Incidence and Risk Factors for Urolithiasis Recurrence After Endourological Management of Kidney Stones: A Retrospective Single-Centre Study

Faris Baowaidan (fbaowaidan@hotmail.com)  
Angers University Hospital

Ahmed S. Zugail  
Angers University Hospital

Youssef Lyoubi  
Angers University Hospital

Thibaut Culty  
Angers University Hospital

Souhil Lebdai  
Angers University Hospital

Elena Brassart  
Angers University Hospital

Pierre Bigot  
Angers University Hospital

Abdel Rahmene Azzouzi  
Angers University Hospital

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Abstract

**Purpose:** Almost half of the patients have had recurrent nephrolithiasis despite undergoing effective treatment. Our objective is to determine the recurrence rate of lithiasis after endourological management of nephrolithiasis and identify the risk factors for these recurrences.

**Methods:** Data were gathered retrospectively from all patients who were treated for nephrolithiasis by endourological management from May 2014 to January 2017 in our university hospital. All patients who had postoperative renal colic and/or stone upon an imaging study were considered to have recurrent disease. The patients were devised into two groups: with and without recurrence. Many variables were also compared between these two groups.

**Results:** A total of 190 patients were included in our study. At the end of a median follow-up of 32 months (range, 13–61 months), 25.8% of patients had a recurrent stone. In the multivariate analysis, the risk factors for recurrence were diabetes (HR: 7.9; \(p < 0.001\)) and smoking (HR: 3.5; \(p < 0.029\)). While the body mass index greater than 25 kg/m\(^2\) (HR: 2; \(p < 0.05\)) appears as a risk factor for recurrence only in the univariate analysis. However, age (HR: 0.96; \(p < 0.003\)) and blood hypertension (HR: 0.37; \(p < 0.027\)) were protective factors. The stone characteristics, urological history, and alcoholism had no apparent effect on stone recurrence.

**Conclusion:** Stone recurrence is common after the management of urinary stones. In this study 25.8% of patients had recurrrd stone disease after endourological management with a median follow-up of 32 months. Our study findings showed that diabetes and smoking are risk factors for recurrence, while age and blood hypertension are protective factors that decreased the risk of recurrence.

Introduction

Urolithiasis is a frequent multifactorial disease with an increasing incidence in industrial countries due to evolving lifestyles. The lifetime prevalence of kidney stone disease is estimated at 1–15%, and the probability of having a stone varies according to age, gender, race and geographic location.\(^1\) The National Health and Nutrition Examination Survey estimated that stone prevalence has increased from 3.8–8.8% (10.6% among men compared to 7.1% among women) in the last 30 years.\(^2\) In France, the prevalence is estimated to be 10%.\(^3\) Urolithiasis affects all age groups but has a male preponderance; however, this predominance decreases gradually in the fifth to sixth decades of life.\(^4\) Stone disease also appears to be more common in Whites than Blacks, with Hispanics and Asians falling in between.\(^2\) In addition, the number of surgical interventions for treating stone disease is also increasing progressively, especially in the new era of minimally invasive techniques, where the treatment of urolithiasis has risen to 161% via the “the gold standard treatment”\(^5\) method of ureterorenoscopy.\(^6\) Stone disease management is drawing attention for opportunities to improve the patient's experience, the metrics of use, and the costs of care.\(^7\) After reviewing the literature, we found many studies have reported the recurrence rate of urolithiasis and their management with various treatment modalities including spontaneous passage,
medical expulsive therapy, extracorporeal shock wave lithotripsy (ESWL) or surgery. In the present study, we aimed to evaluate the frequency of stone recurrence after endoscopic treatment only. We also evaluated the accompanying risk factors of each case.

