Does treatment of non-obstructing nephrolithiasis reduce recurrent urinary tract infections?

A prospective, observational trial from the EDGE consortium

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ABSTRACT

INTRODUCTION: Existing studies link kidney stone treatment to reduced recurrent urinary tract infections (UTIs); however, these studies are limited by their retrospective design and/or lack of comparison group. The present study assesses a prospective, observational cohort of patients with recurrent UTIs who selected observation or intervention for management of their non-obstructing kidney stones to assess for impact on UTI recurrence.

METHODS: From 2020–2025, patients with non-obstructing kidney stones and recurrent UTIs were prospectively enrolled at four centers. After shared decision-making, participants underwent observation or surgical intervention. The primary outcome was UTI recurrence at 12 months post-enrollment, defined as presence of urinary tract symptoms with positive urine culture. The study was powered to detect a 50% reduction in the rate of UTI recurrence between the groups at 12 months.

RESULTS: Among 94 patients recruited, followup data at 12 months was available for 21 observation and 46 intervention patients. There were more staghorn stones in the intervention group (15.2% vs. 0%), and the median stone size was larger (13.5 vs. 6 mm). At 12 months, 81% (n=17) in the observation group and 54% (n=25) in the intervention group had a symptomatic UTI recurrence (p=0.06, non-significant). The subgroup (n=17) of stone-free intervention patients had fewer UTI recurrences compared to the observation group (odds ratio 0.12, 95% confidence interval 0.02–0.66). Causation cannot be confirmed due to the observational nature of the study.

CONCLUSIONS: For patients with recurrent UTIs and stones, surgical intervention is not associated with decreased risk of UTI recurrence at 12 months overall; however, patients who were stone-free after intervention had significantly fewer UTI recurrences on subgroup analysis.

INTRODUCTION

It has long been debated whether non-obstructing renal stones act as a nidus for bacteria and cause symptomatic, recurrent lower urinary tract infections (UTIs). Some stone types, such as struvite, form only in the presence of bacteria. Other stone types can also show bacterial growth when cultured after removal. While urgent drainage of an obstructed system with infection is a steadfast clinical principle,[1,2] the benefit of treating non-obstructing renal stones in other settings is less clear, particularly if the primary goal is to prevent symptomatic recurrent lower UTIs.

The European Association of Urology guidelines list associated lower tract UTIs as a potential indication for treatment (level 3 evidence), acknowledging that the question of whether these otherwise asymptomatic stones should be treated is not clearly answered.[3] Likewise, the American Urological Association guidelines provide a grade C recommendation that non-obstructing stones may be removed in the setting of recurrent UTIs as part of shared decision-making.[4]

The few existing studies evaluating the treatment of non-obstructing stones to reduce UTIs report a benefit to surgical stone treatment;[5-7] however, many studies are retrospective in design, are susceptible to ascertainment bias, and lack an observational cohort for comparison. Because of a lack of comparator, it

KEY MESSAGES

- Surgically treating vs. observing patients with kidney stones and UTIs does not change their risk of developing UTIs in our primary outcome.
- This study may be underpowered to detect large differences, but shows that the magnitude of effect of stone treatment on UTIs is either negative or at least lower than previously reported.
- Rendering patients completely stone-free does appear to reduce their risk of developing UTIs in subgroup analysis.

cannot be known if the UTIs would have improved without surgical treatment.

Within this context, we performed a prospective, multicenter, observational study among individuals with recurrent, symptomatic UTIs and non-obstructing renal stones. We compared patients who were surgically treated to those who were not surgically treated. We hypothesized that treatment of non-obstructing urolithiasis in the context of recurrent UTIs would reduce symptomatic UTI recurrence risk at one year.

METHODS

Design

This was a multi-institutional, prospective, observational study from September 2020 to September 2025 at four academic centers in the Endourologic Disease Group for Excellence (EDGE) research consortium in North America with *clinicaltrials.gov* registration (NCT04495699): Vancouver General & University of British Columbia Hospitals; Mayo Clinic Arizona; Vanderbilt University Medical Center; University of California, San Diego. Informed consent was obtained for all patients for prospective, observational data collection. Institutional review board approval was obtained at all sites.

Study population

The population of interest was patients with asymptomatic, non-obstructing kidney stones and recurrent UTIs. Inclusion criteria were adult patients (age 18 years or older) with non-obstructing stones identified by computed tomography (CT) within six months of screening. Stones could be any size and could be located in one or both kidneys. Patients had to be candidates for either observation or intervention deemed by the treating urologist.

