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Titre: Pre-Operative Risk Factors for Complications After Ureteroscopy for Stone Disease: A French Multicentric Study.

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1 Pre-Operative Risk Factors for Complications After Ureteroscopy for Stone Disease: A 2 French Multicentric Study

3

4 1. INTRODUCTION

5

6 Urolithiasis is one of the most common diseases, with an estimated lifetime
7 prevalence of 14% (1). This illness is increased under impact of health conditions, dietary
8 habits, and the increased rate of metabolic diseases such as obesity, diabetes or metabolic
9 syndrome (2–5). Furthermore, many studies shown climatic impact with an enhanced
10 incidence in warmer regions (6). Due to its high prevalence and recurrence rate, the direct or
11 indirect economic cost of this disease is significant and represent a real public health
12 problem (7–9).

13

14 Continuous progress in endoscopy has allowed the development of minimally
15 invasive techniques and several treatment options are now available for the treatment of
16 kidney and ureteral stones such as shock wave lithotripsy (SWL), ureteroscopy or
17 percutaneous nephrolithotomy (PCNL). While the number of PCNL procedures has remained
18 stable over the past decades, the number of ureteroscopies performed has increased
19 significantly in contrast to the number of SWL (10,11). With its high efficacy and low
20 morbidity, ureteroscopy has become the reference treatment for management of ureteral
21 and kidney stones with increasingly wider indications (12,13). This procedure is not without
22 risk of complications, notably urinary sepsis. Despite numerous studies on this subject, data
23 on preoperative risk factors for complications after rigid or flexible ureteroscopy remain
24 scarce.

25

26 The aim of this study was to investigate the preoperative risk factors of complication
27 in the 30 days following a rigid or flexible ureteroscopy in a large cohort of contemporary
28 patients

29

30 **2. MATERIAL AND METHODS**

31

32 **2.1 Patients and study design**

33

34 After institutional review board approval (CNIL2218286), the charts of all patients
35 who had a rigid or flexible ureteroscopy for urinary stone between January 1st 2017 and 31th
36 December 2018 at five academic medical centers were reviewed retrospectively. We
37 specifically focused on preoperative clinical, laboratory and radiological variables that were
38 available before surgery.

39

40 **2.2 Covariates**

41

42 The following preoperative data were collected for each patient: age; gender; Body
43 Mass Index (BMI); American Society of Anesthesiology (ASA) score (14); World Health
44 Organization (WHO) Performance status (15); age-indexed Charlson's score (16); history of
45 diabetes; history of cardio-vascular disease; history of Chronic Renal Failure (CRF); history of
46 pulmonary pathology; history of neurologic disease (including paraplegic patients, spina
47 bifida and multiple sclerosis); history of Crohn's disease; history of cancer;
48 anticoagulant/antiplatelet intake; history of urinary stone; history of Cacchi-Ricci disease or

49 cystinuria; history of kidney horseshoe; preoperative ureteral stent; history of previous
50 treatment for urinary stone (alkalinization, SWL therapy, ureteroscopy). The data concerning
51 the social context was also noted has social isolation, foreign language, institutionalization,
52 significant distance between the center and the home. Patients were hospitalized in
53 conventional surgery unit or in day case surgery unit according to the habits of each center.
54 The following stones' characteristics were collected for each patient: number; side (right or
55 left kidney or both); location (renal, ureteral or both); median number; median size and
56 median density of stones.

57

58 **2.3 Perioperative data**

59

60 Each patient had a preoperative urine culture and an antibiotic prophylaxis in
61 accordance with EAU guidelines (17). Results of this urine culture were collected from the
62 patients' computer records or from their paper records. The following intraoperative data
63 were gathered: operated side (right, left or both); operating time; use of an access sheath;
64 use of a laser or a lithoclast. Because of the multicenter nature of this study, the operative
65 techniques and materials used (e.g., access sheath, use of an irrigation pump, stent size)
66 were different between centers. Absence of stones was defined as the total absence of
67 residual stones or the persistence of fragments smaller than four millimeters visually or on
68 post ureteroscopy control imaging by ultrasound, CT scan or x-ray (18); postoperative
69 ureteral stent. In accordance with the multicenter nature of the study, the intraoperative
70 and postoperative follow-up protocols could vary depending on the center. all re-admission
71 and all complications that occurred within 30 days of the procedure were collected and
72 graded according to the Clavien-Dindo classification (19).