Methods

Under a protocol approved by the ethical committee of the Faculty of Health Research in Angers University. (Reference no. AUR-2019-157-A). All methods were performed in accordance with the relevant guidelines and regulations. Patients were informed about the study rationale and procedures; written informed consent was obtained from all patients prior to enrolment. Data were gathered retrospectively from all patients who were treated for ureteral or kidney stones by endourological management (EM) including rigid (8F Storz) and/or flexible (Storz Flex-X®, Flex-X2S) ureterorenoscopy and percutaneous nephrolithotomy (MIP Storz) with Holmium laser or pneumatic lithotripsy in our university hospital from May 2014 to January 2017. The operations carried out by doctors with different levels and experience.

After surgery, all patients were followed up at 1st, 3rd, and 12th months of the surgery. They performed metabolic workup, and following a 24-hour urine analysis, their extracted stones were analysed using infrared spectroscopy to guide us to an optimal dietary regimen. Imaging studies by computerised tomography (CT) or ultrasonography with radiography were done for all patients suspected to have a residual stone in perioperative or had renal colic later on.

Patients who were simply followed up after EM with incomplete stone removal intraoperatively, who were lost to follow-up, whose follow-up was less than one year or deceased were excluded from the study. From our medical records, the patients’ demographics (age, sex, body mass index (BMI), pregnancy, smoking, alcoholism), related diseases (diabetes, arterial hypertension, dyslipidaemia, gastrointestinal disease, gout, thyroid disease, and urinary tract anomalies), and their stones characteristics by non-contrast CT (size, location, number, and composition) were evaluated. All patients who had renal colic and/or stone upon an Imaging studies by CT or ultrasonography with radiography after EM were considered to have recurrent disease. The patients were devised into two groups: one with recurrent disease and the other without any recurrence. To perform our statistical analysis, we used SPSS 16.0 (IBM Corporation, New York, USA). We compared the clinicopathological features of patients with or without recurrence using the Chi-square, Student’s t-test, and Cox proportional hazards model. Significant risk factors in univariate analysis were included in a multivariate analysis. Recurrence-free survival was analysed by the Kaplan-Meier method.

Results

We collected 265 patients who were treated for nephrolithiasis using EM at our university hospital during the study period. Seventy-five of them were excluded from our study because of the following reasons: 46 patients were followed up for less than 1 year, 13 patients did not show up for the follow-up after EM, 11
patients were simply followed up after EM with incomplete stone removal intraoperatively, and 5 patients were deceased.

The remaining 190 patients were included in the study, including 115 men (60.5%). The median age and median BMI of the patients were 57.5 years of age (21–93 years) and 25.2 kg/m² (16–44 kg/m²), respectively. The demographic characteristics of the included patients are provided in Table 1.

The stones were analysed in 117 (61.5%) patients. The most common types of stones were calcium oxalate monohydrate stones (n = 44, 23.2%), followed by mixed stones (n = 39, 20.5%), which included mixed calcium oxalate (n=10, 8.5%), calcium oxalate dihydrate stones (n = 13, 6.8%) and uric acid stones (n = 11, 5.8%). The remaining stone characteristics including site, size, number, and other types of stone are presented in Table 1.

At the end of a median follow-up of 32 months (13–61 months), 25.8% of patients (n=49) presented recurrent stones. Only 17% of patients sought medical advice with an imaging study, but those who did not seek any such advice (7%) claimed to have symptoms of renal colic upon questioning via telephone. After shared decision-making, repeat surgery was needed in 13.1% (n=25) of patients, and 5% continued simply follow-up. The risk of stone recurrence in the first year was 10% (n=19), 2nd year was 21% (n=40), and 3rd year was 24.7%. Nine patients (4.7%) presented with a second stone recurrence after the second operation and three of them (1.6%) had a third recurrence.

Survival analysis (Fig. 1) at 20 months showed 81% of patients had no clinical recurrences, and at 40 and 60 months, 70% and 68% of patients had no clinical recurrences, respectively.

