

Long-term results of the treatment of complex ureteral stenosis with extra-anatomic ureteral bypasses

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Introduction Complex ureteral obstruction is a pathology that has always been a challenge for the urologist, especially in patients with high surgical risk or with a short life expectancy.

Material and methods Between 2002 and 2017, 13 extra-anatomical bypasses were placed. A descriptive retrospective study was carried out. An analysis of the permeability time of the prosthesis was performed using Kaplan-Meier curves. Demographic and etiological characteristics as well as early and late complications were analysed.

Results Etiologies were benign in 39% (including 3 transplant recipients) and malignant in 69%. Permeability rates were 90.9% at each of 12, 24 and 48 months, respectively, and 75.8% at 60 months. There were no deaths in the early postoperative period, nor intraoperative complications. The most frequent complications were infections. Three of them were associated with bypass extrusion, which needed to be removed. A total of 5 prosthesis had to be removed. 40% of the patients did not present complications.

Conclusions The extra-anatomical ureteral bypass is an alternative to permanent nephrostomy in the treatment of complex ureteral strictures. Their patency rates after long-term follow-up vary from 90% to 75% at 48 and 60 months, respectively. Their complication rates can be considered acceptable in the patients' clinical contexts.

Key Words: extra-anatomic bypass ◊ complex strictures ◊ upper urinary tract ◊ long-term

INTRODUCTION

Complex urinary obstruction (CUO) is a pathology that has always been a challenge for the urologist. The urinary diversion by stents has been shown to be ineffective in up to half of the patients, mainly with compressive oncological pathology [1, 2].

In most of them, a percutaneous nephrostomy (PN) is implanted as a definitive solution, when endourological treatments such as double J-stents or self-expanding metal stents have failed or are not indicated. This type of device has an impact on the quality of life of the patient, due to the need to change collection bags frequently and periodic changes of the nephrostomy. In addition, it leads to important medical complications, such as repeated

urinary tract infections, renal injuries during the exchange of nephrostomy, obstructions or accidental withdrawal [3, 4].

In the 1980's, the development of new devices to drain urine in patients with ureteral obstructions began [5]. Since then, different techniques have been tried to improve the quality of life of patients with CUO, with minimal invasiveness. Schmidbauer et al. and Minhas et al. used techniques that consisted of the implantation of catheters, which were placed in the subcutaneous tissue. These techniques had the advantage of not needing an external collector device, unlike the PN, which has a great negative psychological impact on the patient. The main disadvantage was the need for periodic exchanges every 4 to 6 months [6, 7].

In 1993, Desgrandchamps published a preliminary report on the placement of an extra-anatomical subcutaneous bypass made of silicone and polytetrafluoroethylene (PTFE). It was similar to the device currently used, without necessary replacement [8]. Since then, numerous articles have been published to advocate the use of this type of device. Although they improve the quality of life of the patient, they are not exempt from complications, especially infections, obstructions and extrusions, which sometimes lead to the removal of the implant. In addition, there are no long-term reports on the permeability rates of these devices in the literature [4, 9–12].

