option for ureteral strictures management remains reconstructive surgery (open, laparoscopic, or robotic surgery). But due to the high postoperative morbidity and some patients being unfit for a major surgery, the endourological management is usually the preferred first option minimally invasive treatment [7].

Laser endoureterotomy has been chosen for many years as a minimally invasive option for US management with encouraging initial success and the possibility of avoiding major surgery. However, the durability of the endoscopic management remains uncertain with a success rate reported from 50% to 80% [8]. Ureteral balloon dilatation is another valid non-invasive alternative, and it could be performed

before or after the laser incision, to increase the success. The rate of success of the ureteral balloon dilatation is reported as 54% [9]. Nevertheless, heterogeneity of the reported series and the variable follow-up duration explain the high recurrence with the necessity for long-term stent placement that directly and negatively impacts the quality of life of these patients.

Recently, the Paclitaxel-coated balloons (PCB) have emerged as a promising treatment in the urethral stenosis with a phase III trial that reported the success rate up to 75% [10]. The pathophysiology of urethral or ureteral fibrosis and the stenosis of the lumen are directly related with the excess of type 3 collagen, and the Paclitaxel is well known to stabilize cellular microtubules and inhibits cell replication by reducing the production of collagen. Furthermore, Paclitaxel inhibits the fibroblast growth and scar formation and avoids the fibrotic reaction in the stenosis etiology [11]. In view of these interesting results, the PCB effect and success could be extrapolated to ureteral stenosis because the mechanisms of the stricture formation are similar. However, the current evidence of the application of the PCB in ureteric stenosis remains limited. The aim of this systematic review is to provide an overview of the PCB outcomes and success rate in the treatment of ureteral strictures. It therefore aims not to draw definitive efficacy conclusions but to provide a structured overview of early findings and methodological trends to inform future research.

Materials and methods

Literature search strategy

We used a comprehensive search strategy. Search terms used were (Ureteral Strictures) AND (Drug-Coated Balloon OR Paclitaxel-Coated Balloon) AND (Optilume™ OR ELUTAX™ OR Ranger™ OR Lutonix™). In addition, we manually searched the relevant references to avoid any omissions. The following databases were searched: PubMed, Web of Science, and Cochrane Library to identify articles up to October 2025, with only studies published in English. The review protocol was specified in advance and registered on the PROSPERO (international prospective register of systematic reviews) website (register number: CRD420251126296). References identified in a first search of the literature and bibliography were also assessed. Case reports and series published as full texts were included. PRISMA guidelines were used, and a flowchart was constructed to reflect the selection process.

Given the limited evidence available, we included all full-text clinical studies, case series, and case reports involving human patients treated with PCB for ureteral strictures,

Table 1 Eligibility criteria of the systematic review

Eligibility criteria
Human (female or male) or animal
Balloon dilation procedures where paclitaxel is delivered locally to the stricture site via a drug-coated balloon to inhibit fibrotic tissue proliferation and reduce recurrence
Case series, case reports, or experimental studies
No restriction in date of publication
English language
Articles in peer-reviewed journals and abstract from major congresses (EAU, WCE, AUA, SIU)
<i>EAU</i> European association of urology, <i>SIU</i> Société internationale d'urologie, <i>WCE</i> World congress of endourology, <i>AUA</i> American urology association

Table 2 Baseline characteristics of studies included

Author	Reference	Year	Study design	Type	Number of patients/samples
Kallidonis	[12]	2022	Case series	Human	25
Contreras	[13]	2024	Case series	Human	21
Rico	[14]	2024	Case report	Human	1
Rico	[15]	2025	Case series	Human	11
Kram	[16]	2018	Experimental	Rat	48
Li	[17]	2024	Experimental	Pig	6
Liourdi	[18]	2014	Experimental	Pig	9
Liatsikos	[19]	2007	Experimental	Pig	10

as well as preclinical animal studies exploring the safety, pharmacology, or histological effects of PCB on the ureter. Abstracts and conference reports were included only if they contained unique patient data. This inclusive approach was chosen to provide a comprehensive descriptive synthesis of the current state of knowledge in an emerging field where large prospective trials are not yet available.