The univariate analysis in Table 2 identified the risk factors for recurrence, BMI greater than 25 (hazard ratio [HR]: 2; $p < 0.05$), diabetes (HR: 3.73; $p < 0.008$) and smoking (HR: 3.1; $p < 0.039$). However, age (HR: 0.96; $p < 0.003$) and high blood pressure (HR: 0.37; $p < 0.027$) were protective factors.

In the multivariate analysis, age (HR: 0.96; $p < 0.003$), diabetes (HR: 7.9; $p < 0.001$), smoking (HR: 3.5; $p < 0.029$) and high blood pressure (HR: 0.26; $p < 0.017$) remained prognostic factors of recurrences. In Fig. 1, the probability of recurrence-free survival (PRFS) in smoking patients decreased from 93% to 80% at 20 months and from 83% to 60% at 40 months in comparison to non-smoking patients. In diabetic patients, the PRFS decreased from 85% to 60% at 20 months and from 70% to 48% at 40 months when compared with non-diabetic patients. However, the PRFS in hypertensive patients increased from 83% to 88% at 20 months and from 60% to 80% at 40 months in comparison with non-hypertensive patients.

On the other hand, sex, urological history (malformation, multiple urinary tract infection, lower urinary tract symptoms, etc.) and alcoholism had no apparent consequence on stone recurrence. Also, stone characteristics including stone composition, location and size were not associated with stone recurrence.

