



# Management of urinary fistulas after partial nephrectomy: results from the U-LEAK study (UroCCR-181)

Marion Ghenassia<sup>1</sup> · Jean-Christophe Bernhard<sup>2</sup> · Gaëlle Margue<sup>2</sup> · Karim Bensalah<sup>3</sup> · Bastien Parier<sup>4</sup> · Jonathan Olivier<sup>5</sup> · Constance Michel<sup>6</sup> · Cécile Champy<sup>7</sup> · Clément Sarrazin<sup>8</sup> · Thibaut Waeckel<sup>9</sup> · Nicolas Branger<sup>10</sup> · Julien Guillotreau<sup>11</sup> · Victor Gaillard<sup>12</sup> · Louis Vignot<sup>13</sup> · Jean-Jacques Patard<sup>14</sup> · Philippe Rouvier<sup>15</sup> · Franck Bruyere<sup>16</sup> · Romain Boissier<sup>17</sup> · Alexis Fontenil<sup>18</sup> · Maxime Vallee<sup>19</sup> · Richard Mallet<sup>20</sup> · Jérôme Gas<sup>21</sup> · Frédéric Panthier<sup>22</sup> · Igor Duquesne<sup>23</sup> · Pierre Bigot<sup>24</sup> · Louis Surlemont<sup>25</sup>

Received: 13 September 2025 / Accepted: 2 February 2026

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## Abstract

**Objectives** Partial nephrectomy can lead to complications such as urinary fistulas, with an incidence ranging from 1 to 17%. Currently, there are no formal guidelines for managing these urinary fistulas. The aim of this study is to assess the time to fistula resolution according to different treatment options.

**Materials and methods** The U-Leak study is a retrospective, observational, and multicenter French cohort based on analyses from the UroCCR database. The inclusion period extends from 2009 to 2024, included patients who underwent partial nephrectomy with post-operative urinary fistula. We identified two groups: patients managed interventionally and patients managed without any drainage. The primary objective was to evaluate the time to resolution of urinary fistulas after partial nephrectomy.

**Results** We included 127 patients, predominantly male (71.7%), with a mean age of 59.4 years. The majority of partial nephrectomies (55.2%) were performed via transperitoneal robotic surgery. Interventional management was applied to 82.4% of patients, 39.5% received a primary double J stent, 17.7% of patients were treated with a bladder catheter combined with a double J and 25.2% received percutaneous drain, bladder catheter or combination of two or three treatment. Twenty-five patients required a second intervention. The median time to fistula resolution was 43 days [13.5–81.5] after the first treatment and 48 days [21.5–67.5] after the second. Overall, 79.8% of fistulas resolved after the first intervention. The median time to resolution was 44 days [29.0–69.5] without interventional treatment and 50 days [23.5–87.0] with treatment, with no statistically significant difference between the two groups ( $p=0.432$ ).

**Conclusion** We did not observe a significant difference in the time to resolution of urinary fistulas after partial nephrectomy between patients managed interventionally and those managed without any drainage.

**Keywords** Kidney cancer · Nephrectomy partial · Complications · Urinary fistula

## Introduction

Renal cancer is a major public health issue, accounting for 3% to 5% of cancer diagnoses worldwide. It is the 6th most common cancer in men and the 10th most common in women [1]. In Western countries, its incidence is rising, while mortality rates are declining [2]. Patients with localized renal tumors have several therapeutic options, including active surveillance, partial nephrectomy, total nephrectomy,

and thermal ablation [3]. Partial nephrectomy is the standard surgical technique, providing better renal function preservation than radical nephrectomy while achieving comparable oncological outcomes [4]. Partial nephrectomy can be performed through open surgery, laparoscopic surgery, or robot-assisted laparoscopic surgery [5]. The complication rate for partial nephrectomy, regardless of surgical approach, ranges from 4.5% to 28% [6, 7]. Specific complications include urinary fistulas and arteriovenous fistulas, with urinary fistulas

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being the most common, occurring at rates between 1 and 17% [8–10]. Several risk factors for urinary fistula after partial nephrectomy have been reported, including tumor size, tumor depth, opening of the collecting system and surgical approach [7, 11–13]. Preoperative imaging and anatomical scoring systems have also been proposed to better predict the occurrence of this complication [14, 15]. Several studies have explored methods to reduce the risk of postoperative urinary fistula, including intraoperative placement of a double J stent, use of hemostatic agents, and placement of a single J stent with an intraoperative leak test [12, 16, 17]. However, none of these techniques has proven effective in reducing fistula risk. Postoperative fistulas may be managed through surveillance, placement of a ureteral stent, bladder catheter, percutaneous drain, or combinations of these treatments. Currently, no clear guidelines exist for managing urinary fistulas after partial nephrectomy. The aim of this study is to assess the time to fistula resolution across different management approaches.