Additional eligibility criterion was a history of recurrent UTIs in the year prior to screening. Recurrent UTI was defined as either 1) three positive urine cultures of at least one organism with symptoms of UTI within 12 months; or 2) two positive cultures with symptoms within six months. A positive culture was required to have at least 100 000 CFU/ml of one or more specific organism. The presence of symptoms without documented positive urine culture, or the presence of asymptomatic bacteriuria did not qualify as a UTI. Mixed organisms without specific speciation also did not qualify as a UTI (providers did not routinely speciate "mixed organisms").

Exclusion criteria at the time of screening were any of: age <18 years; pregnancy; hydronephrosis or evidence of obstruction; presence of a foreign body in urinary tract (e.g., Foley catheter, indwelling ureteral stent, nephrostomy tube) at the time of UTI diagnosis; bladder calculi; urinary diversion or previous surgery involving segments of bowel interposed into the urinary tract. A specific stone size cutoff was not used if, in the opinion of the treating physician, either observation or intervention was an option.

Treatment choice was made by shared decision-making between the patient and their treating urologist based on standard practice. At the time of enrollment, the treatment choice was recorded as observation or intervention, with the surgical approach (shockwave lithotripsy, percutaneous nephrolithotomy, ureteroscopy) also determined by shared decision-making. UTI prevention measures, such as behavioral modifications, over-the-counter supplementation, and/or topical estrogen cream, were provided as per local standard of care. The specifics of method of delivery (in-person, handouts, combination) and recommendations were institution-specific based on local standard of care. All investigators provided evidence-based prevention and management of recurrent UTIs, which did not differ between groups.

Primary and secondary outcomes

The primary outcome was recurrence of UTI between 30 days to 12 months after enrollment, defined as UTI symptoms with urine culture positive for specific organism(s). UTI symptoms included new onset of frequency, urgency, or dysuria. UTIs within 30 days of surgery were excluded since their occurrence during this time period could have been attributable to the surgical intervention.

Secondary outcomes included number of UTIs within 12 months after enrollment (excluding the first 30 days postoperatively), perioperative unplanned healthcare encounters, stone-free rates, and the association of stone-free status with recurrent UTI.

Data collection and followup

Data were collected at baseline, at the postoperative visit if applicable, at six-month followup, and at 12-month followup. Demographic data on patients at baseline were obtained to compare the cohorts, which include age, sex, number of UTIs prior to enrollment, body mass index (BMI), presence or absence of staghorn calculus, comorbidities (including diabetes mellitus, obesity, and hypertension), and total stone burden (total axial diameter). Primary and secondary outcomes were assessed at each timepoint for the cumulative 12-month outcomes. During the followup visits, patients were assessed either in person or by telehealth. If no visit was scheduled at the time of required data collection, then a member of the research team contacted them directly.

Statistical analysis

As an initial analytic step, baseline characteristics and followup primary and secondary outcomes were compared between the observation and intervention groups. The primary outcome was the occurrence of UTI within 12 months after enrollment, analyzed as a binary variable. Logistic regression was used to evaluate the association between treatment groups (observation vs. intervention) and UTI occurrence, adjusting for potential confounders, including age, BMI, and baseline total stone burden (mm).

A prespecified subgroup analysis was performed among intervention-group patients who were stone-free after the procedure, comparing interventional group patients who were stone-free to the observational cohort. The primary analysis followed an intention-to-treat approach; given crossover between groups, a secondary "as-treated" analysis was also performed to capture potential differences in treatment effect. Secondary outcomes were primarily descriptive, as stone-free status and perioperative outcomes were applicable only to the intervention group.

The initial power calculation was based on the primary outcome of the number of UTIs over 12 months and was informed by prior literature reporting post-treatment UTI recurrence rates ranging from 11–52%.[5,6] In one study, the mean number of UTIs decreased from 3.1/year before intervention to 0.5/year after intervention.[5] This study was designed with an estimated 1:1 allocation between intervention and non-intervention groups. Assuming a standard deviation of two UTIs, a total sample size of 56 was calculated to provide 80% power to detect a clinically significant difference of 1.5 UTIs/year between groups, with a two-sided alpha of 0.05.

