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ORIGINAL ARTICLE

Management of urinary-tract fistulas using reversible balloon nephrostomy: a single-center retrospective analysis of 56 patients

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Abstract

Purpose To evaluate the effectiveness of balloon nephrostomy (BN) for treating urinary tract fistulas.

Materials and methods In a single-center retrospective analysis, 56 patients were treated using BN between 2003 and 2014. All causes of urinary tract fistula were included. We assessed the effectiveness of drainage, complications, and the types of reconstruction surgery used. Success was defined as fistula closure without surgery.

Results The cohort consisted of 25 males (54%) and 31 females (55%) with a median age of 63 years who underwent BN for a urinary fistula secondary to surgery, i.e., urologic (40%; $n = 22$), gynecologic (34%; $n = 19$), or digestive (20%; $n = 11$). Of these patients, 48 (86%) had a history of cancer (49% had a tumor progression). Median drainage time was 90 days (10–583), with an average of three successive readjustments needed per patient. We obtained a 21% success rate ($n = 12$), morbidity was 6.5% (urinary sepsis, renal abscess, ureteral stricture), and 7% of patients developed ureteral stricture after balloon removal. There was no recurrence of any fistula within a median follow-up time of 15.2 months.

Conclusion This minimally invasive procedure can be used for selected urinary tract fistulas with few complications. It can also be used safely in populations that have several comorbidities.

Keywords Iatrogenic · Percutaneous treatment · Surgery · Urinary fistula · Unfit population

Introduction

Repairing a urinary tract fistula (UTF) remains challenging. Complications from surgery are the main cause of adverse outcomes [1, 2]. The other main causes are tumor invasion, radiation therapy [3], and trauma [4]. Despite the positive impact of repairing a UTF on a patient's quality of life [5], there is little evidence on the best strategy for managing this pathology [6]. Treatment consists of surgical closure or minimally invasive urinary diversion by either endoscopic or percutaneous means.

The most frequently reported first-line strategies depend on the fistula's location and involve bladder catheterization plus ureteral catheterization (if applicable). This strategy has success rates between 20% [6] and 75% [7], with no further invasive care needed. If this strategy fails, then surgery remains the gold standard [8].

Although the use of balloon nephrostomy (BN) catheters has been suggested, it is not common in most centers. Different percutaneous devices for ureteral occlusion have been described (coils, gelatin sponge, isobutyl-2-cyanoacrylate, detachable balloons, ureteral clipping, etc.) by Avritscher et al. [9]. Reversible occlusion using balloon nephrostomy was described for the first time in 1984 [10] and seems to be an interesting option for treating UTF [5]. This technique avoids urinary leakage, which is often socially distressing and disabling, while avoiding invasive surgery with temporary external urinary diversion.

A Fogarty catheter (FC) with a percutaneous nephrostomy tube is introduced using ultrasound and x-ray guidance parallel through the same tract with a sheath and dual guidewires. The balloon from the FC is inflated inside the ureteropelvic

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junction. The goal is to occlude the fistula by a combination of urinary tract balloon occlusion and external urinary diversion. Consequently, the BN procedure can be used on patients in whom the UTF is located below the ureteropelvic junction.

The BN procedure is still not fully accepted as a treatment for UTF, probably because it is a relatively unknown technique: only two studies have been published on BN for UTF with fewer than ten patients in each study [11, 12]. The aim of our study was to assess the outcomes of the BN procedure when used to treat UTF and to determine its potential future role.

Materials and methods

Patients

This retrospective single-center study included all consecutive patients admitted to our facility between January 2003 and June 2014 who underwent BN to treat UTF. The UTF diagnosis was made clinically and confirmed by radiology (CT scan or pyelography). After approval from our Institutional Review Board, the patients' characteristics and treatment strategies were collected by reviewing their medical records to determine the types of prior therapies and time between the BN procedure and previous or subsequent treatments. We also identified patients with a complex fistula, defined by a fistula with more than two organs involved.