## Materials and methods

### Study design

**U-Leak** (Management of urinary leak after partial nephrectomy) is a retrospective, observational, multicenter French cohort study based on the analysis of prospectively collected data from the UroCCR database (ClinicalTrials.gov: NCT03293563/CNIL agreement DR-2013-206). CNIL decision no. DT-2024-027 of December 31, 2024 authorizing the BORDEAUX UNIVERSITY HOSPITAL CENTER to implement automated data processing for the purpose of creating a health data warehouse, called "UroCCR". Patients were prospectively included between 2009 and 2024 after providing written informed consent. All patients received oral and written information about the objectives and methodology of the UroCCR project and written consent. It was obtained. The study was conducted in accordance with the recommendations of the Declaration of Helsinki. Baseline patient characteristics included age, sex, weight, height, and BMI. Tumor characteristics were also collected such as size, TNM stage, tumor location, and renal complexity score (RENAL score). Using the RENAL score, tumors were classified into three complexity groups: scores between 4 and 6 indicated low complexity (grade 1); scores between 7 and 9 indicated moderate complexity (grade 2); and scores between 10 and 12 indicated high complexity (grade 3) [18]. Surgical data, such as the surgical approach used, were also extracted from the database. Follow-up data were collected, including the presence or absence of urinary fistula, the diagnostic delay of the fistula, the type of management provided, and the time to resolution. The centers included in the study were

contacted to verify the eligibility of the records and to collect the clinical data necessary for conducting the study.

### Analysis strategy

For the analysis of initial management according to clinical presentation, patients were stratified based on clinical findings as follows: asymptomatic, fever, abdominal pain, or a combination of fever and abdominal pain.

Two groups were formed based on patients' initial management. The first group included patients who received interventional management, excluding those treated by radical nephrectomy, percutaneous nephrostomy, or surgical re-intervention. Patients who underwent radical nephrectomy were excluded from final analysis to avoid potential bias, while percutaneous nephrostomy and surgical re-intervention were excluded due to their limited numbers (Fig. 1). The second group included patients managed with surveillance, meaning no intervention was performed.

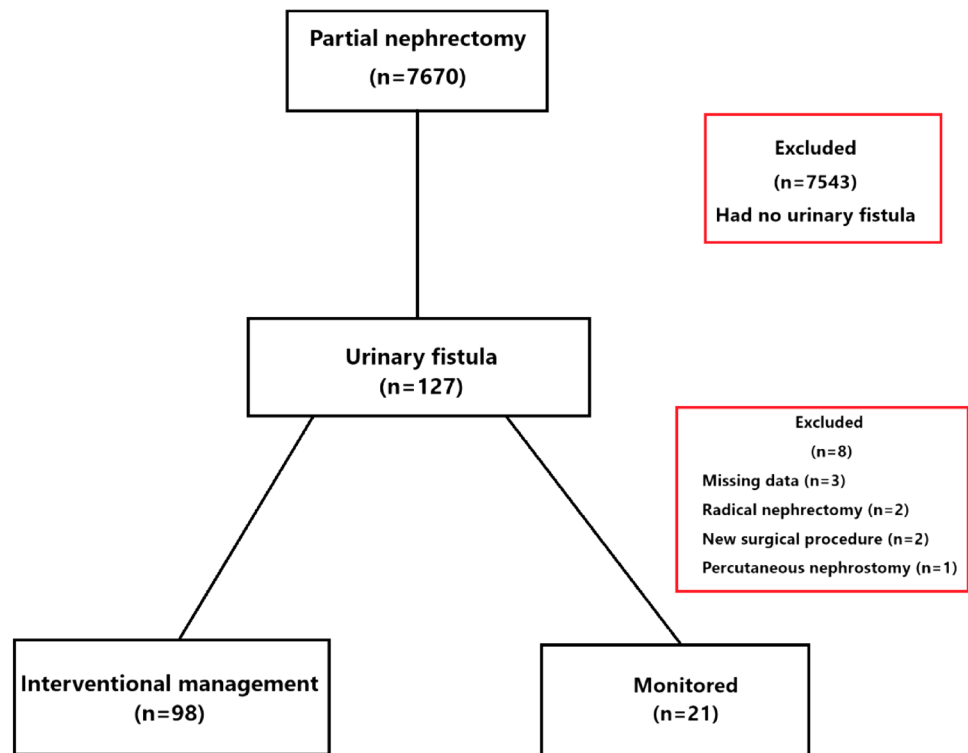
Univariate analyses were performed on these two groups (surveillance vs. interventional management).

