

The evolution of percutaneous nephrolithotomy: Analysis of a single institution experience over 25 years

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Abstract

Introduction: Over time, the incidence of nephrolithiasis has risen significantly, and patient populations have become increasingly complex. Our study aimed to determine the impact of changes in patient demographics on percutaneous nephrolithotomy (PCNL) outcomes.

Methods: A retrospective analysis of a prospectively collected database was carried out from 1990–2015. Patient demographics, comorbidities, stone and procedure characteristics were analyzed. Multivariate logistic regression was used to evaluate differences in operative duration, complications, stone-free rate, and length of stay.

Results: A total of 2486 patients with a mean age of 54±15 years, body mass index (BMI) of 31±8, and stone surface area of 895±602 mm² were analyzed; 47% of patients had comorbidities, including hypertension (22%), diabetes mellitus (14%), and cardiac disease (13%). Complication rate was 19%, including a 2% rate of major complications (Clavien grade III–V). There was a statistically significant increase in patient age, BMI, and comorbidities over time, which was correlated with an increased complication rate (odds ratio [OR] 1.15; *p*=0.010). The overall transfusion rate was 1.0% and remained stable (*p*=0.131). With time, both OR duration (mean Δ 16 minutes; *p*<0.001) and hospital length of stay (mean Δ 2.4 days; *p*<0.001) decreased significantly. Stone-free rate of 1873 patients with available three-month followup was 87% and decreased significantly over time (OR 1.09; *p*<0.001), but was correlated with an increased use of computed tomography (CT) scans for followup imaging.

Conclusions: Despite an increasingly complex patient population, PCNL remains a safe and effective procedure with a high stone-free rate and low risk of complications.

Introduction

Urinary stone disease is a very common condition, with incidence rates ranging from 7–13% in North America.¹ The prevalence of stone disease is rising, with recent evidence

demonstrating an increase from 5.2 to 8.8% in American adults over the past 20 years.² This has been attributed to increasing rates of medical conditions associated with the development of kidney stones, including obesity, diabetes mellitus (DM), metabolic syndrome, gout, and hypertension.³ Specifically, the prevalence of obesity and DM have risen 5.2% and 3.7%, respectively, over the past 10 years, and it is estimated that if this trend continues, obesity and DM will contribute to a further 1.1% increase in stone prevalence by 2030.⁴

Apart from their impact on the development of stone disease, rising rates of medical comorbidities may also have an important influence on surgical outcomes. This is particularly important when considering the substantial increase of patient age and comorbidities over the years.⁵ Multiple series have demonstrated an association between percutaneous nephrolithotomy (PCNL) complications and the presence of patient comorbidities.^{6–11}

Following its introduction in 1976, PCNL has become the mainstay of surgical treatment for large and complex renal calculi.¹² Over the past several decades, many innovations have led to advances in the techniques and equipment used to perform PCNL.¹³ Despite the increasing prevalence of urinary stone disease, the use of PCNL has been relatively constant in North America.^{14,15} Few long-term longitudinal studies have provided insight into independent predictors and the effect over time on PCNL outcomes. We examined the impact of changes in patient demographics and surgical techniques on PCNL outcomes and complications at a single, high-volume academic institution over a period of 25 years.

Methods

Patient selection

A prospective database of all consecutive PCNLs performed between July 1990 and July 2015 was maintained, and no patients were excluded from analysis. Study approval

was obtained from Western University's institutional ethics review board.

Patient demographics included age, sex, body mass index (BMI), American Society of Anaesthesiologists' (ASA) classification, comorbidities, and presence and type of urinary tract abnormality. Patient comorbidities were assessed dichotomously as either the presence or absence of disorders. Imaging, with intravenous pyelography (IVP), ultrasound (US), or computed tomography (CT) was used to identify urinary tract abnormalities.

Stone characteristics included stone size, composition, location, and presence of partial or complete staghorn calculi. Stone burden was approximated by the sum of elliptical surface area ($\text{length} \times \text{width} \times \pi$)/4 for each stone, and categorized into size categories ($<500 \text{ mm}^2$, $500\text{--}1000 \text{ mm}^2$, $1001\text{--}1500 \text{ mm}^2$, $>1500 \text{ mm}^2$) for analysis.¹⁶ Partial staghorn stones were defined as a renal pelvic stone branching into one calyx, whereas complete staghorn stones were classified as branching into more than one calyx. Procedural data included operative time, number and location of tracts, dilation method, lithotripter type, and method of postoperative drainage.