Procedure

Various radiologists who were well trained in this treatment performed the procedure. Under local anesthesia, a renal puncture was performed using ultrasonography and fluoroscopy; a 5.5-Fr FC (Edwards Lifesciences™, Irvine, CA, USA) was introduced through the kidney using a 0.035-inch guidewire (Fig. 1). Its balloon was inflated to 2 ml as soon as the balloon faced the ureteropelvic junction. This stopped the anterograde urinary flow immediately (off-label FC use approved by our IRB) (Fig. 2).

The nephrostomy tube (Argon Medical, Plano™, USA) was then introduced into the pyelon through the same puncture path to drain the urine. Both the FC and BN tubes were attached to the skin. Patients with a lower urinary tract fistula (e.g., in the bladder or urethra) underwent a bilateral BN procedure. Patients with a unilateral ureteral fistula underwent a unilateral BN procedure.

Success was defined as fistula closure without further treatment, as observed on pyelographic screening and during the removal of the percutaneous nephrostomy tube and balloon.

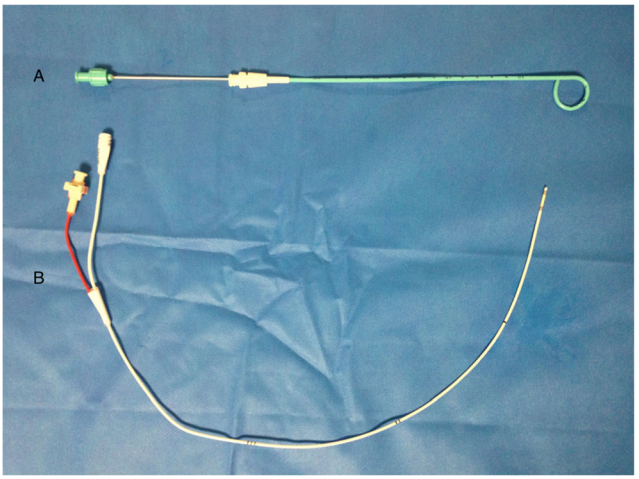

Fig. 1 **a** Nephrostomy 8 FR. **b** Fogarty 5.5 FR

Follow-up

The follow-up was based on anterograde pyelography (through the nephrostomy catheter after balloon deflation) every 3 weeks until BN removal to assess healing of the UTF. The tubes were changed to decrease the risk of infection. Complications were evaluated according to the Clavien–Dindo classification [13]. The length of follow-up was calculated from the date of the BN procedure to the date of the last clinical follow-up (even after healing or surgery to control fistula recurrence).

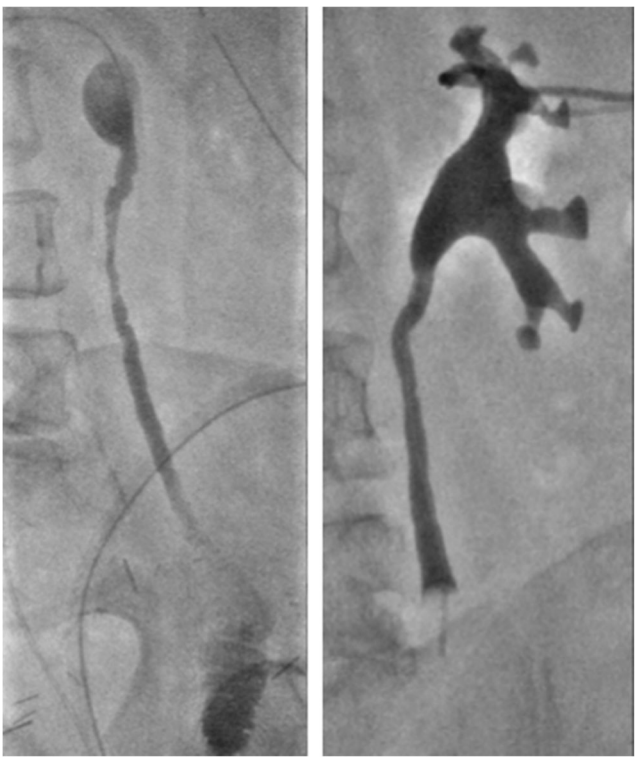

Fig. 2 **a** Before balloon inflation. **b** After balloon inflation

Statistical analyses

Data are presented as counts and percentages of categorical variables and as median (range) for continuous variables. Comparisons between groups were made using the chi-square or Fisher's exact tests for categorical variables and Student's *t*-test or the Mann-Whitney test for continuous variables.