Resolution of urinary fistula was defined using predefined clinical and radiological criteria. Clinical resolution was defined as the absence of urinary leakage symptoms, including fever, abdominal pain, or persistent drainage output. Radiological resolution was defined by the absence of contrast extravasation or urinoma on follow-up imaging, as few patients in the study had imaging available to confirm fistula resolution.

### Primary outcome and statistical analysis

The primary outcome was the time to fistula resolution based on the treatment provided. Secondary outcomes included symptoms at the time of urinary fistula diagnosis, the diagnostic delay of urinary fistula, the fistula resolution rate, and the type of secondary treatment. Continuous variables are presented as means ( $\pm$ standard deviation) or medians (interquartile range) depending on their distribution. Categorical variables are presented as counts (percentage). Missing data were handled by case deletion. The normality of the data was assessed using the Shapiro–Wilk test. Statistical comparisons were conducted with Student's t-test for normally distributed variables and Mann–Whitney U or Kruskal–Wallis tests for non-normally distributed variables. Fisher's exact test and Chi-squared test were applied for categorical variables as appropriate. Multivariate analysis was not performed due to the limited power of the study and the non-normal distribution of certain variables. A p-value  $< 0.05$  was considered statistically significant. Statistical comparisons were performed using the Statistical Package for the Social Sciences (SPSS; Version 28.0.1.1, IBM, Armonk).

**Fig. 1** Flow chart of the patients included in the univariate analysis



## Results

### Descriptive statistics

Baseline characteristics of the patients are presented in Table 1. A total of 7670 patients underwent partial nephrectomy. Of these, 132 patients developed a urinary fistula, representing 1.72%. Five patients were excluded due to missing data, and a total of 127 patients were included in our study. A total of 23 centers participated in the study by including their eligible patients. The included patients were predominantly male ( $n=91$ ; 71.7%) with a mean age of 59.4 years ( $\pm 13.7$ ). A total of 127 patients were included in this study, accounting for 132 tumors, as five patients presented with multiple tumors. Most tumors were located along the equatorial line of the kidney ( $n=56$ ; 44.1%). The mean size of the renal lesions was 5.0 cm ( $\pm 2.7$ ). Most lesions were in contact with the collecting system (62.2%). The most represented tumor stages were T1a (41.8%) and T1b (35.2%). Surgical complexity was classified as high in 39.4% of cases and moderate in 44.4% of cases. The majority of patients underwent robotic transperitoneal surgery (55.2%). The mean operative time was 178.5 min ( $\pm 82.1$ ). Estimated blood loss was 350 mL [200–800]. An intraoperative complication occurred in 14% of patients ( $n=18$ ). These included hemorrhage in 6.3% ( $n=8$ ), pleural breach in 3.1% ( $n=4$ ), vascular injury in 1.5% ( $n=2$ ), digestive tract injury in 0.8% ( $n=1$ ), and complications of unknown cause in 2.3% ( $n=3$ ). Conversion was

required in 4 patients (3%). The mean time to diagnosis of the fistula was 18.5 days ( $\pm 45.9$ ). Patients with urinary fistula most commonly presented with fever ( $n=36$ ; 28.8%), were asymptomatic ( $n=29$ ; 23.2%), or presented with abdominal pain ( $n=24$ ; 19.2%). During fistula management, the majority of patients were hospitalized (83.5%), with a mean hospital stay of 10.6 days ( $\pm 12.4$ ). Patients were managed with the placement of a double J stent in 39.5% of cases, while 17.7% were treated with a bladder catheter combined with the placement of a double J stent, and 16.9% did not received invasive management, only undergoing monitoring, often combined with antibiotic treatment (Table 2). Finally, 79.8% of fistulas ( $n=99$ ) were resolved after the first intervention. Twenty-five patients required a second treatment, including 6 patients who underwent placement of a percutaneous drain (24.0%), 4 patients with a double J stent (16.0%), 4 patients with a ureteral stent (16.0%), and 4 patients who underwent radical nephrectomy (16.0%). The radical nephrectomy rate was 3% in all patients with urinary fistula. The median time to resolution was 43 days [13.5–81.5] after first-line treatment and 48 days [21.5–67.5] after second-line treatment (Table 2).

