Minerva Urologica e Nefrologica
EDIZIONI MINERVA MEDICA

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Minerva Urologica e Nefrologica
DOI: 10.23736/S0393-2249.19.03549-5

Article type: Original article

Article first published online:
Manuscript accepted: November 25, 2019
Manuscript revised: October 30, 2019
Manuscript received: June 23, 2019

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Role of cultural analysis in patients with indwelling ureteral stent submitted to ureteroscopy for stones

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Running head: role of stent culture in ureteroscopy for stones

Keywords: Stent culture; ureteroscopy; stones; infectious complications, UTI

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Conflict of interest: The authors declare that they have no conflict of interest.

Abstract

BACKGROUND: Aim of our study is to analyze the incidence of postoperative infectious complications and to assess its predictors in patients with indwelling ureteral stent treated with ureteroscopy (URS).

METHODS: We retrospectively evaluated data of patients treated with URS from January 2017 to July 2018 at our center. We included 88 consecutive patients with available stent culture (SC) and urine culture (UC). Cefoxitin 2 g iv was given as prophylaxis in all patients with negative preoperative UC; otherwise, the choice of antibiotic was based on antibiogram. Ureteral stent was removed before URS procedure and analyzed. No postoperative antibiotic was given. Multivariable logistic regression analysis was built to assess pre-operative predictors of postoperative infectious complications.

RESULTS: 19 patients (22%) developed postoperative infectious complications and fever was the most common one. E. Faecalis, which is not responsive to common prophylaxis schemes in force in our institution, was the most frequent pathogen isolated. Overall, 26% of patients were found to have a discordance between SC and UC. At multivariable logistic regression analysis preoperative SC positivity (Odds Ratio [OR]: 11.00, 95% Confidence Interval [CI]:1.08-111.41, p=0.04) was the only significant predictor of postoperative infectious complications.

CONCLUSIONS: About one to five patients treated with URS developed an infectious complication and E. Faecalis and E. Coli were the most frequent pathogen isolated. A positive SC is the only independent risk factor for postoperative infection: consequently, an early SC analysis could allow a prompt antibiotic therapy in all patients with positive SC even if mildly symptomatic.

Introduction

Urinary tract infections (UTI) are common complications among hospitalized patients, affecting almost 150 million people per year worldwide (1). About 70-80% of nosocomial or complicated UTI, are related to previous urologic interventions such as indwelling bladder- or ureteral-catheterizations (2),(3). The incidence of UTIs increase especially in patients who received a ureteral stent, which is usually placed for infected or obstructive stones to relieve symptoms, and to avoid development of complications. Bacterial stent colonization is considered one of the key-points in stent-related-UTI's pathogenesis (4). Although the relationship between stent colonization and bacteriuria is largely discussed in literature (5), (6), the relationship between bacterial device colonization and development of UTIs is still under debate: therefore, the majority of patients with a positive stent culture (SC) have asymptomatic bacteriuria, and do not develop a full-blown UTI. Although the administration of short-term antibiotic prophylaxis before ureteroscopy (URS) is recommended in clinical practice (7) (8), there are just a few studies in literature which analyzed the microbiological aspects of a stent-related complicated UTI (9), (4), (10), (11). Moreover, no study assessed the most appropriate antibiotic prophylaxis for a stent removal/substitution. In 2015 a program of antimicrobial stewardship has been created in our institution and internal institutional guidelines regarding prophylaxis in endourological procedures have been drafted (12).

We therefore sought to evaluate patients with ureteral stent with available SC and urine culture (UC) to analyze the incidence of UTI in patients treated with endourological procedures. Moreover, we tried to assess the possible correlation between pre- and intra-operative factors and the development of post-operative infectious complications. Additionally, we studied the microbiological epidemiology of bacteria isolated at our department to evaluate the efficacy of prophylaxis scheme in force in our institution.