Study selection, data extraction

Two authors (L.R and L.B) independently screened all titles, abstracts, and full texts identified by the search with discrepancies on eligibility criteria resolved by consensus and/or discussion and extracted data from the included reports using standardized and piloted forms. Table 1 shows the inclusion criteria.

The following variables were then extracted when available from each of the selected studies: authors, year and journal of publication, number of patients included, and US characteristics (mean length, location and side of the US). Additionally, we examined the etiology of the US

(iatrogenic, after pyeloplasty or ureteroenteric strictures). Treatment success at the latest follow-up was also collected. When further information was necessary, authors were contacted.

Demographic and clinical data were summarized as means, medians, standard deviation (SD), and range, as appropriate or with frequencies and percentages. Baseline values were expressed as mean with SD or median with interquartile range (IQR). All statistical analyses were performed with Stata v.14 (College Station, TX, USA). Due to a low number of patients and lack of comparative studies, a meta-analysis was not performed.

Results

Study selection and characteristics

From the initial search, we identified 89 studies in PubMed, 7 studies in Web of Science, and 0 studies in Cochrane library. Six additional studies were added after the latest search update. After removing duplicates, we screened 94 titles and abstracts, reviewed 16 full-text articles, which led to the identification of eight articles comprising 58 patients that met our inclusion criteria [12–19]. Exclusion criteria encompassed non-English articles, systematic reviews, narrative reviews, opinion letters, expert opinions or opinion articles, clinical guidelines, studies that did not clearly specify the use of paclitaxel, and grey literature due to insufficient detail or lack of peer review. Eight full-text articles assessed for eligibility were excluded: four studies for evaluating paclitaxel in urinary tract locations other than the ureter; one article was excluded due to overlapping patient characteristics from procedures performed at the same institution; two studies investigated drug-eluting agents that did not involve paclitaxel; and one study reported no applicable cases.

Supplementary Fig. 1 shows the flowchart of study selection, and Table 2 shows the main characteristics of the studies included. It is important to clarify that the patient described in the clinical case, who underwent application of a PCB for a ureteroileal stricture, is not included in the patient series reported in the referenced abstract.

Table 3 shows the characteristics and perioperative surgical outcomes of the included studies. Table 4 shows the characteristics of studies in animals.

Two full manuscripts and two abstracts involving humans were found. For the 58 cases included, the mean age at surgery was 62.0 years (Table 3). The male: female ratio was 34/24 (1.41). The underlying indications were ureteroenteric strictures ($n=25$), post-ureteroscopy for urolithiasis treatment ($n=19$), transplanted kidney ($n=1$), post-laparoscopic

Table 3 Characteristics and perioperative surgical outcomes of in-vivo studies included

Author	Reference	Number of patients	Type	Gender	Age	Lesion length	Follow-up	Stricture location	Success rate	Complications
Kallidonis	[12]	25	Ureteroenteric anastomosis ($n=13$); lithiasis ($n=5$), post-surgical complications (iatrogenic $n=5$), transplanted kidney ($n=1$) and post-radiotherapy ($n=1$).	11 female and 14 males	Mean 66.5 ± 12.9 years	Mean 40 ± 28.5 mm	Mean 36 ± 10.5 months	Upper ureter (12%), lower ureter (32%), Uretero-vesical anastomosis (4%), and ureteroenteric anastomosis (52%)	88% at 1-year, defined as no hydronephrosis or improvement of existing residual dilatation on radiological follow-up (CT-scan or Tc-99 m DTPA renogram) post-procedure following the removal of the nephrostomy	One case of febrile urinary tract infection in a female patient (acute pyelonephritis). Treatment antibiotic
Contreras	[13]	21	Post laparoscopic pyeloplasty ($n=7$) and post ureteroscopy ($n=14$)	11 female and 10 males	Mean 54 years	Mean 21 ± 12.5 mm	Mean 14 ± 5.5 months	Upper ureter (52.38%) Lower Ureter (47.62%)	90%, defined as the absence of hydronephrosis in ultrasound or contrasted CT scan at 3 months of the procedure	Back pain ($n=3$) and renal function impairment ($n=1$). Treatment a double J insertion
Rico	[14]	1	Ureteroenteric	male	55 years	10 mm	12 months	Ureteroileal anastomosis	100%	No
Rico	[15]	11 and 15 catheters	Ureteroenteric	9 male and 2 female	Mean 68 years	Mean $15 \text{ mm} \pm 8.5 \text{ mm}$.	Mean $7.72 \text{ months} \pm 3.13$.	Ureteroileal anastomosis. Six patients (54.4%) radical cystectomy with orthotopic ileal neobladder and 45.5% Bricker urinary diversion	72.7% defined success as no signs of hydronephrosis at 30 days postoperative, no postoperative increase of the serum creatinine level or no need of nephrostomy reposition	Not reported