Data on surgical outcomes included length of hospital stay, perioperative complications, rate of secondary interventions, and stone-free status at discharge and three months post-PCNL. Perioperative complications were categorized according to the Clavien-Dindo classification system. Secondary interventions included either second-look nephroscopy, ureteroscopy, or extracorporeal shock wave lithotripsy (SWL) treatment. Stone-free status at the time of discharge and three months post-PCNL was defined as no residual fragments present on imaging, determined by a combination of plain film x-ray kidneys ureters bladder (KUB), US, non-contrast CT, or IVP. The imaging modality preformed was based on surgeon discretion and individualized to patient and stone characteristics.

Detailed surgical steps

All PCNL cases were performed by two different surgeons. Surgeon A performed cases over the time period of 1995–2015, comprising 33.9% of the total cases included in the analysis. Surgeon B performed the remainder of the cases. PCNLs were performed with patients in the prone position. Single-stage PCNL with renal access was achieved using fluoroscopic guidance in the operating room in 97% of cases. The remaining 3% required either US or CT guidance in the interventional radiology suite due to inability to access the ureter in a retrograde fashion, or anatomical factors such as organomegaly, scoliosis, or retrorenal colon, which precluded safe access. The details of our PCNL technique have previously been published.¹⁷ If required, second-look nephroscopy was performed in a clinic cystoscopy suite under local anesthesia or in the operating room during the patient's inpatient hospital stay.

Statistical analysis

Retrospective analysis of the prospectively maintained database was performed. Patients were divided into chronological equal terciles of 852 consecutive procedures each (tercile one: July 1990 to February 2000; tercile two: March 2000 to March 2007; tercile three: April 2007 to July 2015) in order to allow for analysis of changes in variables over time. Chi-squared test was used to evaluate changes in patient characteristics and surgical techniques. A multivariate logistic regression was used to identify the effect of time on operative duration, adverse events, stone-free rate, and hospital length of stay. Statistical analyses were carried out using SPSS v.20 (Armonk, NY: IBM Corp.).

Results

Patient characteristics

Our cohort included 2554 consecutive PCNL treatments in 2486 patients. The mean age was 54 ± 15 years (range 4–91), 55.6% of patients were male ($n=1382$), and the mean BMI was $31 \pm 8 \text{ kg/m}^2$ (15–61). Almost half (46.9%, $n=1166$) of patients had medical comorbidities, most commonly hypertension (21.9%, $n=545$), DM (14.2%, $n=352$), or cardiac (13.0%, $n=322$) conditions. Patient characteristics are detailed in Table 1.

Analysis comparing patient characteristics between terciles revealed significant changes in patient age, BMI, ASA score, and the presence of comorbidities over time. The mean patient age increased from 53 to 56 years ($p=0.009$) and mean BMI increased from 30 to 33 kg/m^2 ($p=0.032$) when compared over terciles. Over time, there was a significant increase in patients with an ASA score of III, which was associated with a corresponding decrease in the number of ASA score I and II patients ($p<0.001$). There was a significant increase in the prevalence of medical comorbidities; specifically, the overall rate of medical comorbidities increased from 20.2% to 38.8% over time ($p<0.001$). The largest increases were observed in the rates of hypertension (11.5% to 35.1%; $p<0.001$) and DM (10.6% to 19.6%; $p<0.001$). There was no difference observed in the rates of renal anomalies over the compared terciles.

Stone characteristics

A total of 54.1% ($n=1381$) of treated stones were left-sided and 5.3% of cases ($n=135$) involved bilateral PCNL. The mean stone burden was $895 \pm 602 \text{ mm}^2$, with 54.3% ($n=1387$) of treated stones measuring less than 500 mm^2 . Stone composition was primarily calcium oxalate (74.2%), with a smaller proportion of stones being calcium phosphate