Materials and methods

This was an institutional review board approved study. We retrospectively evaluated patients submitted to URS for stones at our tertiary referral center from January 2017 to July 2018. All pre-, intra- and post-operative characteristics were collected in a prospectively maintained database. We included all patients treated both for renal and ureteral lithiasis and among them, we selected those who received ureteral stent before surgery; the indications for ureteral stenting included the presence of obstructive stone with pain not responsive to analgesics, ureteral stones associated with urosepsis, impacted stones or previous unsuccessful URS due to uncompliant ureter which required a delayed treatment. Preoperative urinalysis was performed in all patients approximately 3 weeks before surgery: if the urinalysis was positive an antibiotic therapy was decided according the result of UC. In patients with a positive UC, a second UC was performed at the end of antibiotic treatment to verify sterility of urine before the urological procedure. Conversely, in patients with a negative urinalysis no antibiotic treatment was administered and an antibiotic prophylaxis was selected according to our institutional guidelines about stent-related UTI (12), usually a single dose of Cefoxitin 2 g iv, 1 hour up to 30 minutes before surgery. In allergic patients, a single dose of Clindamycin 600 mg iv was administered. In case of emergency procedure in patients already under antibiotic therapy, the ongoing antibiotic was continued. At the beginning of endoscopy, the stent (Cook® stents coated with hydrophilic polimer) was removed under sterile condition and collected for a stent culture (SC).

According to several studies (4),(5),(13),(14),(15),(16),(17),(18) which reported a lower sensitivity of urine analyses compared to stent culture in detecting bacteria, microbiologists were trained to analyze and to report not significant bacterial load (the ones < 100000 CFU) in UC in addition to significant bacteriuria.

Usually results from the SC required from 2 to 5 days; meanwhile, postoperative antibiotics were not systematically given. After surgery patients were monitored for at least 48-72 hours in hospital. Blood examination was performed during the first postoperative day and vital parameters including temperature, heart rate and blood pressure were monitored twice a day until dismission. Patients were treated with an antibiotic only in case of signs or symptoms of infection: in this case the therapy was administered in hospital until 3-5 days after the defervescence of symptoms. We included in infectious complications-group every patient who experienced UTI, urosepsis, severe sepsis or fever. We defined as urosepsis the presence of positive urine and blood culture associated to the presence of at least 2 among body temperature: $\geq$ 38°C or $\leq$ 36°C, tachycardia: $\geq$ 90/min, tachypnea: $\geq$ 20/min, respiratory alkalosis: $paCO_2 \leq 32$ mm Hg (< 4.3 kPa), leukocytosis $\geq$ 12/nL or leukopenia $\leq$ 4/nL or band forms $\geq$ 10% (according to Systemic inflammatory response syndrome -SIRS- criteria) or the appearance of Multiple organ dysfunction syndrome (MODS) (19). We defined severe sepsis the presence of Hypotension from sepsis (systolic blood pressure < 90 mm Hg, mean arterial pressure < 70 mm Hg, or a decrease in SBP by > 40 mm Hg), elevated lactate (above upper limit of normal), decreased urine output (<0.5 ml/kg/hr for more than 2 hours despite fluid resuscitation), presence of Acute lung injury (ARDS- if no pneumonia present: $PaO_2/FiO_2 < 250$; if pneumonia present: $PaO_2/FiO_2 < 200$), Creatinine levels above 2 mg/dL, Total Bilirubin above 2 mg/dL, thrombocytopenia with platelet count < 100,000 and coagulopathy with an INR > 1.5.

Primary and Secondary End Points

The primary endpoint of the study was to evaluate incidence of infectious complications in patients who underwent URS. Therefore, we evaluate concordance between UC-SC positivity and distribution of pathogens colonizing urine and ureteral stents.

Secondary endpoints were to assess pre-operative predictors of complications and predictors of SC positivity.