### Univariate analyses

After stratification of the groups, 98 patients (82.4%) received interventional management, whereas 21 patients (17.6%) did not receive interventional management and were therefore managed with surveillance (Fig. 1). Baseline patient, tumor,

**Table 1** Patient characteristics

Variables	Patients with post-partial nephrectomy fistulas (n = 127)
Age at surgery (mean, standard deviation)	59.4 ( $\pm$ 13.7)
Sex (n, %)	
Male	91 (71.7%)
Female	36 (28.3%)
BMI (mean, standard deviation)	27 ( $\pm$ 5.5)
Tumor size (mean, standard deviation) in cm	4.97 ( $\pm$ 2.66)
Location, 132 tumors (n, %)	
Upper pole	32 (24.3%)
Equatorial	56 (42.4%)
Lower pole	44 (33.3%)
Lesion in contact with the collecting system (n, %)	79 (62.2%)
Renal score (n, %)	
Low	16 (16.2%)
Moderate	44 (44.4%)
High	39 (39.4%)
Missing data: 28	
Tumor stage (n, %)	
T1a	51 (41.8%)
T1b	43 (35.2%)
T2a	11 (9.0%)
T2b	10 (8.2%)
T3	5 (4.1%)
T4	2 (1.7%)
Missing data: 5	
Surgical approach used (n, %)	
Robot-assisted transperitoneal	69 (55.2%)
Lumbotomy	28 (22.4%)
Transperitoneal laparoscopy	20 (16.0%)
Robot-assisted retroperitoneal	5 (4.0%)
Subcostal	3 (2.4%)
Missing data: 2	
Operative time (mean, standard deviation) in minutes	178.5 ( $\pm$ 82.1)
Estimated blood in mL	
Median, [Q1;Q3]	350 [200–800]
Complications (n, %)	18 (14%)
Hemorrhage	8 (6.3%)
Pleural breach	4 (3.1%)
Vascular injury	2 (1.5%)
Digestive tract injury	1 (0.8%)
Others	3 (2.3%)
Diagnostic delay of the fistula in day (mean, standard deviation)	18.5 ( $\pm$ 45.9)
Symptomatology at diagnosis (n, %):	
Fever	36 (28.8%)
Asymptomatic	29 (23.2%)
Abdominal pain	24 (19.2%)
Abdominal pain associated with fever	14 (11.2%)
Discharge at the incision site	6 (4.8%)
Productive drain	5 (4.0%)
Acute renal failure	3 (2.4%)
Hematuria	2 (1.6%)
Clotting in the urinary tract	2 (1.6%)
Discharge at the incision site associated with fever	1 (0.8%)
Swelling at the incision site	1 (0.8%)
Hematuria associated with fever	1 (0.8%)

**Table 1** (continued)

Variables	Patients with post-partial nephrectomy fistulas (n=127)
Other symptoms	1 (0.8%)
Missing data: 3	

*BMI* Body Mass Index

**Table 2** Management of the fistula and resolution time

Variables	Patients with post-partial nephrectomy fistulas (n=127)
Number of hospitalizations (n, %)	101 (83.5%)
Length of hospitalization in day (mean, standard deviation)	10.6 ( $\pm$ 12.4)
Initial management of the fistula (n, %)	
Double J stent	49 (39.5%)
Bladder catheter+double J stent	22 (17.7%)
Surveillance	21 (16.9%)
Bladder catheter	5 (4.1%)
Percutaneous drain	5 (4.1%)
Bladder catheter+double J stent+percutaneous drain	5 (4.1%)
Double J stent+percutaneous drain	4 (3.2%)
Bladder catheter+percutaneous drain	4 (3.2%)
Ureteral stent	4 (3.2%)
Surgical revision	2 (1.6%)
Total nephrectomy	2 (1.6%)
Nephrostomy	1 (0.8%)
Missing data: 3	
Resolution rate after the first treatment (n, %)	99 (79.8%)
Missing data: 3	
Second treatment used after failure of the first: 25 patients (n, %)	
Percutaneous drain	6 (24.0%)
Double J stent+percutaneous drain	4 (16.0%)
Double J stent	4 (16.0%)
Total nephrectomy	4 (16.0%)
Bladder catheter	3 (12.0%)
Nephrostomy catheter	2 (8.0%)
Bladder catheter+Double J stent	1 (4.0%)
Ureteral catheter	1 (4.0%)
Resolution time after the first treatment in day	
Median [Q1, Q3]	43 [13.5;81.5]
Resolution time after the second treatment in day	
Median [Q1, Q3]	48 [21.5;67.5]