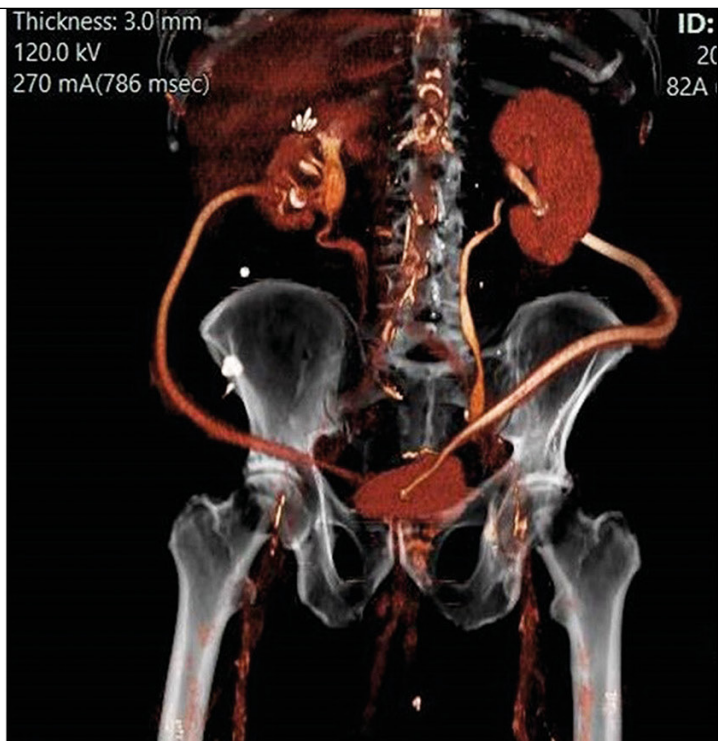
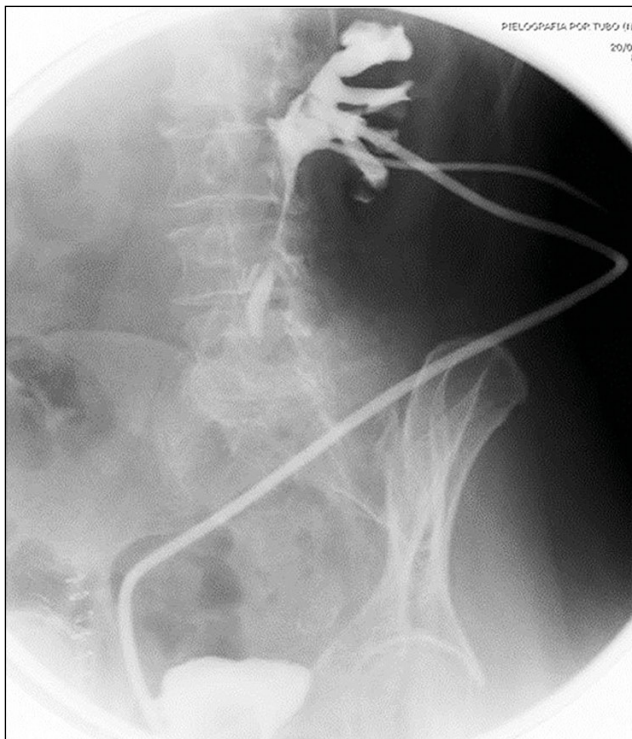
The main aim of this article is to evaluate the long-term results in terms of patency of the treatment of complex ureteral strictures with extra-anatomical ureteral bypass. As secondary objectives, indications and early and late complications are also analyzed.

MATERIAL AND METHODS

Between 2002 and 2017, 13 extra-anatomical bypasses were placed as an alternative to permanent PN in patients with CUO. We define a complex ureteral obstruction as one that is impossible to solve with an endourological approach (including the use of self-expanding metal ureteral stents), since it is impossible to access the lumen.

Surgical technique

The extra-anatomical bypass Detour® (Coloplast Ltd.) is a subcutaneous nephrovesical drainage device composed of a silicone tube covered with a PTFE sheath in its central segment, which adheres to the subcutaneous tissue. First, it is necessary to perform a percutaneous puncture of the urinary tract, guided by ultrasound and X-ray, if the kidney has not yet been drained. Then, the tract is dilated with Amplatz sheaths until a diameter of 29 Fr, which is the calibre of the implant, is reached. The ureteral device is then introduced through the Amplatz and the ring that distinguishes the limit of the PTFE sheath is placed over the renal papillae. The entire procedure is guided by fluoroscopic view. A small suprapubic incision is made, the space of Retzius is dissected and the bladder is opened with a small cut. A blunt tunneler is introduced into the subcutaneous tissue from the suprapubic incision to the renal puncture. Then, the bypass is introduced into the blunt lumen of the tunneler to reach the suprapubic incision. Then the tunneler is removed. The prosthesis is cut to adapt it to the size of the patient, always leaving 2 or 3 centimeters free of PTFE to introduce this part into the bladder. The opening of the bladder is closed after fixing the bypass to its wall (Figures 1 and 2). There is no urinary extravasation if the procedure is performed correctly since the prosthesis fits the bladder and renal papillae. An antegrade



Figures 1 and 2. Anatomical location of the bypass.

pyelogram through the nephrostomy ensures the correct placement of the device. A urethral catheter is left in place for 7 days after surgery. The procedure is performed entirely by urologists.