73

74 **2.4 Statistical analysis**

75 Descriptive statistics were reported as median and interquartile range (IQR) for continuous
76 variables, frequencies, and percentages for categorical variables. Logistic regression was
77 used to perform univariate and multivariable analyses to identify risk factors of
78 complications and major complications after ureteroscopy. Multivariable models included
79 covariates with a $P < 0.2$ in univariable analysis. Finally, we conducted a sensitivity analysis
80 to identify specific predictors Infectious Complications following Ureteroscopy. Statistical
81 analyses were performed using JMP v.16.0 software (SAS Institute Inc, Cary, NC). All tests
82 were 2- sided with a significance level at $P < 0.05$.

83

84 **3. RESULTS**

85

86 **3.1 Patients' characteristics**

87

88 940 patients were included for analysis with a total of 1124 procedures performed.
89 Baseline characteristics are summarized in Table 1. Median age at diagnosis was 54 years old
90 (IQR [42-66]), median BMI was 26.1 (IQR [23.1-30.1]), median Charlson's score was 1 (IQR [1-
91 3]) and median ASA score was 2 (IQR [1-2]). Median number of stones was 1 (IQR [1-2]),
92 median size was 9 mm (IQR [6.25-13.3]) and median density was 900UH (IQR [600-1100]).
93 Rigid ureteroscopy was performed in 494 of the cases. Median operative time was 60min
94 (IQR [40-80]). A preoperative ureteral stent was used in 828 cases (73.6%). 109
95 postoperative complications were observed. According to the Clavien system, postoperative

96 complications were classified as grade 1 in 41 cases (37.6%), grade 2 in 53 cases (48.6%),
97 grade 3 in 13 cases (12%), and grade 4 in 2 cases (1.8%). Table 2 shows the postoperative
98 complications observed in the present series.

99

100 **3.3 Univariate and multivariable analysis for overall complications**

101

102 In univariate analysis, ASA score (odd ratio, OR=1.68, 95%CI [1.03-2.73], p=0.04),
103 WHO performance status (OR=1.50, 95%CI [1.0-2.25], p=0.04) and neurological disease
104 (OR=2.78, 95%CI [1.56-4.95], p=0.005) were predictors of post-operative complications
105 (Table 3).

106

107 In multivariable analysis, Charlson's score (OR=0.79, 95%CI [0.65-0.95], p=0.013) and ASA
108 score >2 (OR=1.48, 95%CI [1.02-2.15], p=0.036) were independent risk factors of
109 postoperative complication (Table 3).

110

111 **3.4 Univariate and multivariable analysis for major complications**

112

113 In univariate analysis, cardio-vascular disease (OR=3.71, 95%CI [1.22-11.2], p=0.032)
114 and BMI (OR=0.87, 95%CI [0.76-0.98], p=0.027) were the only predictors of major
115 complications after ureteroscopy (Clavien-Dindo >2). Only BMI was found in multivariable
116 analysis (OR=0.86, 95%CI [0.77-0.97], p=0.01) (Table 4).