Table 1. Patient characteristics stratified by tercile

Characteristic	Overall	Tercile			p
		First	Second	Third	
Age (years)*	54±15	53±13	53±12	56±12	0.009
BMI (kg/m ²)*	31±8	31±6	30±6	33±6	0.032
ASA score*					
ASA I	12.4	14.6	16.8	7.8	<0.001
ASA II	50.0	51.5	53.2	46.6	<0.001
ASA III	32.8	6.2	23.3	37.8	<0.001
ASA IV	4.8	0.6	3.4	5.9	<0.001
Overall comorbidities*	27.8	20.2	24.4	38.8	<0.001
Hypertension*	21.9	11.5	17.4	35.1	<0.001
Diabetes mellitus*	14.2	10.6	11.2	19.6	<0.001
Cardiac disease	13.0	13.8	10.9	13.0	NS
Pulmonary disease*	7.3	4.9	4.7	11.8	<0.001
Neurologic disease*	7.4	6.3	4.9	10.2	<0.001
Orthopedic condition	5.6	6.1	4.2	6.1	NS
Gastrointestinal disease*	5.5	2.7	4.4	9.0	<0.001
Renal insufficiency*	2.8	1.6	2.0	4.6	<0.001
Renal anomalies	13.7	12.9	14.7	13.6	NS
Calyceal diverticulum	4.5	4.6	5.3	3.2	NS
Solitary kidney	4.0	4.0	4.5	3.2	NS
Horseshoe kidney	2.7	3.1	1.9	2.8	NS
Urinary diversion	2.1	1.2	2.2	2.7	NS
Ectopic kidney	0.7	0.0	0.4	1.7	NS
Transplant kidney	0.2	0.1	0.5	0.1	NS

Values presented as percentage of patients or mean ± standard deviation. *p<0.05 for the difference between terciles. ASA: American Society of Anaesthesiologists' classification; BMI: body mass index; NS: non-significant.

(29.9%) or uric acid (20.0%) in composition. Comparison between terciles of time did not demonstrate any differences in stone burden or composition (Table 2).

Surgical characteristics

The mean operative time for PCNL was 86±37 minutes (range 17–290). Operative time was calculated based on

Table 2. Stone characteristics stratified by tercile

Characteristic	Overall	Tercile			p
		First	Second	Third	
Stone burden					
≤500 mm ²	54.3	54.9	51.7	55.9	NS
501–1000 mm ²	26.2	25.1	28.7	25.0	NS
1001–1500 mm ²	9.1	9.9	8.2	9.3	NS
≥1500 mm ²	4.8	10.0	11.4	9.8	NS
Staghorn stones					
Partial staghorn	18.5	27.1	11.4	15.4	NS
Complete staghorn	14.2	11.3	11.5	18.6	NS
Stone composition					
Calcium oxalate monohydrate	37.5	29.9	50.0	51.2	NS
Calcium oxalate dihydrate	30.5	21.7	41.1	39.8	NS
Calcium phosphate	29.9	20.3	31.3	37.4	NS
Uric acid	20.0	18.3	21.8	20.0	NS
Struvite	13.4	14.0	14.4	13.1	NS
Cystine	6.4	7.5	7.2	4.9	NS

Values presented as percentage of patients. NS: non-significant.

procedural start and stop times. There was a significant change in operative time between terciles, with operative time decreasing a mean of 16 minutes between the first and third tercile ($p<0.001$). A single tract was used in the vast majority of cases (92.4%). No difference in the number of tracts used was noted over time. The majority of tracts were placed in the lower calyx (64.8%), compared with the mid calyx (21.9%) and upper calyx (13.3%). There was an increased number of mid-calyceal access tracts over time, with a corresponding decreased number of lower-calyceal tracts ($p<0.001$). Tract dilation was primarily performed with a balloon dilator (94.1%), compared to the sequential amplatz dilators (5.9%). Over time, there was a significant decrease in the use of the Amplatz dilators ($p<0.001$).

An ultrasonic lithotripter was the primary modality used for stone fragmentation (55.1%) and its use increased over time ($p<0.001$). Comparatively, pneumatic (28.2%) and electrohydraulic (12.9%) lithotripters were used to a lesser extent, and their use was observed to decrease over time ($p<0.001$). A laser was used in the minority of cases (3.8%), and there was a trend towards increased use of the laser over time. A postoperative nephrostomy tube was placed in the majority of cases (99.1%). A ureteric stent was placed in 23.4% of cases, and there was a significant increase in the use of ureteric stents over time ($p<0.001$) (Table 3).