NA Not available

Table 4 Characteristics and outcomes of experimental studies

Author	Reference	Number of cases	Type	Gender	Intervention	Method study	Results
Kram	[16]	48	Animal	Rat	48 male 9-week-old rats underwent either sham surgery ($n = 16$) or ureteroureterostomy with sutured anastomosis, and stenting with either a PTX-DCB ($n = 16$) or an uncoated stent ($n = 16$)	Daily intraperitoneal injections of 5-bromo-2-deoxyuridine for the first 8 days, and sacrificed on day 28. Healing and was assessed histologically and immunohistochemically	In vivo, wound healing was found at the ureteral anastomosis. Proliferation of urothelial cells was lower with PTX-coated stents than uncoated stents
Li	[17]	6	Animal	Pig	Control group 3 pigs with ureteroscopic thermal injury induced stenosis. Experimental group 3 pigs with ureteroscopic thermal injury induced stenosis, followed by PTX DCB on one side and plain balloon on the other side	Drug in blood and local tissues immediately and 4 weeks after dilation, and perioperative complications	All procedures were successful but one. No complications. At 28 days, average PTX in ureteral tissues was 51.1 ng/mg. PTX in blood samples was below quantification limit. The normal ureteral diameter was 6.1 mm, luminal stenosis was 2.8, and increased to 5.6 mm after PTX-DCB. The initial effect of PTX-DCB was better than plain balloons
Liourdi	[18]	9	Animal	Pig	9 PTX balloon dilatation were inserted in right ureter and 9 conventional balloon dilatation in left ureter	Animal sacrifice and ureter removal: Group A immediately, Group B after 12 h, and Group C after 24 h. 2 samples from each ureter for nuclear magnetic resonance spectroscopy and histology and immunohistochemistry using a PTX polyclonal antibody	Reduced inflammation in A and B compared to their controls. PTX was present in urothelium and submucosa in A. And also, in muscle in B and C. PTX in lower in Group C than B
Liatsikos	[19]	10	Animal	Pig	Randomly placed in 10 pigs (1) R-Stent ($n = 10$) (2) PTX-eluting coronary stent ($n = 10$) Percutaneous nephrostomy was placed and the collecting system was visualized. With nephrostomy tube capped, deployment of the stent was finalized	Patency evaluation of ureteric lumen: Radiograph of the nephrostomy tract, IVU, and virtual endoscopy at 24 h and 21 days after the initial procedure, respectively. Conventional ureteroscopy at 21 days. Pathology examination of ureter: same pathologist minimizing possible bias	21-day follow-up: Group 1: 5 completely and 2 partially stenosed. Group 2: no occluded stent Pathology examination. 21 days: Obstructed R-stents with severe inflammation and metaplasia PTX-eluting MS with mild inflammation with permeable ureter

NA Not available, PTX Paclitaxel, DCB Drug-coated balloon

pyeloplasty ($n = 7$), surgical complications (iatrogenic $n = 5$), and post-radiotherapy ($n = 1$). The mean stricture length was 27.9 mm (Table 3). Anatomical distribution included upper ureter ($n = 14$), lower ureter ($n = 18$), ureterovesical anastomosis ($n = 1$) and uretero-enteric anastomosis ($n = 25$). The mean follow-up was 20.7 months (Table 3).

Success definitions varied between case series (no signs of hydronephrosis, no postoperative increase of the serum creatinine level or no need of nephrostomy reposition or improvement of existing residual dilatation on radiological images at 1 or 12 months).

Overall, the success rate was 86.2% (50/58) and ranged between 72.7% and 100%. Five (10.6%) patients presented

with complications, that were treated with double-J stent insertion or antibiotics. In a study including 11 patients, complications were not reported (Table 3).