117

118 **3.5 Sensibility analysis**

119

120 A sensitivity analysis was performed to identify specific predictor of infectious
121 Complications following Ureteroscopy. In univariate analysis, WHO performance status
122 (OR=1.02, 95%CI [0.38-2.70], p=0.010), Charlson's score (OR=2.25, 95%CI [1.03-4.91],
123 p=0.016), neurological disease (OR=2.87, 95%CI [1.16-7.08], p=0.001) and pre-operative
124 positive urine culture (OR=3.30, 95%CI [1.69-6.44], p=0.004) were predictors infectious
125 complication (Table 5).
126 In multivariable analysis, Charlson's score (OR=1.57, 95%CI [0.59-4.15], p=0.018) and
127 positive urine culture (OR=3.49, 95%CI [1.65-7.37], p=0.001) were independent risk factors
128 of infectious complications following ureteroscopy (Table 5).

129

130

131 **4. DISCUSSION**

132

133 Urinary lithiasis is an endemic pathology whose incidence is constantly increasing in
134 industrialized countries. Ureteroscopy currently represents the reference treatment with
135 satisfactory results in terms of efficiency and safety. Its use can be envisaged in first
136 intention for all ureteral stones and for any renal stone with size inferior to 20mm according
137 to the current recommendations (13). Nevertheless, the complication rate is not negligible,
138 and the risk factors are not yet clearly defined, especially the preoperative risk factors.

139

140 Our results suggest that the occurrence of complication after ureteroscopy is closely
141 related to patients' baseline health status and comorbidities. Indeed, the risk factors
142 identified in our univariate analysis were an ASA score >2, an WHO performance status score
143 >=1, and neuro urological disease context. These results were confirmed in the multivariate

144 analysis in which ASA score >2 and Charlson's score appear to be independent risk factors
145 for complications.

146 These results appear to us to be rational and consistent with what is observed in
147 practice, clinical common sense being that an elderly patient with multiple comorbidities
148 carries a higher risk of postoperative complication. Age was not found to be a risk factor for
149 complications in our analysis, but this hypothesis has been confirmed in several publications
150 in the field of ureteroscopy. In a large prospective multicenter study including 11.719
151 patients and evaluating the impact of patients' comorbidities on the results of ureteroscopy,
152 Daels et al. concluded that this operative technique remained effective and safe. However,
153 the risk of complication was significantly higher in elderly patients with multiple
154 comorbidities (20). In 2019, Hanau et al. conducted a single-center retrospective study
155 evaluating risk factors for post-ureteroscopy complications. They concluded that the causes
156 of complication and prolonged hospitalization were mainly related to comorbidities (21).
157 Among the preoperative risk factors, they highlighted were high age, anticoagulant and
158 antiplatelet therapy, history of cardiovascular disease, neuro urological history, high blood
159 pressure, single kidney, chronic renal failure, and immunocompromised patients. Patients
160 with multiple comorbidities have a higher risk of mortality from kidney stone disease than
161 the general population and require robust pre- and postoperative management (22).

162

163 The context of neuro urological disease was also evident in our multivariate analysis.
164 This risk factor for complications has already been described in the literature, although data
165 on this subject remain scarce and insufficient. It is well known that neuro urological patients
166 have an increased risk of developing kidney stone disease, especially in connection with

167 immobilization hypercalcemia or vesico-sphincter dyssynergy (23). The negative impact of
168 neuro urological bladder on the risk of complications after ureteroscopy has been found in
169 several studies and these patients have a higher risk of mortality from kidney stone disease
170 than the general population (21–24). We are of course aware that these patients often
171 require complex management with multiple intersecting risk factors. Moreover, the term
172 neurological bladder encompasses many pathologies with sometimes different
173 physiopathologies that are rarely differentiated in the literature, so the results are not
174 always generalizable. Studies specifically on this population are rare and the subject
175 deserves to be developed in the future.