Urinary culture is performed in all patients and, if positive, antibiotic therapy is administered before the procedure. If negative, antimicrobial prophylaxis is administered at induction of anesthesia (1 g of amoxicillin / clavulanic acid, according to hospital protocols for urology prostheses).

A descriptive retrospective study of the results of the implantation of the prosthesis was carried out. An analysis of the survival time of the prosthesis was performed by means of Kaplan-Meier curves (Log-rank) to obtain the patency rates. The deaths of patients were considered censored data. Demographic and etiological characteristics, as well as complications, were analyzed. We considered early complications those that appeared in the first 30 days after surgery. Late complications were those that appeared after 30 days. Complications were classified according to the Clavien-Dindo rating system. All data were analysed using SPSS statistical software (version 20.0; SPSS Inc, Chicago IL).

The study was carried out in accordance with the Declaration of Helsinki. All patients signed informed consent. The study was approved by the Hospital Ethics Committee.

RESULTS

A total of 13 extra-anatomical bypasses were placed in 12 patients. The characteristics of the patient and the obstruction (including Charlson comorbidity index [13]), as well as the bypass indications, are summarized in Table 1. The serum creatinine concentration was normal in all cases, but those corresponding to the transplant recipients and the patient with upper urinary tract tumour, who had a moderate elevation (from 1.3 to 3.3 mg/dl).

Bypass permeability curve is shown in Figure 3. The median of the correct work time was 141.9 months (IQR 64.5–171.4). Permeability rates were 90.9% at each of 12, 24 and 48 months, respectively, and 75.8% at 60 months.

There were no deaths in the early postoperative period associated with bypass surgery, nor intraoperative complications. After surgery, the parameters of renal function improved or remained stable (both creatinine and glomerular filtration rate). Early and late complications are summarized in Table 2 according to the Clavien-Dindo classification. 40% of the patients did not present complications.

With regard to long-term complications, the most frequent were infections. Five patients (38.5%) had

Table 1. Characteristics of the patients and the obstructions, as well as the bypass indications

Median follow-up (IQR)	52 months (1–171)	
Median age (range)	61 years (33–80)	
Males	66.7% (8/12)	
Cardiovascular risk factors		
Hypertension	66.7% (8/12)	
Dyslipidemia	33.3% (4/12)	
Diabetes	8.3% (1/12)	
Single kidney	33.3% (4/12)	3 transplants 1 genitourinary tuberculosis
Previous abdominal surgery	91.7% (11/12)	
Median Charlson comorbidity index (range)	5 (2–8)	
Obstruction etiology		
Benign	38.46% (5/13)	Renal trasplant: 3 Desmoid tumor: 1 Urogenital tuberculosis: 1
Malignant	61.23% (8/13)	Colon cancer: 3 Rectal cancer: 2 Ovary cancer: 1 Retroperitoneal sarcoma: 1 Upper urinary tract carcinoma: 1
Obstruction location		
Distal	76.92% (10/13)	
Distal + lumbar	15.38% (2/13)	
Lumbar	7.70% (1/13)	
Bypass indications		
Previous surgery failure (ileal substitution, Boari flap, etc.)	7.7% (1/13)	
Failure of endourological procedures (strictures too tight to pass through with a guidewire) in patients no suitable for open surgery	69.2% (9/13)	
Failure of endourological procedures in patients with short life expectancy	23.1% (3/13)	

recurrent urinary infections. Three of them were associated with bypass extrusion. In all cases, the implant had to be finally removed (within a mean period of time from the onset of the infections of one year). One of the cases needed concomitant nephrectomy. The other two remained with percutaneous nephrostomy. Urinary tract infections were caused by several germs. In the cases presented with extrusion, the microorganisms isolated in the culture were *Pseudomonas aeruginosa* and *Staphylococcus epidermidis*. *Enterococcus faecium* was isolated in the remaining patients (Figure 4). The treatment was carried out with broad-spectrum antibiotics (piperacillin tazobactam 4 g / 6 hours, meropenem