Discussion

Ureteral strictures and pathophysiology

Ureteral stricture remains a major challenge for endourologists, with increasing incidence and due to complexity of the condition and decision making. The ureteral fibrosis and the mechanism of physical reduction of the ureteral lumen

are caused directly by an excess of type III collagen. It is already known that the area of stenosis is full of collagen rich connective tissue with overactivation of the smooth muscle cells, which are the major collagen producers in the ureter [20]– [21].

When urothelial disruption occurs, the urine and all the urinary components are transported into the connective tissue of the ureter, and this process of damage to the urothelial wall have a main role in the ureteral stenosis [22]. The urothelial dysfunction increases the permeability for different solutes, and this could be an interesting opportunity to the application of Paclitaxel into the ureteral stenosis because of its ability to stop cell proliferation and the formation of fibrotic tissue.

The pathophysiology of ureteral strictures after pyeloplasty primarily involves ischemia and fibrosis. These processes are a part of the body's healing response to surgical injury or other trauma, which can lead to excessive scar tissue formation and subsequent narrowing of the ureter. Strictures may result from devitalization of the ureter during surgery, or from other contributing factors such as postoperative inflammation, urinary leakage, or inadequate achievement of a tension-free, well-vascularized anastomosis during the repair. The fibrotic response reduces the luminal diameter of the ureter, restricting urinary flow [23].

The pathophysiology of ureteroenteric strictures is primarily driven by ischemia, which leads to the development of fibrotic scar tissue at the site of the ureteroenteric anastomosis. This ischemic insult is most commonly the result of compromised blood supply during reconstructive urinary tract surgery. However, additional contributing factors include chronic inflammation, prior radiation therapy, and certain types of urinary diversion procedures. The formation of fibrotic tissue at the anastomotic site results in luminal narrowing or complete obstruction of the ureter. This impedes urinary flow and may lead to complications such as hydronephrosis and progressive decline in renal function [7].

Although the pathophysiology and mechanisms underlying stricture formation may vary among the most common etiologies, they all share a final common pathway characterized by the development of fibrotic tissue due to excessive deposition of type III collagen. This shared fibrotic response suggests that Paclitaxel may play a significant role in inhibiting scar formation across different types of ureteral strictures by targeting the key processes involved in collagen deposition and fibrosis .

Paclitaxel mechanism of action and rationale

Paclitaxel is a microtubule inhibitor and stabilizer with anti-fibrotic and anti-proliferative properties that inhibit

cell replication, reducing the production of type III collagen [11]. It is currently used and approved as a coating on vascular balloons and recently, special interest has been placed on the possibility of applying them in the urological field due to the ability to inhibit fibroblast growth and scar formation, avoiding the fibrotic reaction in the ureteral stenosis. Many properties make this drug ideal for local drug delivery via ureteral balloon dilatation. Paclitaxel penetrates the urothelial barrier despite its high molecular weight due to its lipophilic properties, allowing quickly cell uptake [24]. Furthermore, Paclitaxel may be impregnated into coating materials to improve the drug delivery via a stent. In the endovascular field, multiple attempts have emerged to improve the drug kinetics by modifying the polymer matrix in which the drug is suspended.

Paclitaxel concentration and time of exposure are very important factors in the drug-penetration mechanism. It is already known that by increasing the concentration of Paclitaxel, the anti-fibrotic effect increases, making this drug directly dose-dependent [11]. In endovascular stents used in hemodynamics, low rates of postoperative stenosis recurrence are achieved with applications of $< 1\mu\text{g}/\text{mm}^2$ (total dose $< 3\mu\text{g}$) [24]. It is important to highlight that the PCB used in the present systematic review studies have a Paclitaxel concentration between 2 and $3.5\mu\text{g}/\text{mm}^2$, which is within the effectiveness and safety range of current publications. Whether higher doses or multiple balloon applications could improve outcomes in complex ureteral strictures remains unknown, and this must be balanced against potential toxicity.

A very interesting experimental study was performed in an animal model to determine the effect of downstream paclitaxel released during PCB treatment, and this reported that a clinically relevant concentration of paclitaxel in the vicinity of the wound did not impair the healing of distal cutaneous lesions, even after multiple PCB deployments [25].