Outcomes

The mean length of hospital stay was 4.1 days (median 3 days, range 1–30), however, this varied significantly with time. Patients in the first tercile had a mean hospital stay of 5.6 ± 2.1 days, while those in the third tercile had a mean stay of 3.2 ± 1.2 days, demonstrating a relative decrease of -2.4 days in hospital stay ($p<0.001$) (Table 4).

At the time of discharge, 86.0% ($n=2090$) of patients were stone-free on imaging. Three-month followup data was available for 73.3% ($n=1873$) of patients, and these patients were observed to have a stone-free rate of 86.7%. The imaging modality performed at followup was observed to change significantly over time, specifically an increased number of CTs were performed, with a corresponding decreasing in the number of IVPs ($p<0.001$) (Table 4). The stone-free rate decreased statistically over time (odds ratio [OR] 1.09; $p<0.001$); however, this was correlated with the increased use of CT scans for followup imaging. Multivariable analysis failed to demonstrate any other factors significantly correlated with stone-free rate.

Over 20% (22.2%, $n=567$) of patients required a secondary procedure to address residual stones, including 16.3% ($n=416$) who underwent secondary nephroscopy, 2.7% ($n=69$) who underwent SWL, and 1.6% ($n=41$) who required ureteroscopy. The rate of secondary procedures decreased over time due primarily to a significant decrease in the number of patients requiring a second look nephroscopy ($p<0.001$) (Table 4).

Table 3. Procedural characteristics stratified by tercile

Characteristic	Overall	Tercile			p
		First	Second	Third	
Tract number					
1	92.4	91.1	90.6	93.7	NS
2	6.7	8.0	6.3	5.6	NS
≥3	0.8	0.7	1.2	0.6	NS
Tract location					
Upper calyx	13.3	10.7	12.7	15.6	NS
Mid calyx*	21.9	12.8	23.7	27.7	<0.001
Lower calyx*	64.8	73.6	59.9	56.3	<0.001
Dilation method					
Amplatz dilators*	5.9	8.1	9.0	0.6	<0.001
Balloon dilator*	94.1	91.9	91.0	99.4	<0.001
Lithotripter					
Ultrasound*	55.1	21.3	69.8	88.5	<0.001
Pneumatic*	28.2	47.5	33.0	11.3	<0.001
Electrohydraulic*	12.9	20.8	10.5	10.8	<0.001
Laser	3.8	3.1	2.4	6.8	NS
Postoperative drainage					
Nephrostomy tube	99.1	99.9	99.2	98.1	NS
Ureteric stent*	23.4	12.1	14.5	43.6	<0.001
Operative duration (mins)*	86±37	95±28	76±23	80±28	<0.001

Values presented as percentage of patients or mean ± standard deviation. * $p<0.05$ for the difference between terciles. NS: non-significant.

Table 4. Clinical outcomes stratified by tercile

Outcome	Overall	Tercile			p
		First	Second	Third	
Hospital stay (days)*	4.1±2.5	5.6±2.1	3.7±1.4	3.2±1.2	<0.001
Ancillary procedures*	20.6	39.2	9.0	13.4	<0.001
Second-look* nephroscopy	16.3	35.3	6.0	7.5	<0.001
Shockwave lithotripsy	2.7	2.8	1.5	3.6	NS
Ureteroscopy	1.6	1.1	1.5	2.2	NS
Followup imaging					
IVP*	6.7	16.0	6.7	0.0	<0.001
Ultrasound	18.8	24.2	19.2	13.1	NS
X-ray KUB*	77.3	68.0	76.1	85.3	<0.001
CT*	4.3	0.4	4.0	7.3	<0.001
Stone-free rate*	86.7	95.0	89.7	73.5	<0.001

Values presented as percentage of patients or mean ± standard deviation. *p<0.05 for the difference between terciles. CT: computed tomography; IVP: intravenous pyelogram; KUB: kidneys ureter bladder; NS: non-significant.

The overall rate of complications was 18.9% (n=483), and the majority of complications (16.6%, n=424) were noted to be minor (Clavien grade I–II). There was an increased rate of complications noted over time (OR 1.15; p=0.010); however, this was correlated with the increased rate of medical comorbidities observed on multivariable analysis. The majority of complications that increased over time were Clavien grade I and II, and there was no statistical difference in the rate of major complications (Clavien grade III–V) over time (Table 5). The overall rate of blood transfusion was 1.0% and did not change throughout the terciles. Two mortalities were reported in the series, including one from a pulmonary embolus and one from intra-abdominal sepsis.