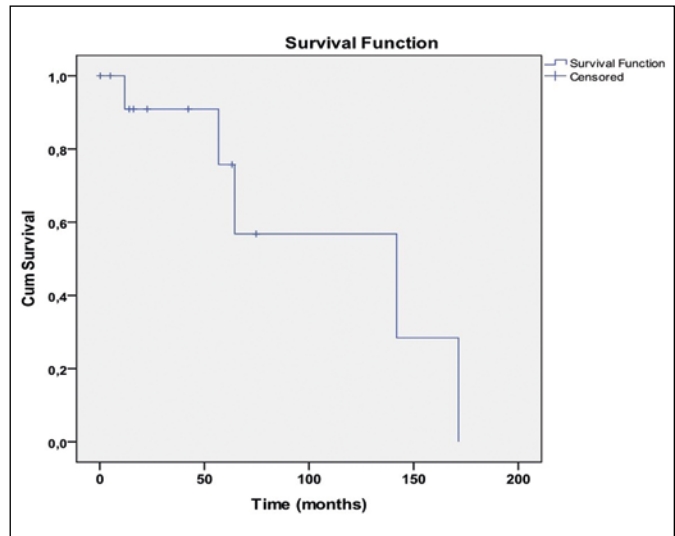
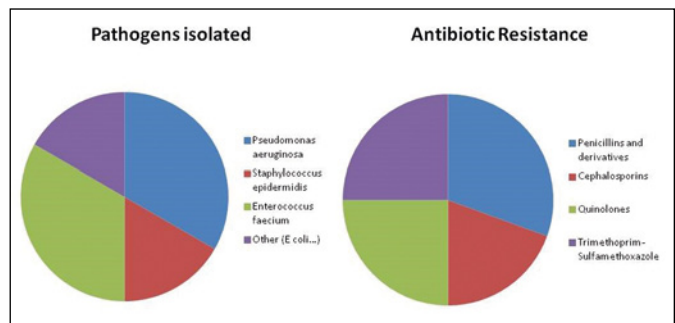
Table 2. Early and late complications, according to Clavien-Dindo classification, and their management

Early complications	%	Management	Clavien-Dindo classification
Surgical wound infection	15.4% (2/13)	Antibiotics	I
Subcutaneous tract cellulitis	7.7% (1/13)	Antibiotics	II
Subcutaneous tract hematoma	7.7% (1/13)	Expectant management	II
Dislodgement of the bladder end	7.7% (1/13)	Re-operation	IIIb
Late complications			
Repeated urinary tract infections	38.5% (5/13)	3 extrusion association + ipsilateral nephrectomy 3 withdrawn (one + ipsilateral nephrectomy)	IIIb
		2 conservative treatment	II
Bladder invasion by colonic cancer	7.7% (1/13)	Tumor excision + bypass withdrawal + ipsilateral nephrectomy	IIIb
Intravesical distal end incrustation (transplant recipient)	7.7% (1/13)	Lithofragmentation with Holmium laser	II
Secondary infection to adjacent eventroplasty mesh infection	7.7% (1/13)	Mesh and bypass removal + ipsilateral nephrectomy	IIIb

500 mg / 8 hours or third generation cephalosporins, for a mean of 3 weeks). A total of 5 bypasses (38.5%) had to be removed. In one patient, an infection of an eventroplasty mesh extended to the bypass. Both had to be removed. The last case was due to an invasion of the bladder due to a local recurrence of colon cancer. These last two cases required nephrectomy. There were no complications secondary to bypass removal.