PCB in ureteral strictures

PCB for ureteral strictures combines ureteral dilatation with the circumferential local delivery application of paclitaxel. Given the promising results in the success of the PCB for US treatment, the present systematic review was performed to assess their investigation in this field. Overall, the studies included could be divided into two major groups: Experimental (*Animal*) studies and Clinical (in-vivo) studies.

Experimental studies

These studies have shown a lower proliferation of urothelial cells in ureteral wounds. In addition, paclitaxel reduced

inflammation in mucosa and submucosa compared to conventional balloon dilatation. Besides, paclitaxel presented a larger ureteral diameter than plain ureteral balloons.

The experimental evidence supporting PCB use in ureteral strictures remains highly heterogeneous. The available animal studies vary considerably in terms of the ureteral injury model (ischemic vs. mechanical), balloon size and pressure, paclitaxel concentration, and histological endpoints. Given these methodological differences and small sample sizes, direct comparison between studies or quantitative synthesis is not feasible. Therefore, these studies should be interpreted as descriptive, providing preliminary biological insight into the potential anti-fibrotic effects of paclitaxel, rather than definitive evidence of efficacy. Larger, standardized experimental studies are required to clarify optimal dosing, delivery kinetics, and tissue safety before widespread translation to clinical practice.

Clinical in-vivo studies

These studies point in the same direction as experimental studies, showing a high success rate for ureteral strictures treated with PCB. However, prospective, larger, and long-term studies are required to assess properly the effect of PCB. Although the definitions of success varied among the included studies, ranging from absence of hydronephrosis, no postoperative increase in serum creatinine, lack of need for nephrostomy repositioning, to radiologic improvement of pre-existing dilation at follow-up intervals of 1 to 12 months, the heterogeneity is an important limitation of the present systematic review. This clarification emphasizes that the pooled success rate should be interpreted with caution, as the underlying criteria used to define successful outcomes were not uniform across the case series.

Limitations and areas of future research

While the primary value of our review is to identify biological rationale and knowledge gaps with the use of PCB, there are several limitations to our review. The small sample size, short follow-up duration and heterogeneous definition of success all limit the generalizability of our study. The role of PCB in patients unfit for major reconstructive surgery also needs to be explored in future studies.

Conclusion

PCB represents an innovative, biologically plausible, and minimally invasive adjunct for ureteral stricture management and provides a valuable alternative in the minimal invasive management of ureteral strictures. While early

clinical and experimental studies show good outcomes, larger randomized studies are required to confirm the effectiveness of this endourological approach. Experimental and clinical studies have shown the ability to reduce the stricture recurrence, but derived from small, heterogeneous studies, and longer follow-up is mandatory to reaffirm these initial results. Patient selection and individualized treatment planning are crucial for optimizing outcomes.

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Declarations

Conflict of interest The authors declare no competing interests.

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Urethroplasty with Paclitaxel-Coated Balloon (PCB) in bladder neck (BN). First case in urology. 9 years of evolution. Series of 45 cases. 60 months of follow-up
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Abstract:

In 2013, at the start of the self-application of a Paclitaxel-coated Balloon Angioplasty in the distal urethra by a cardiologist in Uruguay (Fiandra, M.D., case 0), we began a series of applications in different sectors of the urinary tract in patients with failed rescue procedures after prior procedures. In the bladder neck (BN), between 2015 and 2025, 45 cases were treated. Mean follow-up: 60 months. The most common etiologic causes were post-RP (open, laparoscopic, and robotic) and post-HoLep (coinciding with the learning curve of the procedure in Uruguay). Mean follow-up of 60 months. Results: of these 45 cases, 30/45 (68%) did not require further procedures. There was a significant improvement in quality of life and acceptable flow, with preservation of residual and continence. Relapses occurred within the first year in patients with RT in the stenosis area.