Discussion

Since its inception, PCNL has aimed to provide effective management of large and complex renal stones by achieving a high stone-free rate with minimal complications; however, there have been significant changes in the demographics and characteristics of patients undergoing PCNL. Limited data exist on the effect of changes to PCNL outcomes. Through a retrospective review of a prospectively collected database from a high-volume, single academic center, we evaluated the effect of changing patient and procedural characteristics on the outcomes of PCNL.

Our patient population was observed to become more medically complex over the 25-year period, as demonstrated by increases in age, BMI, ASA score, and the presence of

Table 5. Complications stratified by tercile

Outcome	Overall	Tercile			p
		First	Second	Third	
Overall complications*	18.9	9.9	13.9	32.9	0.010
Clavien-Dindo I*	13.8	7.0	10.6	23.8	0.007
Clavien-Dindo II*	2.8	1.8	1.8	4.8	0.019
Clavien-Dindo IIIA	1.5	0.8	1.4	2.2	NS
Clavien-Dindo IIIB	0.53	0.0	0.1	1.5	NS
Clavien-Dindo IVA	0.2	0.1	0.0	0.5	NS
Clavien-Dindo IVB	0.03	0.0	0.0	0.1	NS
Clavien-Dindo V	0.07	0.2	0.0	0.0	NS
Specific complications					
Urosepsis	2.4	0.5	0.5	1.3	NS
Transfusion	1.0	0.8	0.7	1.4	NS
Embolization	0.6	0.7	0.1	0.8	NS
Pneumothorax	1.1	0.9	1.2	2.8	NS
Colon injury	0.1	0.2	0.0	0.1	NS
DVT/PE	0.4	0.4	0.1	0.6	NS
Death	0.1	0.2	0.0	0.0	NS

Values presented as percentage of patients or mean ± standard deviation. *p<0.05 for the difference between terciles. DVT: deep vein thrombosis; NS: non-significant; PE: pulmonary embolism.

comorbidities. Prior series have shown similar results, with increasing patient age, rates of obesity, and Charlson comorbidity index being observed over time.¹⁸⁻²² In our series, the rates of hypertension and DM demonstrated the largest increase over time; this is consistent with a previous study, which also observed a significant increase in the rates of hypertension and DM in patients undergoing PCNL.¹⁸

The overall complication rate reported in our series was 18.9%, with a 2.3% rate of major complications (Clavien grade III–V). This is consistent with prior literature; for instance, the CROES study reported an overall 20.5% complication rate among an international series of 5803 consecutive PCNLs.²³ The rate of bleeding requiring blood transfusion in our series was 1.0% and did not change significantly over the 25-year period. This is significantly lower than the transfusion rate observed in other studies, which ranges from 4–11%; specifically, the CROES series reported a 7.8% rate of significant bleeding and a transfusion rate of 5.7%.²¹⁻²⁶ A higher reported transfusion rate may be accounted for by an increased proportion of PCNLs requiring multiple tracts for access in some series, as this has been established as a risk factor for bleeding.^{24,25} We observed a 0.5% rate of angioembolization for bleeding in our series, which was stable over time, and consistent with previous studies that have demonstrated embolization rates of 0.3–0.9%.²⁷⁻²⁹

Over the 25-year period, our complication rate increased significantly, and was correlated with the increased rate of medical comorbidities present within the patient population. This is consistent with several previous published reports that have also demonstrated increased complication rates with increased patient age and the presence of medical comorbidities.^{8,18,20,21,30} A recent study determined that complications following PCNL were 2.5 times more common in patients with hypertension and 2.7 times more common in patients with DM.³¹ This further correlates with a recent series, which demonstrated a 2.2 times increased risk of PCNL complications in patients with a Charlson comorbidity index of 3 or greater.¹⁸

Over time, there was a significant decrease in both operative time and hospital length of stay, with operative time decreasing a mean of 16 minutes between the first and third terciles and length of hospital stay decreasing 2.4 days. While the precise reasons for these observations are speculative, we believe the shorter operative time reflects an increased level of efficiency developed by all team members over time. In addition, the adoption of ultrasonic lithotripsy as the primary modality of intracorporeal lithotripsy likely accelerated stone removal and shortened operating room times compared with pneumatic lithotripsy, which was more commonly used earlier in the series. The reduction in hospital length of stay is felt to be the result of a clinical care pathway that is communicated to patients preoperatively, implemented by nursing and house staff experienced with

post-PCNL care, and includes early postoperative imaging. The increased use of a postoperative stent observed throughout the series was felt to be due to a combination of factors, including increased upper calyx access, a larger number of tubeless procedures, and more complex patients.