176 Another risk factor often quoted in literature is the presence of a positive preoperative urine
177 test. The univariate and multivariable analysis of this factor were not significant but there
178 was a trend ($p=0.06$) for both of them. Urinary tract sepsis was the most frequent
179 complication type with 42.2% of reported complications in our population. This is consistent
180 with what is found in the literature. It can be assumed that the presence of a germ in the
181 urine preoperatively increases the risk of urinary sepsis despite the implementation of
182 preoperative antibiotic therapy. In a large systematic review from EULIS (EAU Section of
183 Urolithiasis), Chug et al. analyzed risk factors for septic complications after ureteroscopy
184 which are the most frequent along with postoperative pain and hematuria (24). Among the
185 preoperative risk factors, they highlighted were positive pre-operative Urinary Tract
186 Infections (UTIs) or prior history of UTIs, patients with higher Charlson comorbidity index or
187 elderly patients, patients with a neurogenic bladder and with high BMI.

188 These results are in good agreement with those previously discussed although we
189 have not been able to demonstrate the impact of high BMI as a risk factor for complications

190 Clavien \leq 2. However, we took a closer look at the risk factors for major complications
191 (Clavien $>$ 2). In univariate analysis, the only two factors identified were BMI and
192 cardiovascular history. BMI was the only independent factor found in the multivariable
193 analysis. Data in the literature regarding the impact of BMI on the post-ureteroscopy
194 complication rate are currently conflicting. Indeed, analyses of several studies did not find a
195 significant difference in the short-term complication rate between obese patients and
196 patients with a normal BMI (10,25,26). However, some studies have obtained results
197 confirming the implication of a high BMI in the risk of postoperative complications. Ishii et al.
198 analyzed the results of ureteroscopy in 835 obese or morbidly obese patients in a systematic
199 review (27). The rates of postoperative complications were comparable to patients with a
200 normal BMI. However, they observed a significantly higher Clavien 1-2 complication rate in
201 morbidly obese patients. In a French retrospective study evaluating risk factors for
202 outpatient management failure, in other words complication, BMI was significantly higher in
203 patients in the failure group (28). Obesity was also found to be a risk factor for mortality in
204 the context of kidney stone disease (22).

205 The main strength of our study is its multicentric nature. The inclusion of patients
206 from different regions with different stone characteristics ensured that our results had good
207 applicability to the general population and allowed us to limit center-effect bias. This is
208 tempered by several limitations that must be recognized. The main one is the retrospective
209 nature of our study, with the set of biases inherent to this design, which limits the scope of
210 our results. The collection of stone characteristics such as size, density or location was
211 largely dependent on the subjectivity of the various operators. Some of these data were not
212 always described in the reports. Despite a large population, our study did not find a

213 relationship between positive urine culture, history of urinary tract infections and risk of
214 post ureteroscopic sepsis. However, this relationship has been described several times in the
215 literature. This is probably explained by a lack of power in our study. In addition, it is highly
216 likely that the number of postoperative complications is underestimated. Indeed, the
217 declaration of complications is not always found in the hospitalization reports. In addition,
218 many patients turn to outpatient medicine for the management of these complications and
219 many of them therefore go unnoticed by the surgeons. Some centers have set up a
220 systematic call of the patient within 24 hours after the operation in the framework of day
221 case surgery. These data could be interesting but are difficult to collect. Moreover, they only
222 cover complications that occurred immediately after the operation.

223

224 **5. CONCLUSION**

225

226 In our study we found that the baseline characteristics and comorbidities of the
227 patients were the main risk factors for short-term complications after ureteroscopy.
228 Ureteroscopy remains a relatively safe and effective procedure. However, we advise
229 surgeons to take precautions with fragile patients with multiple comorbidities.