All statistical tests were two sided, and differences were considered statistically significant when $p < 0.05$. Analyses were conducted using Stata 13.0 software (StatCorp LP, College Station, TX, USA).

Results

A total of 56 patients were included: 25 males (45%) and 31 females (55%). Median age was 63 years (33–88). Forty of the fistulas (71%) were related to surgical complications, seven (13%) were post-radiation therapy, five (9%) to secondary tumor invasion, and one (2%) was caused by trauma (Table 1). Most patients ($n = 48$, 86%) had a history of cancer, including 23 (49%) who were still being treated for this disease. Twenty-five had undergone radiation therapy (44%), and 19 (34%) had received chemotherapy. Ten (18%) patients were in palliative care.

Table 1 Fistula etiology

	$n = 56$	%
Tumor invasion	5	9%
Cervical cancer	3	5%
Ovarian cancer	1	2%
Lymphoma	1	2%
Surgery	41	71%
Hysterectomy	4	7%
Hysterectomy + adnexectomy	5	9%
Pelvic tumor resection	2	4%
Sigmoidectomy	1	2%
Rectal cancer surgery	3	5%
Hartmann surgery	4	7%
Abdomino perineal resection	2	4%
Posterior pelvic exenteration	2	4%
Transurethral resection of bladder	1	2%
Partial cystectomy	1	2%
Cystoprostatectomy	7	13%
Anterior pelvic exenteration	6	11%
Prostatectomy	2	4%
Brachytherapy	2	4%
Cervical cancer	2	4%
Radiotherapy	7	13%
Uterine tumor	1	2%
Bladder cancer	1	2%
Prostate cancer	5	9%
Trauma	1	2%

UTFs were located in the urinary tract as follows: 19 (34%) on the ureter, 35 (63%) in the bladder, and 2 (3%) posterior to the urethra (Table 2). Forty-six patients had not received a previous treatment (82%); thus, BN was conducted as the first-line treatment for the UTF. Forty-two patients (91.3%) received BN during the first 10 days after diagnosis. Ten patients had undergone a previous treatment, including insertion of a bladder catheter in four cases, a ureteral catheter in three cases, and three patients had undergone surgery before another procedure. In six patients, the UTF was complex and involved at least three different organs.

The average BN drainage time was 90 days (10–583), with a median number of 3 (0–11) BN readjustments required per patient (FB deflation, inadvertent extraction). Nineteen patients had a unilateral BN, and 37 had a bilateral BN.

BN treatment was successful in 12 cases (21%). Thirty-eight patients (79%) needed further surgical repair, of which 19 (34%) had conservative surgery without urostomy and 19 (34%) had surgery with urostomy. The success rate of combined BN and surgery was 55%. Six patients (11%) were excluded because of missing data (Table 3).

Morbidity after BN was 7.5%: one urinary sepsis (Clavien II), one cutaneous abscess (Clavien IIIa) and two ureteral strictures secondary to balloon inflation (Clavien IIIb). These last two patients required drainage for more than 4 months. A ureteral stricture occurred secondarily after BN removal in five patients (9%).

Patients successfully treated using BN for a UTF required significantly less drainage time than other patients, i.e., 79 (± 56) vs. 133 (± 118) days ($p = 0.03$). Of the 12 patients treated successfully with BN, six patients had a ureteral fistula and six had a bladder fistula. No predictors of success could be identified in univariate analysis (Table 4). For all patients treated successfully with BN, no fistula recurrence was identified within a median follow-up of 15.2 months (range: 1–85).