Keywords: Urethroplasty with Paclitaxel-Coated Balloon (PCB)

History

In 2013, Dr. Fiandra self-application of Peripheral Angioplasty Balloon with Paclitaxel to In 2014, a randomized series was started, involving 10 patients. Protocol used: low rays, 2 stages: pre-dilation with balloon without drugs, 5 min, dilation with balloon with Paclitaxel, 5 min. No vesical catheter. All patients included had at least two procedures previously. In 2015, Urotronic (the company was created the same year) patented Optilume Balloon In 2016, a series of presentations at CAU Congress, Panamá. A 3-year follow-up, 75% no additional procedures. Acceptable flow and residual. Change in quality of life. In 2018, Dra. Picciardo's abstract,

a distal urethral stricture (anterior) post-vesical catheter. 7 mm Balloon with Paclitaxel, no pre-dilation (Case 0) 176 patients. Randomized. Anterior urethra less than 3 cm, 1 year of follow-up. In 2 stages, with Optilume Balloon, 5-day catheter. Endoscopy and RX. With a vesical catheter. 74.4%, good results. In 2022, Journal of Urology. Robust III series: 126 patients, randomized anterior urethra < 3 cm. 1 year, 75% with good results. 5-day catheter. Endoscopy and RX. In 2022, FDA approval was granted for anterior urethral use. In 2024, publication in the SAU Journal, personal casuistic in the urethra, 120 cases. 10 years.

History

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Urethroplasty with Paclitaxel-Coated Balloon (PCB), 10 years of experience

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Uruguay Uroplasty

Balloons with Paclitaxel. Balloons of Peripheral Angioplasty.

All our experience was with the only balloons available for peripheral angioplasty at that time, Paclitaxel-coated, with appropriate diameters and lengths for the high and low urinary tracts. We began with Medtronic balloons and then used Boston Balloons (Ranger) of 7mm.

PCB. The 4-step technique

- 1) RGU: evaluation and lesion topography
- 2) Placement of guided wire under Rx.
- 3) Pre-dilation with bare balloon 7-8-12 mm, 5 min, pressure of maximum support
- 4) Dilation with a balloon with Paclitaxel 8-10 mm by 5 min

RGU optional voiding phase (documentation)

No vesical catheterization

From 8/2020, Elutax balloons were used (only those with measures higher than 7 mm in diameter and lengths up to 80 mm that were available in our setting with certification CE)

These balloons are used with measures of 8-10-12 mm in diameter according to height, and the characteristics of stenosis.



Clinical case

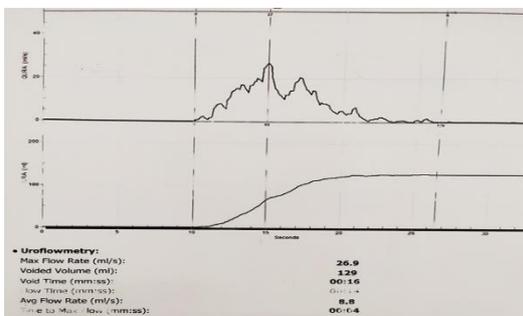
63-year-old patient (doctor), radical prostatectomy (open RP). Complete urinary retention (CUR) occurred for 24 hours, and then the vesical catheter was removed. An

immediate plasty (de novo) was performed. Pre-dilatation and dilation with a balloon 7 mm. Photos 1 and 2

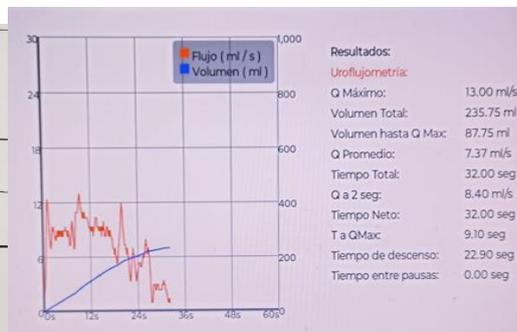


An urgent PCB in the bladder neck (BN) with a 7mm balloon was performed in the Rx ward under sedation and analgesia. No vesical catheter was used. Urgent urination.

To date (9 years of evolution), normal quality of life, no other procedures were needed, no urine incontinence, no residual. Photos 3, 4, and 5



Initial flow



Present Flow



At the starting point of that experience, we began a randomized series including benign cases of

prostatic surgery (prostatic urethra included) as well as malignant cases (bladder neck reconstruction) with

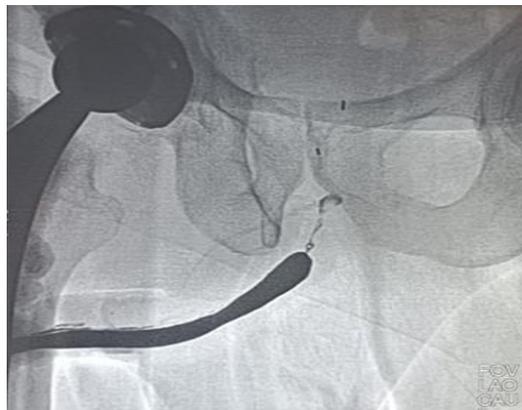
post-procedure stenosis (2 or 3 previous procedures of endoscopic resolution)