230

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232

233 The authors have no conflicts of interest to declare.

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235

236 **7. AUTHORS CONTRIBUTIONS**

237

238 Study conception: Hugo Georges Arthur Dupuis; Zine-Eddine Khene ; Jean-Nicolas Cornu

239

240 Data collection: Hugo Georges Arthur Dupuis ; Louis Surlemont ; Kevin Saout ; Abdel

241 Bakayoko ; Héloïse Ducouso ; Hubert Bugel ; Christian Pfister

242

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321

322

323 **7. LEGENDS**

324 Table 1 : Patient, stone and operative characteristics

325

326 Table 2: Short time complications (occurring within the first 30 days)

327

328 Table 3: Univariate and multivariable analysis to predict overall complications after
329 ureteroscopy

330

331 Table 4: Univariate and multivariable analysis to predict major complications after
332 ureteroscopy

Table 1 : Patient, stone and operative characteristics

	Total (n=1124)	No postoperative complication (n=1015)	Postoperative Complication (n=109)	p
Median age (IQR)	54 (42-66)	54 (42-66)	50 (36-65)	0.12
Gender (%):				
Female	462 (41.1)	411 (40.5)	51 (46.7)	0.2
Male	662 (58.9)	604 (59.5)	58 (53.2)	
Median BMI (IQR)	26.4 (23.2-30.1)	26.5 (23.2-33.3)	25.8 (23-29.2)	0.29
ASA score (%):				
1-2	929 (82.6)	846 (83.3)	83 (76.1)	0.04
3-4	170 (15.1)	146 (14.4)	24 (22)	
WHO performance status (%)				
0	746 (66.3)	680 (67)	63 (57.7)	0.05
≥ 1	369 (32.8)	324 (31.9)	45 (41.2)	
Charlson's comorbidity index (IQR)	1 (0-3)	1 (0-3)	1 (0-2)	0.04
Comorbidities (%):				
Cardio-vascular disease	148 (13.1)	132 (13)	16 (14.6)	0.6
Diabetes	180 (16)	158 (15.5)	21 (19.2)	0.3
Chronic renal failure	60 (5.3)	53 (5.2)	7 (6.4)	0.6
Pulmonary disease	82 (7.3)	74 (7.3)	8 (7.3)	0.9
Hepatic disease	13 (1.15)	13 (1.2)	0	0.1
Neuro urological disease	80 (7.1)	63 (6.2)	17 (15.5)	<0.01
Crohn's disease	16 (1.42)	14 (1.3)	2 (1.8)	0.7
Cancer	63 (5.6)	58 (5.7)	5 (4.5)	0.6
History of urolithiasis (%)	412 (36.6)	381 (37.5)	40 (36.6)	0.8
Anticoagulant/antiplatelet treatment (%)	83 (7.38)	72 (7)	11 (10)	0.3
Social context (%):				
Foreign language	23 (2)	20 (1.9)	3 (2.7)	0.6
Institutionalization	40 (3.5)	33 (3.25)	7 (6.4)	0.1
Stone location (%)				
Renal	625 (55.6)	558 (55)	67 (61.4)	0.1
Ureteral	686 (61)	627 (61.7)	59 (54.1)	0.1
Both	196 (17.4)	178 (17.5)	18 (16.5)	0.7
Median number of stone (IQR)	1 (1-2)	1 (1-2)	1 (1-2.75)	0.38
Median mm size of stone (IQR)	9 (6.28-13.28)	9 (6-13)	9.15 (6.35-15)	0.31
<5mm	94 (8.36)	86 (8.47)	8 (7.33)	0.63
5-10mm	515 (45.8)	468 (46)	47 (43.1)	0.43
>10mm	498 (44.3)	441 (43.4)	54 (49.5)	0.29
Median UH density (IQR)	900 (600-1100)	900 (600-1100)	917 (644-1200)	0.11
Preoperative ureteral stent (%)	828 (73.6)	756 (74.4)	72 (66)	0.05
positive urine culture (%)	263 (23.4)	230 (22.6)	33 (30.2)	0.06

Table 2 : Short time complications (occurring within the first 30 days)

	Complications (n=109)
Clavien-Dindo (%)	
1-2	91 (83.4)
>2	15 (13.7)
Type of complications (%)	
Urinary sepsis	46 (42.2)
Pain	42 (38.5)
Vomiting	1 (0.9)
Hematuria	21 (19.2)
Urine retention	5 (4.5)
Acute renal failure	1 (0.9)
Readmission (%)	48 (44)

Table 3 : Univariate and multivariable analysis to predict overall complications after ureteroscopy