Statistical analyses

Descriptive statistics of categorical variables focused on frequencies and proportions. Means, medians, and Interquartile Ranges (IQR) were reported for continuously coded variables. The Kruskal-Wallis test and chi-square test were used to compare the statistical significance of differences in medians and proportions, respectively. Univariable and multivariable logistic regression model were used to assess predictors of infectious complications. Multivariable models were adjusted for age, gender, presence of diabetes mellitus (DM), pre-operative creatinine, pre-operative UC, time of maintenance of ureteral stent, SC positivity, type of surgery and concordance between UC-SC. Statistical significance was considered at $p<0.05$. Statistical analyses were performed using STATA 14.0® (Stata Corp., College Station, TX, USA).

Results

Baseline characteristics

From January 2017 to July 2018 a total of 285 patients underwent ureteroscopy for renal or ureteral calculi at our institution. Indwelling ureteral stents were placed before the procedure in 153 patients; among them 88 patients had UC and SC's results available and were included in the study. Patients' characteristics are reported in **Table 1**. Median age was 56 years (Interquartile range [IQR] 46-64) and most of the patients were man (57%). Overall, 22 (25%) patients had positive pre-operative UC whereas 37 (42%) had SC positivity. **Figure 1** depicts the spectrum of isolated pathogens from UC and SC**.**

Overall, 19 patients (22%) experienced infectious complications. The majority of them were female (p=0.02) and had higher creatinine values (p=0.006) and higher stone dimension (p=0.005). Fever was the most common postoperative complication with 12 cases, while 2 patients had pyelonephritis, 3 urosepsis and in 2 cases there was severe sepsis which required intensive care. Most of the complications occurred between the 2nd and the 3rd postoperative day, with median time of 52 hours (IQR 24-72). Overall, 25/88 (28%) patients had discordance between positivity of SC and UC (SC-/UC+ or SC+/UC-).

Considering the type of microorganism detected, 83% of patients with concordance in positivity had also concordance between pathogens found in UC and SC: Enterococcus Faecalis was the most frequent pathogen followed by Escherichia Coli and Candida Albicans. 3 (17%) patients had different pathogens found in UC and SC.

Predictors of post-operative infectious complications

Univariable and multivariable logistic regression analyses were built to assess pre-operative predictors of complications. At univariable analyses infectious complications were found associated with: female gender [Odds Ratio (OR) 5.25, 95% Confidence Interval (CI):1.68-16.3, p=0.004], pre-operative creatinine (OR:0.02, CI:0.70-6.26, p=0.02) and positivity of SC yes vs. no (OR:4.06, CI:1.37-12.04, p=0.01). At multivariable analyses positivity of SC only (OR:11.00, CI:1.08-111.41, p=0.04) remained associated with complications.

Predictors of SC positivity

Univariable and multivariable logistic regression analyses were built for find pre-operative predictors of SC positivity: at univariable analyses the presence of pre-operative positive UC was found associated with SC positivity (OR:11.13, CI:3.32-37.23, p<0.001). This result was confirmed at multivariable analyses (OR:12.43, CI:3.17-48.64, p<0.001).

Discussion

Over the last 10 years, endoscopy has become an important option for the treatment of renal and ureteral stones (20). Despite the reasonably safety profile, URS can be burdened by post-operative complications such as ureteral damage, hematomas (21)and infectious complications (22) characterized by not negligible mortality rates (23), (24): for this reason a critical use of antibiotics prophylaxis and therapy is required to counteract the increasing rate of bacterial drug resistance (25), healthcare costs and drug side-effects(26).

