A SURVEY REGARDING PREFERENCE IN MANAGEMENT OF BILATERAL STONE DISEASE and COMPARISON OF CLAVIEN COMPLICATION RATE IN BILATERAL VERSUS UNILATERAL PERCUTANEOUS NEPHROLITHOTOMY

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Abstract

Purpose: To discuss complications of simultaneous bilateral percutaneous nephrolithotomy (SB-PCNL) when compared to unilateral percutaneous nephrolithotomy (U-PCNL) and survey surgeon preference in bilateral stone disease management.

Materials and Methods:

A database of all participating PCNL patients who received treatment at Indiana University Health Methodist Hospital within a 10-year period from 2006 to 2015 by a single surgeon (JL) was utilized. Perioperative data as well as complications, as defined according the Clavien grading system, were recorded. A survey of members of the Endourological Society was performed regarding surgical management in the setting of bilateral stone disease.

Results

A total of 563 patients were identified over the study period with 129 undergoing SB-PCNL. Overall, SB-PCNL patients had a longer procedure (176.9 vs115.6 min, $p<0.0001$), were more likely to undergo a secondary procedure (73% vs 44 $p<0.001$), and had a longer hospital stay (3.2 vs 2.3 days, $p<0.001$). Notably, there were no differences in number or severity of complications between the two groups.

A total of 153 endourologists completed the survey. Of these 58 (38%) perform bilateral PCNL under anesthesia. The top reasons for electing to not perform

bilateral PCNLs included: duration of bilateral procedures (53%), bilateral renal injury (48%), rarely perform bilateral surgery (35%).

Conclusions

Although procedure length was longer in the SB-PCNL group there were similar rates of complications and severity between U-PCNL and SB-PCNL. A majority of endourologists surveyed do not perform bilateral PCNL but would perform bilateral URS with duration of the procedure and concern for bilateral renal injury representing the most common reasons.

Introduction

Since the first PCNL in 1976, percutaneous nephrolithotomy (PCNL) has become the standard of care for treatment of large and complex nephrolithiasis. [1] While recent reports have demonstrated that PCNL is a safe procedure with acceptable post-operative complication rates, there are certain circumstances where there is a theoretical increased risk of complications. [2 3 4] Bilateral stone disease presents a unique challenge to the treating urologist, in particular when there is significant stone burden warranting PCNL. SB-PCNL was first reported by Colon-Perez in 1987 and while there is a hypothetical increased risk to simultaneous bilateral PCNL (SB-PCNL), multiple investigations have demonstrated its safety and efficacy as well as decreased cost in the complex stone patient[5 6-9]. However, a study from Hungary did report an increased risk of complications with SB-PCNL compared to unilateral PCNL (U-PCNL).[10]

Although complication rates associated with PCNL in the reported literature are low, classification of these complications can be difficult as there are currently many surgical technique variations, including radiologist assisted access as well as other ancillary procedures, utilization of lithotripsy and scope technology, and surgical approaches, which can lead to varied interpretation of what constitutes a complication.[2] With this in mind, recent publications have aimed to categorize complications utilizing the widely accepted modified Clavien classification.[11] Although there have been reports utilizing the modified complication classification system comparing SB-PCNL and U-PCNL, these have typically been small series. The lack of robust literature regarding this clinical question led to the development of a survey submitted to the Endourological Society email listserv. Therefore, we aim to add to the current body of literature with a large institutional series and to discuss surgeon preference and rationale regarding bilateral stone disease cases.

Patients and methods

Patients

A prospectively maintained database of all participating PCNL patients who received treatment at Indiana University Health Methodist Hospital within a 10-year period from 2006 to 2015 by a single surgeon (JEL) was utilized for analysis. Preoperative data including age, gender, comorbidities, anatomical anomalies, and preoperative serum creatinine and hemoglobin levels were recorded. Additionally, intraoperative data including stone size, total surgical

time, length of stay, and secondary procedures were documented. Finally, postoperative data, including serum creatinine and hemoglobin levels at 24 hours after surgery, and complications, as defined according the Clavien grading system, were recorded.

Technique

Following the placement of a 5 Fr ureteral and bladder catheters, the patient was placed in the prone position. Renal access was obtained using an 18-gauge diamond tip access needle with the number and location of access points decided based on the anatomy of the kidney as well as the complexity of the stones. Renal access was obtained by the urologist using a triangulation technique. After verification of access with urine aspiration, a 0.035-inch hydrophilic guidewire was passed through the needle and into the renal collecting system. In most situations the guidewire, after being positioned in the ureter, was exchanged for an Amplatz super stiff working wire; a second safety wire was also placed down the ureter. Finally, balloon dilatation was performed and a 30 Fr working sheath was placed into the calyx of interest.[12] For bilateral PCNL, a 5 Fr ureteral catheter was placed in each of the two ureters at the beginning of the procedure. The more complex side was always treated first.

A combination of rigid and flexible nephroscopy was performed, and lithotripsy was carried out using a combination of ultrasonic, pneumatic, and holmium laser energy. In most cases of PCNL, a 10 Fr Cope loop catheter was left in the renal collecting system and a 5 Fr open-ended catheter was placed

antegradely in the ureter. All patients had a blood draw on postoperative day (POD) 1 as well as a noncontrast CT scan. All patients with fragments on their CT scan underwent a secondary procedure on POD 2. Nephrostomy tube removal was attempted on postoperative day one if the CT indicated that the renal unit was stone free. If residual fragments remained after a secondary procedure, patients underwent a third procedure to render them stone free.