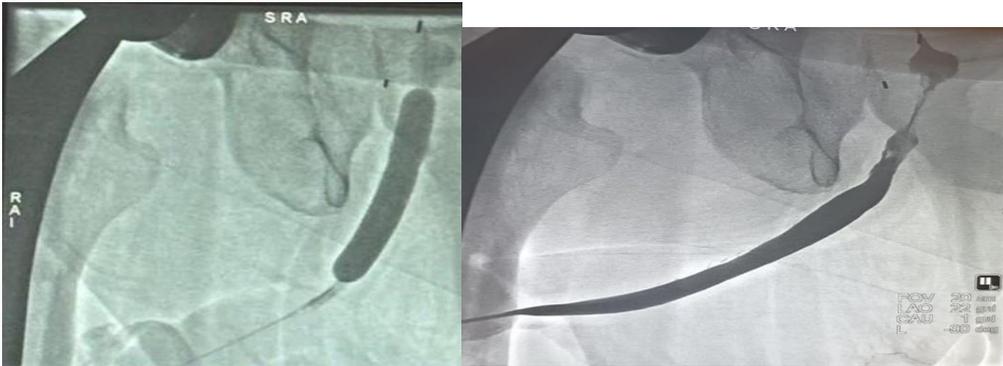
CV series 45 cases

Randomized, post-surgical procedures. One only case of “de novo”. Follow up between 9 years and 12 months. Mean 60 months. Between 52 and 84 years old, with a mean age of 72. Two previous procedures, with a mean of 2/45 and vesicostomy, 3/45 with vesical catheterization, 5/45 RT post-surgery, and a stenosis mean of 18 months.

Preparation, mid-stream urine, and plan of

procedure with Urethrocytography and measurement of vesical residual. The evaluation of the “prostatic factor” in LUO is mandatory and essential for the prognosis and evolution. From the first series performed, the postoperative indication was 7 days of antibiotics and corticosteroids (low doses), which significantly decreased the irritative symptoms.