First of all, in our study we analyzed the incidence of UTI in patients with a ureteral stent treated with URS, to identify the main microorganisms responsible of stent and urine's colonization. About one fifth of our patients experienced infectious complications. Fever remains the most common postoperative complication followed by urosepsis, pyelonephritis, and severe sepsis which required intensive care treatment. Our results are in concordance with Somani et al. (27) study which reported fever as the most common post-operative infectious complication. Moreover, we found that 42% of patients treated with URS had positive SC. Our results are similar to those found by Shabeena et al (28) who reported an incidence of positive SC of about 47%. We found that the main responsible for stent colonization were E. Coli and Enterococcus Faecalis with the same incidence (22%). The E. Coli is described as the most frequent pathogen colonizing ureteral stent also in previous literature (29), (28) (30). However, our results are in contrast to those reported in the last Italian study which reported Proteus Mirabilis, Klebsiella and gram positive species as the most frequent pathogens after E.coli (29) . Moreover, in the urinalysis the E.Coli (ESBL- or ESBL+) was the most frequent germ isolated in the urine sample (36% of cases), followed by E. Faecalis (32% of cases). We can consequently assert that E. Faecalis is one of the main responsible of post-operative infectious complications: this result is particularly interesting since is commonly resistant to the antibiotic prophylaxis in force in our institution based on microbiological isolations performed in 2015 (Cefoxitin 2 g).

In our study, positivity of SC was the only significant predictor of development of post-operative infectious complications (p=0.04). This result confirms that stent may serve as a nidus for bacteria's proliferation that therefore probably plays an important role in post-operative infections. Surprisingly, no other pre-operative variable was associated with infectious complications. Our results are in contrast with Grabe et al. (13) study in which reported that bacteriuria, placement of ureteral stent or percutaneous nephrostomy were related with infectious complications. The difference in results could be attributed to the different inclusion criteria and design of the studies. Even if we found a correlation between positivity of UC and positivity of SC, about 21% of our patients had a negative UC with a positive SC. Of the total of 19 patients with negative UC and positive SC 6 (21%) have developed a post-operative infectious complication whereas 4 patients with positive UC and negative SC did not have infectious complications. These results regarding concordance between positivity of UC and SC are consistent with previous literature (4),(5),(13),(14),(15),(16),(17),(18). We can therefore deduce that UC by itself, is not a risk-factor for infectious complications, but it may become when associated with a device's contamination. Moreover, as before mentioned, the bacteria isolated from UC can be different from those isolated from SC. Given the low sensitiveness of urine analysis reported in our study and literature and the strong association between SC positivity and development of infectious complications, a stent analysis should be recommended to prevent the appearance of these kind of complications. In particular, knowing that urosepsis usually occurs within 48 h from surgery and that its early diagnosis and treatment can considerably improve both survival and morbidity, we believe that an early reporting of results of SC may allow a prompt administration of a targeted antibiotic therapy and improve survival. This treatment should be administered in all patients (included those without symptoms) who undergoes URS with a positive SC because are those with an increased risk of post-operative infectious complications. Given the current lack of techniques to accelerate the results of the SC, we believe that a rapid response on the possible positivity/negativity of the SC with the type of pathogen involved (Gram -/+) but without the result of the antibiogram, could be a potential valuable compromise to select patients for the antibiotic therapy after URS. Moreover, since E. Faecalis is the major responsible of urine and stent colonization antibiotic prophylaxis should be switched from cephalosporin to other types of antibiotic.

Our study is not without limitations: first and foremost are the limitations inherent to its design; while the data-collection was prospective, the analyses were retrospective. Moreover, the limited number of patients didn't allow an evaluation regarding the relationship between the type of antibiotic and the development of post-operative infections. Lastly, the information regarding the reason of pre-URS stenting (stones associated with urosepsis, previous failure of URS procedure for uncompliant ureter or impacted stone) was not included in our dataset, consequently its possible relationship with infections was not analyzed in our study.

Conclusion

About one fifth of our patients treated with URS experienced infectious complications caused mainly by E. Faecalis and E.Coli. The positivity of SC was the only independent risk factor for postoperative infections. Since discordance between UC and SC is common, we suggest to performing a stent analysis with an early report in all patients with a stent, treated with URS in order to allow an early antibiotic therapy if positive culture, to prevent infectious complications.