and surgical characteristics were compared according to initial management strategy (surveillance versus interventional management). No statistically significant differences were observed between the two groups regarding age, sex, body mass index, tumor size, tumor location, RENAL score, tumor stage, surgical approach, operative time, estimated blood loss, or perioperative complications. Although a higher proportion of tumors in contact with the collecting system and of high RENAL complexity was observed in the interventional management group, these differences did not reach

statistical significance. (Table 3). For the analysis of initial management based on symptomatology, we chose to focus on the main clinical symptoms (fever, abdominal pain, or a combination of both) as well as asymptomatic patients. There was no significant difference between initial management and symptomatology ( $p=0.308$ ) (Fig. 2). There was no statistically significant difference between the surgical approach and time to fistula resolution ( $p=0.79$ ), nor between surgical complexity and time to resolution ( $p=0.06$ ). Similarly, no significant association was found between initial management and the symptom-based approach ( $p=0.308$ ). A statistically significant difference was observed between tumor location and fistula resolution time, with a more favorable outcome for tumors located in the inferior pole (mean resolution time: 33 days,  $p=0.04$ ) and a less favorable outcome for lesions in the equatorial region (mean resolution time: 59 days,  $p=0.01$ ). There was no statistically significant difference between the time to resolution and the tumor location relative to the collecting system ( $p=0.44$ ) (Table 4). The median time to resolution of urinary fistulas without interventional treatment was 44 days [29.0–69.5], while the time with interventional treatment was 50 days [23.5–87.0]. There was no statistically significant difference between the time to resolution and the initial management ( $p=0.432$ ) (Fig. 3).

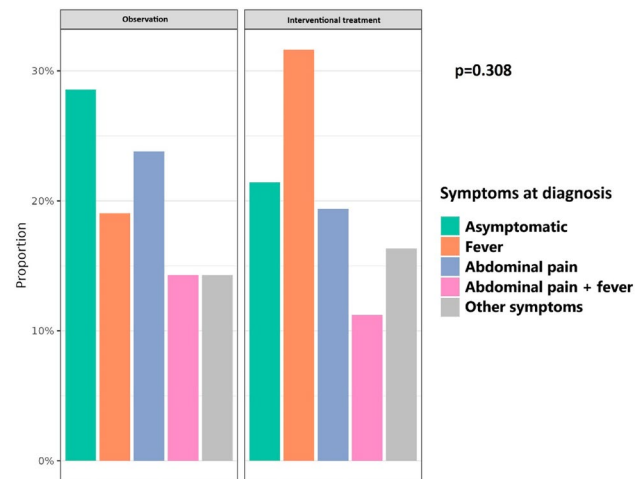
## Discussion

To the best of our knowledge, this study represents the largest analysis of the time to resolution of urinary fistulas based on different management strategies. Numerous studies have focused on urinary fistulas after partial nephrectomy, mainly by identifying risk factors and preventive measures, while optimal management strategies remain poorly defined. Collecting system injury, tumor size and tumor location have been consistently reported as major predictors of urinary fistula occurrence [11, 15]. In our cohort, most tumors were in contact with the collecting system and had a mean size of approximately 5 cm, in line with previously described high-risk profiles. To address potential confounding factors, baseline patient, tumor, and surgical characteristics were compared between surveillance and interventional management groups. No statistically significant differences were observed between the two groups, although residual confounding cannot be entirely excluded given the retrospective design of the study. Several preventive strategies, including intraoperative