**Discussion**
Symptomatic urinary calculi can cause great discomfort to patients. Although many stones pass spontaneously, the methods used to treat calculi may cause significant morbidity. The costs associated with the treatment of nephrolithiasis were also substantial, especially endourological ones. Consequently, the study of stone recurrence and its risk factors after EM is of great importance. Early studies have shown recurrent rates of urolithiasis at 30–50% within 5 to 10 years after an initial stone episode. Similarly, two other studies reported recurrence rates as high as 50% within 10 years of the first stone episode. Asplin and Chandoke assessed the mean rate of recurrence of stones to be up to 30% at 5 years, 50% at 10 years, and 80% at 20 years. On exploiting data from the Rochester Epidemiology Project from 1984 to 2003, the recurrence of kidney stone nomogram for predicting stone recurrence was developed and showed symptomatic recurrence after the initial stone event at the following rates and time points: 11% in 2 years, 20% in 5 years, 31% in 10 years, and 39% in 15 years. The comparison of these results with that of our results indicates that EM is not superior in reducing the general recurrence rate. Surprisingly, the rate of our repeat surgery by EM (13.1%) was similar to that of a study conducted by Rebuck et al. However, they had excluded those patients with fragments found initially within the ureter and those who underwent repeat surgery within 6 weeks after the initial procedure. In contrast, other data have reported an increased rate of repeat surgery: 21–27% within 120 days. Although the efficacy of stone surgery has been traditionally assessed by early postoperative radiological evaluation, we chose to omit all patients from our study with any residual fragments after EM. This is because the urological literature struggles consistently to define the objective outcomes that are central to any improvement effort. The term “clinically insignificant residual fragments” (CIRFs) was introduced almost 33 years ago to describe the debris after a “successful” ESWL. However, CIRFs were soon reported to be associated with recurrence of symptoms and with repeat surgery. In a previous assessment of residual fragments after percutaneous nephrolithotomy, the presence of any detectable stone fragment was associated with a repeat surgery rate of about 30% at 5 years. Epidemiologic studies have correlated stone disease with three medical conditions that are part of the metabolic syndrome: obesity, diabetes mellitus, and hypertension. This finding caused physicians to consider urolithiasis as a risk factor for and consequence of the metabolic syndrome and not as an isolated disorder of urine composition. Our results confirm that diabetes mellitus and a BMI greater than 25 only in the univariate analysis are risk factors for recurring stone disease. Interestingly, hypertension was found to be a protective factor that increased recurrence-free survival. Diabetes mellitus and nephrolithiasis have been shown to have a reciprocal relation. An antecedent diagnosis of diabetes mellitus increased the risk of future development of nephrolithiasis and that of nephrolithiasis increased the risk of the onset of diabetes mellitus. Obesity and weight gain are independent risk factors for the development of nephrolithiasis in both genders. Nephrolithiasis appeared to be a risk factor for the development of hypertension, but the opposite does not appear to be clear. A significant percentage of hypertensive subjects have a greater risk of renal stone formation, especially when hypertension is associated with excessive body weight and increased consumption of salt and animal proteins. In hypertensive men and women, oxaluria and calciuria are higher compared to the normotensive. Thus, we assumed that dietary modification plays a major role in hypertensive patients, reflecting a significant
decrease in the risk of stone recurrence. In addition, the use of antidiuretic medication, especially thiazides, in cases of hypertension can reduce stone recurrence by reducing urine calcium excretion and supersaturation. There is no credible evidence that cigarette smoking and alcohol drinking influence the occurrence and recurrence of urolithiasis as stated by Detsyk and Solomchak. However, this finding is in contrast to our results that demonstrate that smoking decreases the recurrence-free survival. The most important finding of this study is the high probability of stone recurrence in young adult patients whilst the patient's gender did not affect the recurrence rate. Kang et al. displayed that more than 40% of young adult patients suffered recurrence despite the shortest follow-up period; this was twice the rate in patients aged >60 years. However, young adults tend to be confident about their health and ignore the possibility of recurrence; therefore, they are often lost to follow-ups. The stone's location, number and diameter are known predicting factors of residual fragments but are not linked to recurrence of the disease. We did not find any relation between stone composition and recurrence rate; this may be because a large number (38.4%) of patients were not analysed. A close and multidisciplinary follow-up for the known stone composition with high risk of recurrence as in the cases of cystine stone can prevent them from recurrence. The number of patients that presented with pure struvite and pure carbapatite is not significant for analysis. Finally, a urological history of dysuria, renal colic, recurrent urinary tract infections and/or malformations did not affect recurrence. Similarly, Trinchieri et al. reported that urinary risk factors did not influence stone recurrence. The limitations of our study are largely attributable to its retrospective design. Prospective tracking of data would be ideal but would require foreseeing which parameters would retain significance in the future. Retrospective studies, in general, could lead to sampling bias. All patients were instructed to follow general recommendations for the prevention of stone recurrences such as fluid intake, diet, and lifestyle modification. Also, the patient’s compliance with such modifications could be a confounding factor that affected the analyses. Moreover, the interval between the time of first stone formation and the time of diagnosis also merit consideration because it is possible that the time of initial stone formation could be earlier than the time of diagnosis. Another issue is that this study was done in a single centre in France. The prevalence of urolithiasis seems to depend on the geographic location, weather, and socioeconomic characteristics of different populations. For example, higher temperatures have been associated with clinical kidney stone presentation, a daily mean temperature of 30 °C is associated with significantly increased episodes compared to a daily mean temperature of 10 °C in 4 major metropolitan areas studied: Atlanta, Chicago, Dallas, and Philadelphia. However, our study was done in a stable, local metropolitan population with easy access to management care programs. Hence the low follow-up loss percentage of 4.9%. Moreover, medical records were highly accessible in this specialty centre that delivers around 90% of care to its region. The subjectivity of considering renal colic as the sign of recurrence could have affected our calculations because not all patients sought medical advice for their symptoms (7%) and imaging follow-ups were not done to all the patients. Yet, we can consider it as a strength point because it is a clinically important outcome and mitigates lead-time bias for patients with more frequent follow-ups and surveillance imaging.
Conclusion

Stone recurrence is common after urological management of urinary stones. In this study 25.8% of patients had recurred stone disease after EM with a median follow-up of 32 months. Our study findings showed that diabetes and smoking are risk factors for recurrence, while age and blood hypertension are protective factors that decreased the risk of recurrence.