DISCUSSION

CUO represents a major challenge in urology. There are different alternatives: ileal conduit, autotransplant, Boari flap, etc., but these options must be adjusted to the patient's clinical situation. The benign or malignant origin of the disease, previous surgeries and/or radiotherapy, renal function and surgical risk should also be taken into account. When common surgical techniques are not indicated, a stent is usually implanted, which can fail in up to 50% of oncological cases [1, 2]. The next option is the im-

**Figure 3.** Bypass permeability curve.**Figure 4.** Pathogens and their antibiotic resistance.

plantation of a metallic stent, but they can also fail or are not an option when the stenosis is too tight to pass a guidewire. In these cases, most patients are treated with a PN, with the subsequent impact on their quality of life [3, 4]. In these cases the extra-anatomic bypass should be considered as an option. This paper analyzes the results in terms of patency, as well as the early and late complications, after the implantation of a ureteral extraanatomic bypass in patients with stent failure, exhibiting high risk for invasive surgeries and not presenting as suitable for endourological resolution.

To our knowledge, there are no studies in the literature with such a long term follow up as this study, which has a mean of 52 months and a maximum of 171 months. In addition, a survival curve to obtain patency rates has never been performed before. This has allowed us to obtain long-term bypass patency rates. The median of correct work time was 141.9 months. Patency rates were 90.9% at each of 12, 24 and 48 months, respectively, and 75.8% at 60 months (4,10–12,14)].

In our series, the indication for the implantation of the bypass was distributed in oncological and non-oncological pathology. This was in contrast to other series where oncological pathology is dominant [4, 9, 10]. In contrast, other publications report a majority of benign etiologies [12, 15].

Oncology patients included 3 colon cancers, 2 rectal cancers, 1 ovarian cancer, 1 retroperitoneal sarcoma, and 1 upper urinary tract cancer. In these patients, the short life expectancy and the need for a permanent NP (double J stent failure) determined the indication for the bypass. In transplant recipients, the prohibitive surgical risk in 2 patients (1 due to severe heart failure and the other due to a hepatorenal transplant associated with multiple digestive hemorrhages) and ureteral blockage treated with various surgical interventions, including ureteropyelostomy to the native ureter, in the other, determined the indication.

The case of urinary tuberculosis corresponds to a single kidney with an ileal conduit that developed an uretero-ileal stricture. The implant of a heat-expandable metal stent had previously failed. Finally, the case of desmoid tumor was a patient with multiple abdominal operations. The patient presented an evisceration in the immediate postoperative period and an eventroplasty mesh was placed. Subsequently, the patient presented a high risk of major abdominal surgery and the stricture could not be resolved by endourological approach.

The procedure was performed entirely by urologists, the standardized way previously published [4]. Other groups have described a percutaneous approach not only of the kidney but also of the bladder [16, 17]. No significant intraoperative complications, such as bowel injury or renal bleeding during the puncture, were found in our cohort, which are reported in other series [14].

Two patients presented early complications. This corresponds to an incidence of 16.7%, which is similar to the values found in other series [9, 14]. Dislodgement of the bladder end occurred in one patient, treated through immediate reoperation. A similar complication was reported by Haddad [15]. The same patient developed posteriorly a subcutaneous hematoma managed conservatively, also reported in other series [18]. Cellulitis, which appeared in one patient, has also been previously described in the literature [4].

The rate of late complications was slightly higher in our cohort, mainly in relation to infections. Recurrent infections affected 38.5% of the patients in our series. These differences with respect to infections may be justified for several reasons. The main infectious complications (bypass chronic infection

and extrusion) occurred after periods of more than 4.4 years. This implies that these complications appear after a long-term evolution and most studies have a shorter surveillance period [4, 9, 10, 12, 14].

However, infectious complications are reported by many authors [4, 10, 11, 14, 15]. The presence of this type of adverse events in people who carry prosthetic material is still usual. This is explained by the existence of bacteria with mechanisms of adherence to foreign materials. Broad-spectrum antibiotics were used due to the high rate of antibiotic resistance, as described in other articles [19]. In patients who underwent extrusion (53–83 months), this was due to a chronic bypass infection and presented a positive urinary culture to bacteria highly adherent to the prosthetic material. The three devices had to be removed, in one case a concomitant nephrectomy had to be performed. Bynens et al. reported a complete obstruction of the bypass due to *Candida* infection, successfully resolved with antifungal therapy [20].