Notes

Conflict of interest: The authors declare that they have no conflict of interest.

Funding: none

Tables

Table 1 - Baseline characteristics of patients with indwelling stent who underwent ureteroscopy (URS) for calculi

Variables	Overall (n =98,100%)	Complicated (n=19, 21.6%)	Uncomplicated (n=69, 78.4%)	p value
Age, years				
Mean	55.7	52.4	56.7	0.4
IQR	46.0-64.5	43.0-61.0	47.0-65.0	
Gender				
Male	50 (56.8%)	5 (16.3%)	45 (65.2%)	0.02
Female	38 (43.2%)	14 (73.7%)	24 (34.8%)	
BMI, kg/m2				
Mean	26.38	25.8	26.5	0.3
IQR	22.7-29.31	21.6 - 31.2	23.4 - 29.0	
Creatinine, mg/dL				
Mean	1	0.8	1.0	0.006
IQR	0.7-1.0	0.5-0.9	0.8-1.0	
DM				
No	79 (89.8%)	17 (89.5%)	62 (89.9%)	0.9
Yes	9 (10.3%)	2 (10.5%)	7 (10.1%)	
CKD				
No	85 (96.6%)	19 (100.0%)	66 (95.7%)	0.3
Yes	3 (3.4%)	0 (0.0%)	3 (4.3%)	
Site of stone				
Renal	13 (14.8%)	2 (10.5%)	11 (15.9%)	0.6
Ureteral	61 (69.3%)	15 (79.0%)	46 (66.7%)	
Multiple	14 (15.9%)	2 (10.5%)	12 (17.4%)	
Side				
Right			30 (43.5%)	0.6
Left	37 (42.0%)	7 (36.8%)	38 (55.1%)	
	49 (55.7%)	11 (57.9%)	1 (1.4%)	

Bilateral	2 (2.3%)	1 (5.3%)		
Dimension Not known <10 mm bet. 10 and 20 mm >20 mm	 2 (2.3%) 53 (60.2%) 30 (34.1%) 3 (3.4%)	 0 (0.0%) 12 (63.2%) 4 (21.0%) 3 (15.8%)	 2 (2.9%) 41 (59.4%) 26 (37.7%) 0 (0.0%)	0.005
Stent time, days Mean IQR	 120.5 53-135	 115.1 59-137	 122 50-153	0.8
>90 days stent No Yes	 38 (43.7%) 49 (56.3%)	 8 (42.1%) 11 (57.9%)	 30 (44.1%) 38 (55.9%)	0.8
Positive UC pre-surgery No Yes	 66 (75.0%) 22 (25.0%)	 12 (63.2%) 7 (36.8%)	 54 (78.3%) 15 (21.7%)	0.2
Prophylaxis No Yes	 6 (6.8%) 82 (93.2%)	 0 (0.0%) 19 (100.0%)	 6 (8.7%) 63 (91.3%)	0.2
Type of antibiotics Cefoxitina Cefotaxime Others	 56 (68.3%) 10 (12.2%) 16 (19.5%)	 14 (73.7%) 1 (5.3%) 4 (21.0%)	 42 (66.7%) 9 (14.3%) 12 (19.0%)	0.5
Type of surgery URS RIRS Combined surgery DJ substitution	 56 (64.4%) 29 (33.4%) 1 (1.1%) 1 (1.1%)	 14 (73.7%) 5 (26.3%) 0 (0.0%) 0 (0.0%)	 42 (61.8%) 24 (35.2%) 1 (1.5%) 1 (1.5%)	0.7
Operation time, minutes Mean IQR	 49.9 32.0-64.0	 55.8 39.5-66.0	 48.3 31.0-64.0	0.2
SC positivity No Yes	 51 (57.9%) 37 (42.1%)	 6 (31.6%) 13 (68.4%)	 45 (65.2%) 24 (34.8%)	0.009
Concordance UC-SC No Yes	 23 (28.4%) 63 (71.6%)	 7 (36.8%) 12 (63.2%)	 18 (26.1%) 51 (73.9%)	0.3