During recruitment, we observed unequal sample sizes in this observational study, as more patients were opting for intervention. Therefore, the sample size goal was adjusted to 45 in intervention and 20 in observation group to maintain the a priori-determined power with unequal sizes. Statistical analysis was performed using R (version 4.2.0).

RESULTS

Between September 2020 and September 2025, 94 patients were enrolled. Thirty patients opted for observation, and 64 patients opted for intervention (Figure 1). In the observational group, six patients underwent a stone procedure during the followup period, five of which were elective. In the interventional group, five patients opted against stone procedure after initial enrollment. The primary outcome of 12-month followup data was available for 21 observational patients and 46 interventional patients for the intention-to-treat analysis (Table 1).

Among the final analytic cohort, all patients in the observation group (n=21/21) and 83% of patients in the intervention group (n=38/46) were female. Median UTIs in the year prior to recruitment for both groups

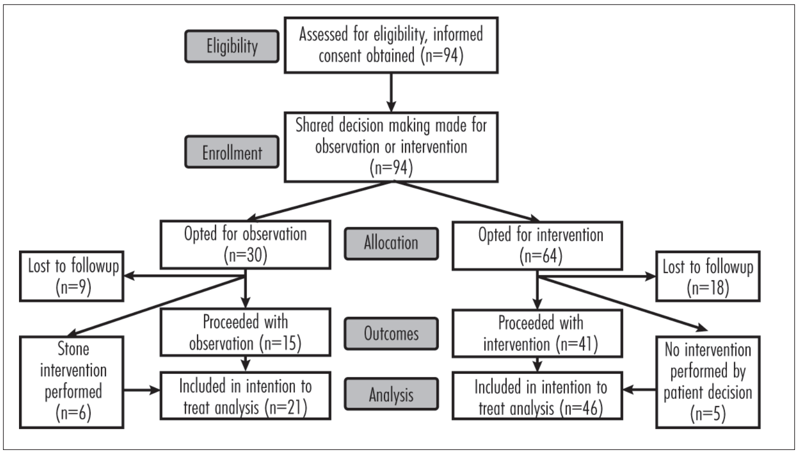

Figure 1. Flow diagram of patient enrollment, allocation, outcomes, and analysis.

Table 1. Baseline participant characteristics by group, intention-to-treat analysis			
	Observation	Intervention	p
Number, N	21	46	n/a
Age (years, median, Q1-Q3)	65 (51–74)	66 (54–71)	0.4
Sex			
Female	21 (100%)	38 (83%)	0.1
Male	0 (0%)	8 (17%)	
Patient race			
White non-Hispanic	14 (67%)	43 (94%)	0.02*
Asian/American Indian/Alaska Native	3 (14%)	1 (2%)	
Hispanic	1 (5%)	2 (4%)	
Black/African American	2 (10%)	0 (0%)	
Other/More than one race	1 (5%)	0 (0%)	
BMI (kg/m^2, median, Q1-Q3)	30 (26–33)	30.5 (26–34)	0.4
Number of UTIs in year before recruitment (median, Q1–Q3)	3 (2–6)	3 (2–4)	0.2
Staghorn			
Yes (<50% of collecting system)	0 (0%)	7 (15.2%)	0.1
Yes (>50% of collecting system)	0 (0%)	0 (0%)	
No	21 (97%)	39 (84.8%)	
Enrollment stone size (total axial diameter mm, median, Q1–Q3)	6 (3.5–14)	13.5 (9–20)	0.06
Diabetes			
No	15 (71.4%)	32 (69.6%)	1
Yes	6 (28.6%)	14 (30.4%)	
Hypertension			
No	12 (57.1%)	24 (52.2%)	0.9
Yes	9 (42.9%)	22 (47.8%)	
Coronary artery disease			
No	20 (95.2%)	42 (91.3%)	1
Yes	1 (4.8%)	4 (8.7%)	
Gout			
No	21 (100%)	45 (97.8%)	1
Yes	0 (0%)	1 (2.2%)	
Chronic kidney disease			
No	20 (95.2%)	41 (89.1%)	0.7
Yes	1 (4.8%)	5 (10.9%)	
Procedure received			
Shockwave lithotripsy	0 (0%)	1 (2.2%)	p<0.0001*
Ureteroscopy	4 (19%)	32 (69.6%)	
Percutaneous nephrolithotomy	1 (4.8%)	8 (17.4%)	
None	16 (76.2%)	5 (10.9%)	

were similar (n=3). The median stone diameter at time of enrollment, measured as total sum of all axial diameters, was greater in the intervention group than the observational group, although not significantly so (13.5 mm vs. 6 mm, p=0.06) (Table 1). There were seven patients (15.2%) in the intervention group and zero patients (0%) in the observation group who had a partial staghorn calculus involving <50% of the collecting system. No patients had complete staghorn calculi in either arm. These represented patients with large stones, but who were, other than infections, asymptomatic and who in the opinion of the treating physician would qualify for observation.