The removal of the prosthesis, of which we documented 5 cases, was reported in other studies. Janitzky shows an incidence of 10% with an average surveillance of 23 months. In other documents, although the incidence is lower, there are reported cases of returning to a permanent nephrostomy keeping the bypass in place [9, 14]. Chronic infection of the implant and extrusion were reported by Jurczok et al. in 10% of their cohort and by Jabbour et al. in 8.5% of theirs [9, 10]. Bladder invasion by cancer, which lead to complete removal of the prosthesis, has also been reported in the literature [21].

One of the patients presented lithiasic obstruction of the distal end of the ureteral bypass. This condition was successfully resolved with Holmium laser. These types of complications are rare and we find few references in the literature [10, 15]. Wilhem et al. reported an occlusion of the bypass with acid uric lithiasis, insufficiently managed through endoscopic intervention and solved with forced chemo-litholysis [22].

With respect to transplant recipients, the use of self-expanding metallic stents and ureteral bypasses has been shown to be effective in complex stenosis caused by treatment failure or in patients at high surgical risk, with similar effectiveness and rate of complications [23, 24, 25]. This allows a delay in the return to dialysis, which has an annual mortality rate of 16.1% [26].

In comparison with other extra-anatomic drainage techniques, such as stents or nephrocutaneous devices, we consider that extra-anatomical ureteral shunt is a better alternative. Since it has a larger lumen (29Fr), this leads to a lower obstruction rate. It does not need periodic exchanges and, in compari-

son with nephrocutaneous devices, it does not need an external collection bag [7, 10, 27, 28].

With respect to PN, patients reach a complication rate of 60%, including urinary infection, pain, intermittent haematuria, obstruction by debris, urinary leakage, and inflammation of the skin at the point of insertion. Cracking, twisting, or accidental ripping out of the percutaneous tube may result in multiple replacements. The need for an external bag for urinary drainage can be difficult to manage at home and cumbersome. All of this has a great impact on the patients' quality of life as it affects their social and psychological well-being [3, 4, 6, 7, 14, 29]. With extra-anatomic bypass, 40% of the patients in our series did not present complications. There were also no complications secondary to bypass removal either. It is important to consider that bypass does not need to be exchanged, unlike PN. Moreover, there is no need for an external collection bag.

Intraoperative complications of PN include bleeding, infection, sepsis, or, less likely, the appearance of fistulas [6, 7, 29]. Since the anterior PN tract is generally used when performing an extra-anatomic bypass placement, the risk of some of these complications might be less. There were no intraoperative complications in this series.

Regarding efficiency, in our institution, the cost of extra-anatomic bypass is approximately ten times greater than that of a conventional percutaneous nephrostomy (this includes only the cost of the device). It should be noted that the latter must be exchanged periodically and that the median correct bypass working time in our series was 141.9 months. Therefore,

in at least the 40% of patients without complications, extra-anatomic bypass was also efficient.

Therefore, we advise urologists to know about this alternative so that it may be available to their patients in certain cases.

This study has some limitations, mainly the retrospective nature and the small cohort of patients. The information obtained would have been even more precise if a prospective study had been carried out and the quality of life of the patients had been studied with standardized questionnaires.

CONCLUSIONS

Extra-anatomical ureteral bypass is a feasible alternative to permanent nephrostomy in the treatment of complex ureteral obstruction in patients with failed previous surgery, high surgical risk or short life expectancy. Their patency rates after long-term follow-up vary from 90% to 75% at 48 and 60 months, respectively. Their complication rates, although not low, can be considered acceptable in the patient's clinical context. Infectious complications are the most common, and their treatment is performed through broad-spectrum antibiotics.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest. No funding was received for the development of the study.

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