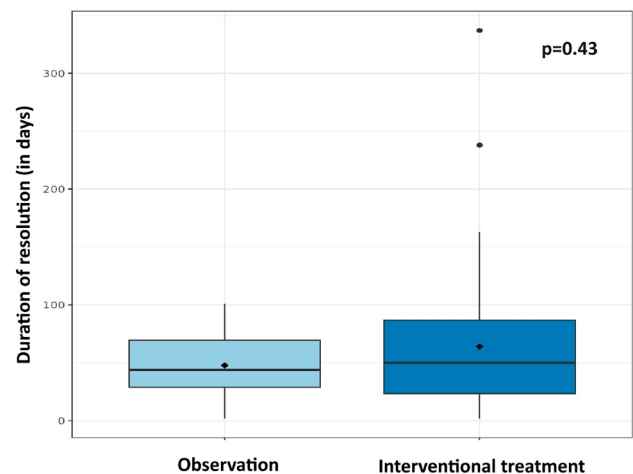
**Table 3** Baseline patient, tumor, and surgical characteristics according to initial management strategy

Variables	Observation	Interventional treatment	
Age at surgery (mean, standard deviation)	54.7 ( $\pm$ 12.0)	59.9 ( $\pm$ 13.9)	p=0.085
Sex (n, %)			p=0.34
Male	13 (15.5%)	71 (84.5%)	
Female	8 (22.8%)	27 (77.2%)	
BMI (mean, standard deviation)	26 ( $\pm$ 6.28)	27 ( $\pm$ 5.06)	p=0.2
Tumor size (mean, standard deviation) in cm	4.86 ( $\pm$ 1.94)	4.92 ( $\pm$ 2.77)	p=0.6
Location, 132 tumors (n, %)			
Upper pole	76 (85.4%)	22 (73.3%)	p=0.13
Equatorial	51 (77.3%)	47 (88.7%)	p=0.1
Lower pole	64 (82.0%)	34 (82.9%)	p=0.91
Lesion in contact with the collecting system (n, %)	34 (77.3%)	64 (85.3%)	p=0.27
Renal score (n, %)			p=0.22
Low	4 (28.6%)	10 (71.4%)	
Moderate	9 (22.5%)	31 (77.5%)	
High	4 (10.5%)	34 (89.5%)	
Tumor stage (n, %)			p=0.77
T1a	9 (18.75%)	39 (81.25%)	
T1b	8 (19.05%)	34 (80.95%)	
T2a	1 (0.1%)	9 (0.9%)	
T2b	1 (0.11%)	8 (0.89%)	
T3	2 (0.4%)	3 (0.6%)	
T4	0 (0%)	2 (100%)	
Surgical approach used (n, %)			p=0.66
Robot-assisted transperitoneal	13 (20.3%)	51 (79.7%)	
Lumbotomy	3 (10.7%)	25 (89.3%)	
Transperitoneal laparoscopy	4 (22.2%)	14 (78.8%)	
Robot-assisted retroperitoneal	1 (25.0%)	3 (75.0%)	
Subcostal	0 (0%)	3 (100%)	
Operative time (mean, standard deviation) in minutes	184 ( $\pm$ 85.2)	179 ( $\pm$ 84.6)	p=0.62
Estimated blood in mL			p=0.99
Median, [Q1;Q3]	350 [162–775]	350 [200–725]	
Complications (n, %)	1 (6.25%)	15 (93.75%)	p=0.3

ureteral or double J stent placement, have been evaluated but failed to demonstrate a reduction in postoperative urinary fistula rates [16, 19]. Accordingly, only one patient in our series had a double J stent placed intraoperatively. In our series, the average time to the appearance of fistulas was 18.5 days, which is longer compared to the literature. Peyton et al. conducted a retrospective study on 975 patients, finding that the

**Fig. 2** Initial management based on symptoms**Table 4** Resolution time according to surgical approach and tumor location

Location	Resolution time in day (median, interquartile range)	
Upper pole	49 [8.5–96]	p=0.9
Equatoriale	59 [32.5–89]	p=0.01
Lower pole	33 [9.5–64]	p=0.04
Lesion in contact with the collecting system	48.5 [16.5–92]	p=0.44