Discussion

Urinary tract fistulas can be treated using different methods such as a retrograde ureteral stent, bladder catheter, or immediate or delayed surgery. However, the optimal treatment of UTFs has not been defined because of their low prevalence, which has resulted in small cohorts of patients per study [14].

Our study is the first to report the outcomes of balloon nephrostomy treatment in a fairly large cohort (56 patients). We included all patients with a urinary fistula in order to obtain the most representative population. We have shown that BN successfully treated the urinary fistula (ureteral,

Table 2 Population

Population		n (%)
Sex	Male	25 (45)
	Female	31 (55)
Age (years)		63 (33–88)
Cancer		48 (86)
Radiotherapy		25 (44)
Chemotherapy		19 (34)
Tumor evolution		21 (52)
Etiology	Iatrogenic	55 (98)
	Traumatism	1 (2)
Fistula origin	Urology	22 (44)
	Gynecology	19 (34)
	Digestive	11 (20)
Fistula outflow	Vagina	16 (27)
	Colon	15 (27)
	Peritoneum	13 (20)
	Cutaneous	5 (9)
	Ileum	4 (5)
Bladder type	Native	40 (71)
	Bricker	10 (18)
	Neo-bladder	6 (11)
Localization	Ureteral	19 (34)
	Bladder	35 (63)
	Urethra	2 (3)
Previous treatment	Bladder catheter	$n = 4$
	Ureteral catheter	$n = 3$
	Early surgery	$n = 3$
No previous treatment	$n = 46$ (82)	

bladder) in 21% of cases, and these patients needed less drainage time compared with patients who failed BN (79 vs. 133 days, respectively; $p = 0.03$). These results suggest that BN can effectively treat UTFs in certain patients.

Table 3 Fistula treatment

	n (%)
Success	**12 (21)**
Conservative surgery	**19 (34)**
Epiplooplasty	3 (5)
Uretero-bladder reimplantation	10 (18)
Ureteral catheter	6 (11)
No conservative surgery	**19 (34)**
Definitive nephrostomy	8 (14)
Bilateral ureterostomy	5 (9)
Cystectomy with Bricker	5 (9)
Unilateral ureterostomy	1 (2)
No follow-up	**6 (11)**

Table 4 Univariate analysis of success

	Success	Failure	
Ureteral	6	13	
Bladder	6	29	ns
Urologic fistula	5	17	
Gynecologic fistula	5	14	
Digestive fistula	2	9	ns
Native bladder	9	31	
Bricker	1	10	
Neo-bladder	2	6	ns
Radiotherapy	3	22	
No radiotherapy	7	24	ns
Colostomy	1	18	
No colostomy	11	8	$p = 0.0001$
Vagina	2	14	
Digestive	2	17	
Skin	1	4	
Peritoneum	5	8	ns
Drainage < 4 months	10	21	
Drainage > 4 months	2	17	ns
Drainage > 6 months	1	8	

Only two studies have reported the management of UTFs using non-detachable BN. Horenblas et al. reported on seven patients [11], and Zairi et al. on reported on ten [12]. These populations were similar to our retrospective sample, with 80% of cases of UTF caused by cancer [12]. Nevertheless, Horenblas et al. reported needing a longer median drainage time (94 days; range: 45–169) [11] whereas Zairi et al. reported a shorter time (55 days; range: 7–210) [12] compared with our study. The effectiveness of BN was lower in our study (21%) than in these two other studies (71% [11] vs. 40% [12]). This can be attributed to the fact that our cohort included more patients with several comorbidities (18% were in palliative care and 16% died before fistula closure).

Treatment of ureteral fistulas using a ureteral stent has a reported success rate of 64% and 72% [15, 16]. In our study, the success rate was 32% in those with a ureteral fistula. Franke et al. had a 55% success rate when detachable balloons were used to treat ureteral fistulas [17], which helps to support our hypothesis that BN could be an alternative to surgery when treating a UTF and could also be used as a first-line treatment (but with repeat repositioning).