Abbreviations

Endourological management (EM), extracorporeal shock wave lithotripsy (ESWL), body mass index (BMI), computerized tomography (CT), hazard ratio (HR), the probability of recurrence-free survival (PRFS), clinically insignificant residual fragments (CIRFs).

Declarations

Author’s contribution

F.B: project development, data collection, and manuscript writing. A.S.Z: project development, and manuscript writing. Y.L: data collection. T.C: project development. S.L: project development. E.B: project development. A.R.A: manuscript editing. P.B: project development, data analysis, and manuscript editing.

Competing interests:

the authors declare no competing interests.

References


**Tables**

**Table 1: Patients and stones characteristic**
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, male n (%)</strong></td>
<td>115 (60.5)</td>
</tr>
<tr>
<td><strong>Median age (years)</strong></td>
<td>57.5 (21–93)</td>
</tr>
<tr>
<td><strong>Median duration of follow-up (months)</strong></td>
<td>32 (13–61)</td>
</tr>
<tr>
<td><strong>Median BMI</strong></td>
<td>25.2 (16–44)</td>
</tr>
<tr>
<td><strong>BMI &lt;18.5</strong></td>
<td>6 (3.2)</td>
</tr>
<tr>
<td><strong>BMI &gt;25</strong></td>
<td>113 (59.5)</td>
</tr>
<tr>
<td><strong>25&lt; BMI &lt;30</strong></td>
<td>75 (39.5)</td>
</tr>
<tr>
<td><strong>BMI &gt;30</strong></td>
<td>38 (20)</td>
</tr>
<tr>
<td><strong>Urological history, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Renal colic</td>
<td>20 (10.5)</td>
</tr>
<tr>
<td>Renal malformation</td>
<td>7 (3.7)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>12 (6.3)</td>
</tr>
<tr>
<td>Recurrent urinary tract infection</td>
<td>7 (3.7)</td>
</tr>
<tr>
<td><strong>Medical history, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>50 (26.3)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>19 (10)</td>
</tr>
<tr>
<td>Smoking</td>
<td>35 (18.4)</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>28 (14.7)</td>
</tr>
<tr>
<td>Cardiovascular Disease</td>
<td>33 (17.4)</td>
</tr>
<tr>
<td>Chronic renal failure</td>
<td>4 (2.1)</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>19 (10)</td>
</tr>
<tr>
<td><strong>Type of stone, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Not analysed</td>
<td>73 (38.4)</td>
</tr>
<tr>
<td>Calcium oxalate monohydrate</td>
<td>44 (23.2)</td>
</tr>
<tr>
<td>Calcium oxalate dihydrate</td>
<td>13 (6.8)</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>11 (5.8)</td>
</tr>
<tr>
<td>Carbapatite</td>
<td>6 (3.2)</td>
</tr>
<tr>
<td>Struvite</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Cystine</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Mixed without predominance</td>
<td>39 (20.5)</td>
</tr>
</tbody>
</table>

**Stone location, n (%)**

<table>
<thead>
<tr>
<th>Location</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Right kidney</td>
<td>70 (36.8)</td>
</tr>
<tr>
<td>Left kidney</td>
<td>114 (60)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>6 (3.2)</td>
</tr>
</tbody>
</table>

**Number of stone, n (%)**

<table>
<thead>
<tr>
<th>Number of Stones</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Single stone</td>
<td>111 (58.4)</td>
</tr>
<tr>
<td>Multiple stone</td>
<td>79 (41.6)</td>
</tr>
</tbody>
</table>

**Cumulative diameter of stone in mm**

<table>
<thead>
<tr>
<th>Diameter</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11 (2–60)</td>
<td></td>
</tr>
</tbody>
</table>

**Median duration of follow-up (months)**

<table>
<thead>
<tr>
<th>Duration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>32 (13–61)</td>
<td></td>
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</tbody>
</table>