**Fig. 3** Resolution time according to management. \*Excluding patients: missing data (3 patients), radical nephrectomy (2 patients), percutaneous nephrostomy (one patient) new surgical procedure (2 patient)

time to detect urinary fistula was 3.5 days [20]. However, in this study, the diagnosis was based on the presence of productive drains. This difference may be explained by the evolution of surgical practices, particularly the progressive discontinuation of routine immediate postoperative drainage. Regarding symptomatology at diagnosis, most patients in the studies presented with abdominal pain, fever, or productive drains. Fever and abdominal pain are clinical signs consistent with

the findings of our study. However, only 4% of patients in our cohort had a productive drain. Furthermore, we lack precise data on the proportion of patients who underwent postoperative drainage. The hospitalization duration was comparable, averaging around 10 days [11]. For initial management, most patients were treated with the placement of a double J stent, sometimes combined with a bladder catheter, or through simple observation. This approach is common in the literature [11, 20, 21]. Notably, two patients underwent extended nephrectomy due to a ureteral injury diagnosed postoperatively based on a productive drain. Only 25 patients (20%) required a second treatment because the first management was insufficient. The radical nephrectomy rate was 3% in all patients with urinary fistula. In comparison, Kundu et al. reported a failure rate of conservative treatment (observation) of 31% in a cohort of 52 patients with urinary fistula after partial nephrectomy. None underwent radical nephrectomy as a second-line treatment [21]. In the study by Peyton et al., there was one failure of conservative treatment that required nephrectomy 45 days after the initial surgery [20]. The median time to fistula resolution, regardless of the treatment approach, was 43 days in our study, which is shorter than the times reported in other studies. In our cohort, fistula resolution was defined according to clinical criteria rather than systematic radiological confirmation, which represents a subjective endpoint and may account for the shorter resolution times observed. Some have also evaluated management strategies after multiple lines of treatment failures, including percutaneous electrocoagulation [22], endoscopic electrocoagulation [23], percutaneous cryoablation of the fistula [24], and injection of fibrin glue or N-butyl cyanoacrylate at the fistula site [25, 26]. None of these treatments were used in our cohort [27].

## Strengths and limitations

This study's primary strength lies in its multicenter design, encompassing data from 23 centers, which enhances the external validity of our findings. The inclusion of high-volume centers with diverse patient populations allows for a comprehensive assessment, suggesting that the results may be generalizable. However, the study has several limitations. First, its retrospective and observational nature introduces potential biases, such as missing or incomplete data, that could affect the robustness of the conclusions. Additionally, the sample size is relatively small, which limits the statistical power to detect differences between management strategies. Finally, the lack of a standardized protocol for fistula management across centers may introduce variability in the results. While randomized controlled trials addressing this research question would be challenging due to the low incidence of urinary fistulas and the heterogeneity of clinical presentations,

alternative methodological approaches such as observational studies with a control cohort or matched analyses could help to further address this knowledge gap and refine management strategies following partial nephrectomy.

Time to fistula resolution was mainly assessed using clinical criteria, as follow-up imaging was not systematically performed in all patients, which may have introduced some heterogeneity in outcome assessment.

## Conclusion

This study did not demonstrate a statistically significant difference in the time to resolution of urinary fistula between patients managed interventionally and those monitored without intervention. These results suggest that the effectiveness of different management strategies remains uncertain. It therefore appears necessary to conduct randomized controlled trials to evaluate the impact of various interventions on fistula resolution and to establish clear recommendations for the optimal management of this rare but potentially major complication.

**Author contributions** Approval UroCCR multicentre database (NCT03293563), which is IRB-approved, for which the CNIL authorization number DR-2013–206 was obtained. Human Ethics and Consent to Participate declarations: Informed Consent signed by the patients. Funding Declaration: no Funding.

**Funding** No funding.

**Data availability** No datasets were generated or analysed during the current study.

## Declarations

**Conflict of interest** The authors declare no competing interests.

**Ethical approval** Approval UroCCR multicentre database (NCT03293563), which is IRB-approved, for which the CNIL authorization number DR-2013–206 was obtained.