For bladder fistulas, treatment using a bladder catheter is not very effective, and published success rates vary between 6% and 12% [6, 18]. In our study, the success rate was 17% for bladder fistulas. Surgery is the gold-standard strategy used today, but it needs preparation. BN could save time and aid urinary tract healing, while reducing necrosis and fibrin

accumulation. Thus, BN could increase the chances of success [19] and improve quality of life pending surgery.

We did not analyze urethral fistulas because only two patients had this condition in our cohort. However, we observed spontaneous closure of these two urethral fistulas.

Patients' quality of life with a bladder fistula is not improved by any catheter procedure because of the discomfort caused by the catheter and urinary leakage through the vagina or rectum. According to Li et al., out of 116 patients with a bladder catheter, 84.5% had bladder-catheter discomfort [20]. The use of BN could decrease these side effects when surgery is pending [21] and also avoid urine lost through the fistula, which is often socially distressing and disabling. For patients with a history of pelvic radiation therapy, the success rate was lower in our study than that described in the literature [22].

We observed very few complications related to nephrostomy, like Degirmency et al. [23]. This safe procedure is associated with a low complication rate (< 10%). In our study, the most common complication was ureteral stricture, which occurred in two cases subsequent to positioning or pressurizing of the balloon. These two cases needed drainage for > 4 months. There were no other serious complications related to nephrostomy (except for infectious diseases).

One drawback with BN was catheter displacement, which needed to be readjusted under fluoroscopic guidance (Clavien IIIa). In our study, an average of three BN readjustments was required per patient. In addition, ureteral stricture was observed in five patients after balloon removal: this side effect has not been described in other studies [11, 12, 17]. This may be because our median follow-up period (15.7 months) was longer than in other similar studies.

This retrospective study was based on medical records and included heterogeneous causes for the urinary fistulas; there were no data as fistula size. Because of the limited sample size, we were not able to determinate the predictive factor of success. We would have liked to compare our results with a control group treated using simple percutaneous nephrostomy, but the number of patients was insufficient.

The major cause of urinary fistula is obstetrical complications, but this was not included in this study because this population is not comparable to our population, patients are younger with fewer comorbidities [5], and the gold standard for this pathology is surgery with very good outcomes [24]. BN is not performed in our center for those cases and thus cannot be proposed for those patients.

Another bias was patient selection because we did not have specific selection criteria (fistula size, localization, patient age, etc.) for BN. All patients in our study had several comorbidities and a high risk of poor healing (history of surgery, cancer, radiation therapy, etc.).

The clinical problem of investigation is a challenging one to treat, and scientific assessment of a minimally invasive therapeutic option to generally advance care in this field is considerably compassionate. Our heterogeneous and ill population may have decreased our success rate, which may explain the disparity found between the different drainage times reported in other studies. However, we included all causes of fistula formation to assess the effectiveness of BN in all types of UTFs.

The main objective of our study was to evaluate the place of BN for treating UTFs. We can conclude that BN is a good therapeutic option for selected ureteral fistulas in patients with several comorbidities. A percutaneous approach using BN can be adapted to a population that is unfit for surgical repair: the procedure has a low complication rate and can treat many patients when combined with conservative surgery.

Surgery remains the gold standard for treating fistulas. However, BN could help to drain fistulas when surgery is pending. This improves the patients' quality of life and prevents urinary leakage. It could also improve the surgical outcomes by giving more time to prepare the patient for surgery (by optimizing nutrition, physical activity, etc.) to improve healing. Indeed, no recurrence of the fistulas was observed in our population.

Conclusion

This minimally invasive procedure can be used safely on selected urinary fistulas in populations that have several comorbidities. It should be considered a palliative procedure or an intermediate treatment for those who need to be prepared to surgery.

Compliance with ethical standards

Conflicts of interest None.

Ethical standards The patients' characteristics and treatment strategies were collected by screening medical records after approval from our Institutional Review Board.

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