**Recurrent stone, n (%)**

<table>
<thead>
<tr>
<th>Recurrent Stone</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>49 (25.8%)</td>
<td></td>
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</tbody>
</table>

Table 2: Univariable and multivariable Cox regression analysis of predicting factors for 190 patients treated by retrograde flexible ureteroscopy and intracorporal lithotripsy for intrarenal stones.
<table>
<thead>
<tr>
<th></th>
<th>Univariable</th>
<th></th>
<th>Multivariable</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>p value</td>
<td>HR (95% CI)</td>
<td>p value</td>
<td>HR (IC)</td>
</tr>
<tr>
<td>Male gender (versus female)</td>
<td>0.36</td>
<td>1.35 (0.7-2.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Age (continuous)</td>
<td><strong>0.003</strong></td>
<td><strong>0.96 (0.94-0.98)</strong></td>
<td><strong>0.003</strong></td>
<td><strong>0.96 (0.94-0.98)</strong></td>
</tr>
<tr>
<td>BMI &lt;18.5 (vs. &gt;18.5)</td>
<td>0.66</td>
<td>1.45 (0.2-8.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BMI &gt;25 (vs. &lt;25)</td>
<td><strong>0.05</strong></td>
<td><strong>2 (1-4)</strong></td>
<td>0.086</td>
<td>1.9 (0.9-4.2)</td>
</tr>
<tr>
<td><strong>Medical History</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes (vs. no diabetes)</td>
<td><strong>0.008</strong></td>
<td><strong>3.73 (1.4-9.8)</strong></td>
<td><strong>0.001</strong></td>
<td><strong>7.9 (2.2-27.9)</strong></td>
</tr>
<tr>
<td>Dyslipidaemia (vs. no dyslipidaemia)</td>
<td>0.55</td>
<td>0.74 (0.28-1.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cardiovascular disease (vs. no cardiac disease)</td>
<td>0.20</td>
<td>4.3 (1.2-14.8)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hypertension (vs. no hypertension)</td>
<td><strong>0.027</strong></td>
<td><strong>0.37 (0.15-0.89)</strong></td>
<td><strong>0.017</strong></td>
<td><strong>0.26 (0.1-0.78)</strong></td>
</tr>
<tr>
<td>Alcoholism (vs. no alcoholism)</td>
<td>0.3</td>
<td>1.9 (0.54-7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tobacco use (vs. no Tobacco)</td>
<td><strong>0.039</strong></td>
<td><strong>3.1 (1.05-9.5)</strong></td>
<td><strong>0.029</strong></td>
<td><strong>3.5 (1.1-11.1)</strong></td>
</tr>
<tr>
<td><strong>Urological history</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal colic</td>
<td>0.65</td>
<td>1.2 (0.45-3.5)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Renal malformation</td>
<td>0.3</td>
<td>2.2 (0.48-10.3)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dysuria</td>
<td>0.94</td>
<td>0.95 (0.2-3.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Recurrent urinary tract infection</td>
<td>0.48</td>
<td>0.45 (0.1-3.9)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Stone composition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium oxalate monohydrate (vs. others)</td>
<td>0.55</td>
<td>0.77 (0.3-1.8)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Calcium oxalate dihydrate (vs. others)</td>
<td>0.115</td>
<td>0.2 (0.1-1.5)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Uric acid (vs. others)</td>
<td>0.19</td>
<td>2.3 (0.65-8.2)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Stone localisation, right kidney (vs. left)</strong></td>
<td>0.31</td>
<td>1.4 (0.72-2.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Unique stone (vs. multiple stones)</td>
<td>0.12</td>
<td>0.59 (0.31-1.1)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cumulative stone diameter (continuous)</td>
<td>0.587</td>
<td>0.96 (0.819-1.120)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

HR = hazard ratio
CI = confidence interval
Survival analysis at 20 months showed 81% of patients had no clinical recurrences, and at 40 and 60 months, 70% and 68% of patients had no clinical recurrences, respectively.