In the intervention group, stone composition was most commonly calcium oxalate monohydrate (44%), followed by apatite calcium phosphate (30%) (Supplementary Table 1; available at *cuaj.ca*). Stone and urine cultures obtained at the time of intervention were most commonly no growth, followed by *E. coli* and *Proteus* (Supplementary Table 1; available at *cuaj.ca*).

Unplanned perioperative healthcare encounters in the first 30 days occurred in 10 (21.7%) patients in the intervention group, and in 1/6 (17%) observation patients who received a procedure. The unplanned encounters in the intervention group included one blood transfusion post-percutaneous nephrolithotomy, one spontaneous pneumothorax post-ureteroscopy requiring chest tube insertion, and emergency room visits for fevers, hematuria, or pain requiring urgent treatment. In the observation group, no patients required multiple procedures. In the intervention group, six patients underwent a secondary procedure in the subsequent 12 months for additional attempts at stone clearance or acute stone event.

At 12-month followup, 81% (n=17) of the observation group and 54% (n=25) of the intervention group had one or more symptomatic UTIs (p=0.06) (Table 2). The cultured organism was most commonly *E. coli* for both groups (Supplementary Table 1; available at *cuaj.ca*). The difference in rates of symptomatic UTI recurrence was not statistically significant on logistic regression adjusting for patient age, BMI, and stone size for either the intention-to-treat analysis (odds ratio [OR] 0.29, 95% confidence interval [CI] 0.08−1.05) or for the "as-treated" analysis (OR 0.50, 95% CI 0.14-1.71) (Table 3). The binary presence or absence of UTI was reported as the most clinically relevant outcome, while the median number of UTIs in the observation group was 2 (1–3) and the median number of UTIs in the intervention group was 1 (0–2) (p=0.09) (Supplementary Table 2; available at *cuaj.ca*).

Among patients who underwent intervention, 17 of 46 were stone-free, defined as no stones present of any size on imaging at followup. The imaging modality most frequently used among intervention patients at followup was ultrasound (50%, n=23), followed by CT (37%, n=17), and kidney-ureter-bladder (KUB) (9%, n=4). Imaging modality information was not available in 15% of patients (n=7). In the subgroup of these stone-free patients, 24% of patients had a recurrent UTI within 12 months. A subgroup analysis was performed for patients who were stone-free post-intervention (n=17) compared to those who underwent observation (n=21) (Table 4). In the intention-to-treat analysis, stone-free status was associated with lower odds of experiencing a UTI within 12 months (OR 0.12, 95% CI 0.02–0.66). This finding was statistically significant; however, this finding was not statistically significant in the "as-treated" analysis (OR 0.22, 95% CI 0.04–1.20).

DISCUSSION

In this study of individuals with recurrent UTI and non-obstructing renal stones, we report the following key findings.

First, surgically treating vs. observing patients with kidney stone does not change their risk of developing UTIs in our primary outcome. This should be interpreted in the context of the power calculation, which was powered to detect a clinically significant reduction in UTIs by approximately 50% based on previous literature. The negative findings of this study indicate that any effect on UTIs from stone surgery are less than the 50% that was previously reported. This finding should be paired with the understanding that rendering a patient completely stone-free does appear to reduce their risk of developing UTIs in our subgroup analysis. These findings seem conflicting but actually are aligned. Our study simply shows that one must remove all stones to see the benefit of UTI prevention.

Our findings add to the current literature on asymptomatic upper tract urinary calculi in the setting of recurrent UTIs. Specifically, our prospective, observational design, with both an observational group and an interventional group, allows for assessment of the impact of surgery on stones and infections. Previous retrospective studies have been designed as a pre- and post- intervention analysis, which does not allow for assessment of natural history without intervention. While a prospective, randomized trial would provide even stronger evidence, prior to the current study, there was inadequate equipose to justify designing such a trial, since previously available data supports stone treatment.