**Human ethics and consent to participate** Informed consent signed by the patients.

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## Authors and Affiliations

Marion Ghenassia<sup>1</sup> · Jean-Christophe Bernhard<sup>2</sup> · Gaëlle Margue<sup>2</sup> · Karim Bensalah<sup>3</sup> · Bastien Parier<sup>4</sup> · Jonathan Olivier<sup>5</sup> · Constance Michel<sup>6</sup> · Cécile Champy<sup>7</sup> · Clément Sarrazin<sup>8</sup> · Thibaut Waeckel<sup>9</sup> · Nicolas Branger<sup>10</sup> · Julien Guillotreau<sup>11</sup> · Victor Gaillard<sup>12</sup> · Louis Vignot<sup>13</sup> · Jean-Jacques Patard<sup>14</sup> · Philippe Rouvier<sup>15</sup> · Franck Bruyere<sup>16</sup> · Romain Boissier<sup>17</sup> · Alexis Fontenil<sup>18</sup> · Maxime Vallee<sup>19</sup> · Richard Mallet<sup>20</sup> · Jérôme Gas<sup>21</sup> · Frédéric Panthier<sup>22</sup> · Igor Duquesne<sup>23</sup> · Pierre Bigot<sup>24</sup> · Louis Surlemont<sup>25</sup>

✉ Marion Ghenassia  
ghenassiamarion@gmail.com

Jean-Christophe Bernhard  
jean-christophe.bernhard@chu-bordeaux.fr

Gaëlle Margue  
gaelle.margue@chu-bordeaux.fr

Karim Bensalah  
karim.bensalah@chu-rennes.fr

Bastien Parier  
bastien.pariier@aphp.fr

Jonathan Olivier  
Jonathan.OLIVIER@chu-lille.fr

Constance Michel  
cmichel@ghpsj.fr

Cécile Champy  
cecile.champy@aphp.fr

Clément Sarrazin  
csarrazin1@chu-grenoble.fr

Thibaut Waeckel  
thibaut.waeckel@icloud.com

Nicolas Branger  
BRANGERN@ipc.unicancer.fr

Julien Guillotreau  
jguillotreau@clinique-pasteur.com

Victor Gaillard  
victor.gaillard@chru-strasbourg.fr

Louis Vignot  
vignot.l@chu-nice.fr

Jean-Jacques Patard  
jean-jacques.patard@ch-mdm.fr

Philippe Rouvier  
philippe.rouvier@aphp.fr

Franck Bruyere  
F.BRUYERE@chu-tours.fr

Romain Boissier  
Romain.BOISSIER@ap-hm.fr

Alexis Fontenil  
Alexis.FONTENIL@chu-nimes.fr

Maxime Vallee  
Maxime.VALLEE@chu-poitiers.fr

Richard Mallet  
rmallet@afu.fr

Jérôme Gas  
jerome.gas@clinique-pontdechaume.fr

Frédéric Panthier  
frederic.panthier@aphp.fr

Igor Duquesne  
igor.duquesne@aphp.fr

Pierre Bigot  
PiBigot@chu-angers.fr

Louis Surlemont  
Louis.Surlemont@chu-rouen.fr

- 1 Department of Urology, CHU Rouen, Rouen, France
- 2 Department of Urology, CHU Bordeaux, Bordeaux, France
- 3 Department of Urology, CHU Rennes, Rennes, France
- 4 Department of Urology, Bicêtre Hospital, APHP, Le Kremlin-Bicêtre, France
- 5 Department of Urology, CHU Lille, Lille, France
- 6 Department of Urology, Saint Joseph Hospital, Marseille, France
- 7 Department of Urology, Henri Mondor University Hospital, AP-HP, Créteil, France
- 8 Department of Urology, CHU Grenoble, Grenoble, France
- 9 Department of Urology, CHU Caen, Caen, France
- 10 Department of Urology, Paoli Calmettes Institut, Marseille, France
- 11 Department of Urology, Pasteur Clinic, Toulouse, France
- 12 Department of Urology, CHRU Strasbourg, Strasbourg, France
- 13 Department of Urology, CHU Nice, Nice, France
- 14 Department of Urology, CH Mont-de-Marsan, Mont-de-Marsan, France
- 15 Department of Urology, CHU La Pitié Salpêtrière, Paris, France
- 16 Department of Urology, CHRU Tours, Tours, France
- 17 Department of Urology, CHU Conception, APHM, Marseille, France
- 18 Department of Urology, CHU de Nîmes, Nîmes, France
- 19 Department of Urology, CHU de Poitiers, Poitiers, France
- 20 Department of Urology, Francheville Polyclinique, Périgueux, France
- 21 Department of Urology, Clinique du Pont de Chaume, Montauban, France
- 22 Department of Urology, Tenon Hospital, Paris, France
- 23 Department of Urology, Cochin Hospital, APHP, Paris, France
- 24 Department of Urology, CHU de Angers, Angers, France
- 25 Department of Urology, CHU de Rouen, Rouen, France