In our series, the stone-free rate at three-month followup was 86.7%, which compares favorably to previous reports that demonstrate a stone-free rate of 76–92%.^{23,32,33} The variation in stone-free rates published in the literature can be attributed to differences in the definition of stone-free, timing, and type of imaging modalities used. Our motivation was to provide a pragmatic approach to outcome assessment that would reflect reasonable clinical practice. As a result, followup imaging modality was performed at the discretion of the surgeon, and was primarily a combination of KUB and US, with selective use of CT. We believe that routine CT followup for all patients is unnecessary, and is associated with higher costs and radiation exposure.

In our series, there was minimal difference in stone-free rates at the time of discharge and at three-month followup. This can likely be attributed to use of second-look nephroscopy in order to treat residual stones during the same inpatient hospital admission. In addition, a considerable proportion of our patients are referred from urologists outside our center. As a result, three-month followup data was only available in 73.3% of our patients, which may limit the accuracy of the three-month stone-free rate.

The stone-free rate in our series was noted to decrease significantly over time, and this was correlated with the increased use of CT scans for followup imaging. This is likely secondary to the increased detection of residual fragments with the higher sensitivity of CT compared with KUB and US. Considerable debate exists within the literature regarding the optimal timing and modality for imaging following PCNL, and the definition of clinically significant residual fragments. While up to 26% of patients with residual fragments following PCNL require additional surgical intervention, the risk of this depends on the size and location of the residual fragment;³⁴ however, multiple other series have demonstrated that the presence of small, ‘insignificant’ fragments is not associated with increased rates of reintervention.³⁵⁻³⁷

The decreased stone-free rate observed over time in our series may also be partially attributable to the increased rates of obesity and medical comorbidities. Prior CROES analysis demonstrated a decreased stone-free rate and significantly higher re-treatment rates in obese compared with normal weight patients.³⁸ Furthermore, an increased rate of secondary procedures following PCNL has been observed in patients with both DM and metabolic syndrome.³¹

Over time, we have trended toward using more ureteral stents post-PCNL although the majority of patients, even in the most recent tercile, did not have a stent placed. Our explanation for this observation is our greater use of an upper

pole/supracostal tract in more recent times. To minimize the risks of pleural effusion exacerbated by ureteral obstruction, we typically place a stent in these patients. Our use of nephrostomy tube placement post-PCNL remains almost universal, and reflects our philosophy of providing renal access in case second-look nephroscopy is required and a preference of providing a short period of renal drainage without a stent when possible to reduce patients' stent-related morbidity. When deemed appropriate, however, we are adopting tubeless PCNL and, in select cases, an ambulatory protocol.

There are several limitations to this study that warrant discussion. As a retrospective review, there is inherent observation bias and association between factors cannot prove causation. In addition, changes in personnel staffing, trainee involvement, and the introduction of new equipment were not specifically accounted for in the series. Finally, variation in the imaging modality used to assess for residual stone fragments may have resulted in deviation of the stone-free rate over time. Over the course of the study period, there was an increase in the use of CT imaging at followup, which may have resulted in lower stone-free rates later in the series.

Conclusions

PCNL remains the gold standard treatment for the management of large and complex renal calculi. Trends over time have demonstrated increasing patient age, BMI, and medical comorbidities, which have corresponded with increased complication and decreased stone-free rates. However, despite an increasingly complex patient population, PCNL remains a safe and effective procedure, resulting in a high stone-free rate and low risk of complications.

Competing interests: Dr. Violette has been a speakers' bureau member for Janssen and Sanofi (no honoraria). Dr. Taillly has received honoraria from Cook Medical and Storz. Dr. Denstedt holds a patent for a product marketed by Cook Medical. Dr. Razvi receives royalties for a product marketed by Cook Medical; and receives endourology fellowship support from Cook Medical and Storz Medical. The remaining authors report no competing personal or financial interests related to this work

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