In a 2015 study by Omar and colleagues, among 120 patients with non-obstructing renal stones and recurrent UTIs who were rendered stone-free from surgical intervention, there were 48% who did not have further infections after surgery.[6] In the 2019 study by Agarwal and colleagues,[5] 46 patients were identified who underwent surgical intervention for non-obstructive upper tract calculi who also had recurrent UTIs. Stone-free status was not a required criterion for inclusion. After treatment, 64% of patients were rendered stone-free, and only 11% had a recurrent UTI after treatment.[5] For both studies, the lack of a comparison group has raised the question of whether the effects observed were due to regression to the mean. Here, our study findings confirm a benefit in patients undergoing intervention. Specifically, achieving stone-free status is necessary to have a clinical benefit.

Table 2. Clinical outcomes during the followup period

	Observation	Intervention
Recurrent UTI 12 months after recruitment		
Yes	17 (81%)	25 (54%)
No	4 (19%)	21 (46%)
# UTIs after 12 months (median, Q1-Q3)	2 (1–3)	1 (0–2)
Residual or known stone after intervention		
Yes	17 (81%)	22 (48%)
No	4 (19%)	17 (37%)
Unknown	0 (0%)	7 (15%)
Rate of UTI among patients who were stone-free at 12 months	3/4 patients (75%)*	4/17 patients (24%)
Unplanned healthcare encounter post intervention		
No	5 (83%)*	36 (78.3%)
Yes	1 (17%)*	10 (21.7%)

*These patients initially opted for observation but opted for surgery during the observation period. UTI: urinary tract infection.

Table 3. Multivariable logistic regression model for the outcome of recurrence of UTI by 12 months

Intention to treat analysis	OR	95% CI LB	95% CI UB	p
Treatment (referent=intervention)	0.29	0.08	1.05	0.06
Patient age (per year)	0.98	0.94	1.02	0.31
Patient BMI (per kg/m^2)	1.07	0.98	1.16	0.12
Largest stone axial diameter (per mm)	0.97	0.88	1.07	0.57
As treated analysis	**OR**	**95% CI LB**	**95% CI UB**	**p**
Treatment (referent=intervention)	0.50	0.14	1.71	0.27
Patient age (per year)	0.98	0.95	1.02	0.34
Patient BMI (per kg/m^2)	1.06	0.98	1.15	0.14
Largest stone axial diameter (per mm)	0.96	0.88	1.06	0.40

BMI: body mass index; CI: confidence interval; LB: lower bound; OR: odds ratio; UB: upper bound; UTI: urinary tract infection.

Table 4. Multivariable logistic regression model for the outcome of recurrence of UTI by 12 months, observation group vs. interventional group for only those patients who were stone-free after intervention

Intention to treat analysis	OR	95% CI LB	95% CI UB	p
Treatment (referent= intervention)	0.12	0.02	0.66	0.01
Patient age (per year)	0.98	0.93	1.04	0.53
Patient BMI (per kg/m^2)	1.07	0.92	1.24	0.39
Largest stone axial diameter (per mm)	0.98	0.84	1.13	0.73
As treated analysis	**OR**	**95% CI LB**	**95% CI UB**	**p**
Treatment (referent= intervention)	0.22	0.04	1.20	0.08
Patient age (per year)	0.98	0.93	1.03	0.39
Patient BMI (per kg/m^2)	1.08	0.94	1.23	0.27
Largest stone axial diameter (per mm)	0.88	0.75	1.03	0.11

BMI: body mass index; CI: confidence interval; LB: lower bound; OR: odds ratio; UB: upper bound; UTI: urinary tract infection.

Several systematic reviews link kidney stone treatment to reduced rates of urinary infections postoperatively;[8,9] however, the studies within are either retrospective in design, lack a comparator group, or are focused on perioperative infections. These represent distinct study designs from the present study. In addition, non-obstructing stones may be operated upon for reasons other than recurrent UTIs, including pain.[10]

Several lines of evidence have linked upper tract calculi as a nidus for lower UTI. Epidemiologic data have linked kidney stone disease with a higher risk of UTI compared to non-stone formers.[11] A positive stone culture at the time of endourologic procedure is associated with postoperative sepsis,[12,13] suggesting that certain stones could actively harbor bacteria that could result in infections. While struvite stone formation is directly correlated with bacteria presence in the upper tract,[14] the majority of the stone composition types in this study were calcium-based stones, and only 11% of intraoperative stone culture data had *Proteus* species.