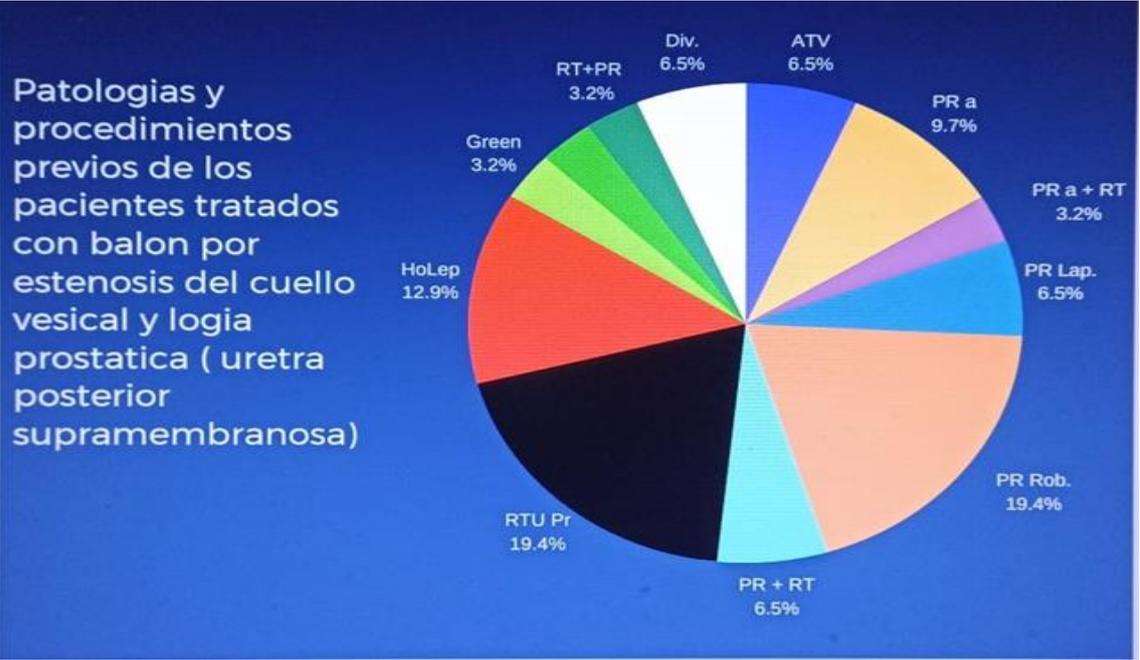


Case 38 Post HoLEP



Flow 3 weeks after Case 38

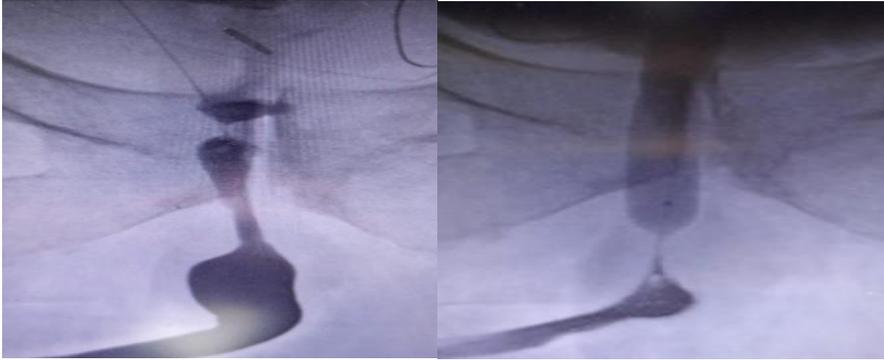
- Procedures via BPH
 - 42%
 - HoLEP 13%
- Radical Prostatectomy (RP) 36%
- Robotic 19%
- Open 10%
- Radical Prostatectomy + TURP 12%



Results

These results show a clear improvement in the patient's quality of life. Residual improvement (decrease) in case of undistended bladders with preserved detrusor tone 3/45 failures before the year (average 6 months, 6%), 7/45 failures before the second year (average 14 months, 15%), 3/45 failures before the third year (average 26 months, 6%), 2/45 failures before the fifth year (average 45 months, 5%), 30/45 no other procedures were needed (60 months, 68%).

Good results were achieved, 68%. 4/45 in 2 PCB procedures (9%), 3/45 in 3 procedures (8%), and 1/45 had complete urinary incontinence (UI). This last patient had RP+RT+TURP. Satisfaction level reached 95% (external auditory). Approximately 99% maintained continence, and a similar percentage also improved their quality of life, 1/45 had urinary retention (hypocontractile bladder) in which a post-procedure catheterization (20 days) was required.



Case 41 post-laparoscopic RP

Conclusions.

Uroplasty with Paclitaxel-Coated Balloon (PCB) is an ambulatory procedure with low morbidity, an acceptable benefit-cost ratio, and ease of performance. It requires minimal preparation (obligatory urine culture), no irradiation, and no complications. No endoscopy or posterior catheter is needed (“no touch technique”). Although the patient may experience slight discomfort or bleeding during the first 48 hours, the results are rapid (immediate urination), and the procedure is well-accepted. Moreover, it does not invalidate subsequent surgeries or cause adverse reactions. It is also easily universalized. To achieve good results, it requires prior team planning and evaluation of the prostatic (in men) and vesical components of the urinary tract.

Takeaways

In cases of post-surgical urinary tract stenosis, PCB may be considered the first option because it is easy to perform and

does not cause additional damage. Patients who undergo PCB with a graft have not experienced any additional inconvenience (1 or 2 attempts). It is affordable, requires no surgical instruments, is ambulatory, and does not require a catheter. It has good results, minimal symptomatology, no added harm, and can be repeated without inconvenience. It does not invalidate surgeries with grafts. It has a shorter duration in irradiated patients and in procedures where high energy in the urethra is required (TURP, laser).

This tool has good results in the urinary tract for both genders and has already been proven effective in children and the elderly. As of this publication, Europe, Asia, and America (where it started) are validating this procedure. Variations in techniques are also being developed (combined procedure: mini-UI + PCB) that seem to improve the initial result and symptomatology.

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