IQR= interquartile range, BMI= body mass index, DM= diabetes mellitus, CKD= chronic kidney disease, UC= urine culture, SC= stent culture

Table 2 – Univariable and multivariable logistic regression analyses predicting infectious complications in patients with indwelling stents treated with ureteroscopy (URS)

Variables	Univariable analysis		Multivariable analysis	
	OR (CI 95%)	**p value**	**OR (CI 95%)**	**p value**
Age	0.97 (0.94-1.00)	0.08	0.95 (0.91-0.99)	0.02
Gender Female vs Male	1.77 (0.75-4.19)	0.2	1.25 (0.40-3.89)	0.7
DM yes vs no	1.11 (0.27-4.47)	0.9	1.93 (0.35-10.49)	0.4
Creatinine	1.42 (0.64-3.13)	0.9	1.62 (0.41-6.31)	0.5
Pre-operative positive UC yes vs no	11.13 (3.32-37.23)	<0.0001	12.43 (3.17-48.64)	<0.0001
Permanence of stent, days	1.00 (0.99-1.00)	0.9	1.00 (0.99-1.00)	0.8

OR= odds ratio, CI=confidence interval, DM= diabetes mellitus, UC=urine culture, SC= stent culture

Table 3 – Univariable and multivariable logistic regression analyses predicting positivity of stent culture (SC)

Variables	Univariable analysis		Multivariable analysis	
	OR (CI 95%)	**p value**	**OR (CI 95%)**	**p value**
Age	0.98 (0.94-1.01)	0.2	0.99 (0.94-1.04)	0.9
Gender Female vs Male	5.25 (1.68-16.33)	0.004	2.88 (0.63-13.14)	0.2
DM yes vs no	1.04 (0.19-5.48)	0.9	2.49 (0.244-25.38)	0.4
Creatinine	0.02 (0.00-0.52)	0.02	0.06 (0.00-1.76)	0.1
Pre-operative positive UC	2.1 (0.70-6.26)	0.2	0.55 (0.06-4.46)	0.6
Permanence of stent, days	0.99 (0.00-1.00)	0.7	0.99 (0.99-1.00)	0.8
Positive SC	4.06 (1.37-12.04)	0.01	11.00 (1.08-111.41)	0.04
Type of surgery (renal vs ureteral)	0.62 (0.20-1.94)	0.4	0.89 (0.21-3.61)	0.8
Concordance UC-SC	0.60 (0.20-1.77)	0.3	3.6 (0.41-31.76)	0.2

OR= odds ratio, CI=confidence interval, DM= diabetes mellitus, UC=urine culture, SC= stent culture

Figure legends

Figure 1 - Spectrum of isolated pathogens from urine culture (UC) and stent culture (SC)

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	Escherichia Coli	Eschierichia Coli ESBL+	Enterococcus Faecalis	Enterecoccus Hirae	Proteus Mirabilis	Candida Albicans	Candida Glabrata	Staphilococcus Epidermidis	Staphilococcus Haemoliticus	Steptococcus Agalactiae	Klebsiella Oxytoca	Pseudomonas Aeruginosas	Lactobacillus Acidophilus	Coryneobacterium Amycolatum	Coryneobacterium Tubercolostearicum	Bacillus Species
UC	27,3%	9,1%	31,8%	4,5%	0,0%	9,1%	0,0%	0,0%	0,0%	9,1%	4,5%	4,5%	0,0%	0,0%	0,0%	0,0%
SC	21,6%	0,0%	21,6%	2,7%	0,0%	16,2%	0,0%	2,7%	10,8%	5,4%	2,7%	5,4%	5,4%	2,7%	2,7%	2,7%