Our findings suggest that while a history of struvite stones and *Proteus* bacteriuria would be suggestive that stone clearance would reduce UTI recurrence, the clinical benefit plausibly extends to all individuals with any stone type and who have had a history of confirmed recurrent UTIs.

Our study also highlights the importance of shared decision-making in treatment choice. Patient experiences relating to choosing surgery vs. observation for kidney stones depend on perceived outcomes.[15] Patient counseling should involve discussion that achieving stone-free status may require multiple, staged procedures, and alternative approaches should be considered (e.g., percutaneous or bilateral procedures). While the goal is elimination of UTI risk, postoperative UTI carries morbidity.

In this study, one in five individuals who underwent intervention had an unplanned postoperative healthcare event. Furthermore, the perioperative phase will require exposure to perioperative antibiotics, which could contribute to antimicrobial resistance.[16]

Finally, there may be anatomic and stone factors (e.g., parenchymal calcifications) that make stone-free status impossible with currently available surgical techniques. Nevertheless, in this study of selected patients, who were clinically eligible for either observation or intervention, a benefit was observed among individuals who were rendered stone-free.

Our analysis, in consultation with the statisticians who are coauthors on this paper, included both an "as-treated" and intention-to-treat analysis. The intention-to-treat analysis is an analysis of the original group to which patients were allocated. This helps to account for confounders if the patients who crossed over were biased in some way, such as having more symptoms of infection. The "as-treated" analysis is an analysis based on whether or not the patients actually received intervention. This type of analysis helps to eliminate contamination from intervention/observation patients being in the other group.

In terms of outcomes, the primary outcome UTI recurrence was not different between groups, regardless of the intention-to-treat or per-protocol analysis. Of note, the "as-treated" analysis for the subgroup of stone-free patients differed from the intention-to-treat analysis. Whereas the intention-to-treat analysis was statistically significant for intervention to reduce UTI among stone-free patients, the "as-treated" analysis was not. This could either indicate that stone-free patients actually did not have reduced UTI rates, or this could be a result of bias within the "as-treated" group. For example, patients with a predisposition for recurrent UTIs may have been more likely to cross over into the intervention group, biasing the results in that analysis.

Limitations

Study limitations include the observational, non-randomized study design, including the potential for selection bias and residual confounding. The study cannot establish a causal relationship between the presence of a non-obstructing stone and recurrent UTIs; however, a randomized controlled trial was felt not to be feasible prior to this manuscript due to existing evidence suggesting a strong benefit to stone removal.

The decision to pursue stone removal is often driven by physician and patient factors, which were not fully captured or adjusted for. The unequal distribution of arms likely suggests that patients who see a urologist more frequently have their stones removed rather than observed. All stones, even the larger stones, were deemed candidates for observation, as well as intervention based on location and size.

The limited sample size means that specific patient and stone characteristics that would most benefit from intervention cannot be ascertained. Multiple imaging modalities were used as standard of care, limiting confidence in true stone-free rate; however, the overall the heterogeneity of the imaging modalities used to assess stone-free status likely reduced the sensitivity of confirming stone-free status (e.g., compared to all participants receiving CTs to classify). This would likely bias the results towards the null. Yet, in this study, we observed the finding of a statistically significant result by stone-free status despite standardizing postoperative imaging type.

The population was primarily women, and the study findings may not be generalizable to men. The recruitment took five years at dedicated research centers. This represents, in large part, the strict inclusion criteria of culture-documented UTIs prior to enrollment, since many patients who report UTIs do not have cultures available. Nevertheless, a strength of the prospective design minimizes ascertainment bias, and including patient populations from multiple sites reduces site-specific bias and increases generalizability.

CONCLUSIONS

In this study for patients with recurrent UTIs and non-obstructing renal stones, surgical intervention was not associated with a significantly decreased risk of UTI recurrence; however, individuals rendered completely stone-free did experience a decreased risk of UTI recurrence. Although potentially viewed as conflicting, this information could assist in shared decision-making between the patient and surgeon when considering stone removal in the setting of recurrent UTIs.

COMPETING INTERESTS: The authors have no relevant conflicts of interest to report.

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