	Univariable analysis			Multivariable analysis		
	Odds ratio	(95% CI)	<i>p</i>	Odds ratio	(95% CI)	<i>p</i>
Age	0.99	(0.97-1.00)	0.13	0.99	(0.97-1.01)	0.65
BMI	0.98	(0.94-1.02)	0.37			
ASA score	1.68	(1.03-2.73)	0.04	1.48	(1.02-2.15)	0.03
PS	1.5	(1.00-2.25)	0.04	1.24	(0.88-1.74)	0.21
CCI	0.91	(0.83-1.01)	0.1	0.79	(0.65-0.95)	0.01
Antiaggregant/antiplatelet treatment	1.41	(0.71-2.78)	0.3			
Cardio-vascular disease	1.15	(0.65-2.01)	0.61			
Diabetes	1.28	(0.77-2.12)	0.32			
Neuro urological disease	2.78	(1.56-4.95)	0.005	1.17	(0.44-3.06)	0.74
Stone size	1.01	(0.98-1.03)	0.32			
Positive urine culture	1.55	(0.98-2.46)	0.06	1.57	(0.98-2.53)	0.06
Preoperative ureteral stent	0.65	(0.43-1.00)	0.05	0.7	(0.43-1.11)	0.13
PS= WHO performance status; CCI= Charlson's comorbidity index						

Table 4 : Univariate and multivariable analysis to predict major complications after ureteroscopy

	Univariable analysis			Multivariable analysis		
	Odds ratio	(95% CI)	<i>p</i>	Odds ratio	(95% CI)	<i>p</i>
Age	1	(0.97-1.04)	0.63			
BMI	0.87	(0.76-0.98)	0.02	0.86	(0.77-0.97)	0.01
ASA score	2.18	(0.77-6.12)	0.13	2.49	(0.70-8.82)	0.15
PS	2.73	(0.94-7.93)	0.06	1.62	(0.46-5.63)	0.44
CCI	1.04	(0.82-1.31)	0.72			
Antiaggregant/antiplatelet treatment	1.01	(0.12-8.12)	0.98			
Cardio-vascular disease	3.71	(1.22-11.2)	0.03	2.42	(0.65-8.98)	0.18
Diabetes	1.42	(0.39-5.14)	0.61			
Neuro urological disease	2.03	(0.45-9.17)	0.40			
Stone size	1	(0.93-1.07)	0.96			
Positive urine culture	0.71	(0.19-2.61)	0.60			
Preoperative ureteral stent	0.52	(0.18-1.48)	0.23			
PS= WHO performance status; CCI= Charlson's comorbidity index						

Table 5 : Univariate and multivariable analysis to predict sepsis after ureteroscopy

	Univariable analysis			Multivariable analysis		
	Odds ratio	(95% CI)	<i>p</i>	Odds ratio	(95% CI)	<i>p</i>
Age	1.32	(0.30-5.80)	0.71			
BMI	1.35	(0.68-2.66)	0.39			
ASA score	0.77	(0.37-1.57)	0.15			
PS	1.6	(1.25-2.15)	0.010	1.73	(1.16-2.54)	0.007
CCI	2.25	(1.03-4.91)	0.016	0.79	(0.64-0.96)	0.022
Antiaggregant/antiplatelet treatment	1.07	(0.37-3.11)	0.89			
Cardio-vascular disease	1.21	(0.53-2.77)	0.65			
Diabetes	1.51	(0.73-3.11)	0.27			
Neuro urological disease	2.87	(1.16-7.08)	0.001	1.27	(0.35-4.54)	0.70
Stone size	2.87	(0.55-14.8)	0.20			
Positive urine culture	3.30	(1.69-6.44)	0.004	3.15	(1.51-6.55)	0.002
Preoperative ureteral stent	0.65	(0.34-1.21)	0.18			
PS= WHO performance status; CCI= Charlson's comorbidity index						