Complications within 30 days of the procedure were recorded and classified according to the Clavien system of grading complications with the categorization recommended by de la Rosette et al.[11]. All analyses were performed using JMP®, Version 12.0. (SAS Institute Inc., Cary, NC, 1989-2007), using two-tailed testing with a significance level of 0.05.

Results

Preoperative characteristics

A total of 563 patients were identified over the study period with 129 undergoing SB-PCNL. Clinical baseline characteristics are presented in Table 1. Mean age was 53 (IQR 43-65) and 54 (IQR 44-65) years, p=0.60 with mean BMI of 32.0 (IQR 25.1-36.6) and 32.1 (IQR 21.3-39), p=0.89 between the U-PCNL and SB-PCNL groups, respectively. There was a significant difference in baseline renal function between the two groups with mean serum creatinine values of 1.02 (IQR, 0.79-1.13) and 1.13 (IQR, 0.84-1.25), p=0.02 for U-PCNL and SB-PCNL, respectively. Likewise, the diagnosis of gout (p=0.01) and horseshoe kidney (p=0.04) was significantly higher in the SB-PCNL cohort.

Intra- and postoperative characteristics

Overall, patients who underwent SB-PCNL had a longer duration of their procedure (176.9 vs115.6, p<0.001), were more likely to undergo a secondary procedure (73% vs 44, p<0.001), even when stratified on a renal unit basis (62% vs 44, P<0.001). Thus, the stone free rate after the primary procedure was 27 vs 56% (p<0.001) in the SB-PCNL and U-PCNL groups, respectively. The SB-PCNL group had a longer length of hospitalization (3.2 vs 2.3 days, p<0.001). The procedure was terminated early once in each group, due to return of purulence with initial puncture in the SB-PCNL and hemorrhage in U-PCNL group. We also identified a conversion from contralateral URS with U-PCNL to SB-PCNL in three cases. Similarly, renal function at 24 hours post-op (1.43 vs 1.23, p=0.002) and mean hemoglobin (11.2 vs11.7 p=0.007) were both significantly decreased in the SB-PCNL group compared to the U-PCNL cohort. By 48hrs post-operatively, the renal function was no longer significantly different between the two groups (p=0.15). The proportion of infectious stones was similar between the two groups with 10% of both cohorts having infectious stones, struvite or carbonate apatite, on analysis. The numbers of complications between the two groups were not statistically different with 33% of the SB-PCNL cohort and 27% (p=0.15) of the U-PCNL experiencing a complication (Table 2). Likewise, within the complication group there were no differences in severity of complications when comparing the U and SB-PCNL groups.

Survey Results

Regarding the survey to the Endourological Society, a total of 153 urologists completed the survey. Of these, 58 (38%) perform bilateral PCNL under the same anesthesia, 74 (48%) perform bilateral URS but not bilateral PCNL, and 21 (14%) do not perform bilateral stone procedures under the same anesthetic. Those who do not perform bilateral PCNL were willing to offer their patients staged PCNLs (88%), unilateral PCNL and contralateral URS (10%) and/or unilateral PCNL with observation of the contralateral side (5%). Reasons for electing to not perform bilateral PCNLs included: rarely perform bilateral renal stone surgery (35%), duration of bilateral procedures (53%), bilateral renal injury (48%), bleeding risk (34%), patient discomfort (23%), reimbursement (13%), burden of bilateral procedure to operating room staff (11%), and hospital policy (6%) (Figure 1). Urologists who were willing to do unilateral PCNL and contralateral URS (n=9) felt their method of treatment was safer (56%), had less risk of acute kidney injury (78%), and less blood loss (11%). Regarding bilateral ureteroscopy, 131 urologists (85%) were willing to perform bilateral URS under the same anesthesia, while 14% would do staged URS, and 1% would do unilateral URS and observe the contralateral side.

Finally a clinical scenario of a patient with bilateral 2.5cm stones, amenable to PCNL was given. When offered management options, those who perform bilateral PCNL, chose bilateral PCNL most often (74%), staged PCNL (12%), staged URS (5%), bilateral URS (5%), and unilateral PCNL with contralateral URS (4%). Urologists who do not perform bilateral PCNLs elected to perform

staged PCNL (83%), staged URS (12%), unilateral PCNL and contralateral URS (3%), and bilateral URS (2%).

Discussion

Over a ten-year period within a single surgeon experience of U and SB-PCNL we identified no significant difference in the number of complications or severity of complications when using the CROES PCNL study group assigned Clavien complication grading system. The vast majority of our complications were grade I or II. While patients undergoing SB-PCNL did have lower postoperative hemoglobins on the first postoperative day, this was not clinically significant as there was no difference in transfusion rates between groups. Furthermore the SB-PCNL group had a higher baseline creatinine compared to the U-PCNL so the difference in renal function between groups is minimal. As expected, the procedure length and hospital stay was significantly longer and rate of secondary procedures was likewise higher in the SB-PCNL cohort. However, procedure length was not twice that of U-PCNL and thus a more efficient procedure for the patient. There was a single Clavien V complication in a patient who was found to have widely metastatic colorectal cancer shortly after his procedure and was placed on hospice and died within 30 days of his procedure.

We also found that the majority of endourologists surveyed do not offer bilateral PCNL to their patients as an option for treatment. The most common concerns for not performing bilateral procedures were the duration of the procedure, concern for bilateral renal injury and rarely performing the procedure. While a recent survey investigation of endourologists queried other patient management topics,[13] to our knowledge this is the first survey to the Endourological field investigating procedural preference in the setting of bilateral stone disease.

A recent systematic review by Jones et al into the safety and feasibility of SB-PCNL notes only 11 investigations with a total of 594 patients meeting inclusion criteria over a span of 18 years.[14] While our patients were significantly older than the review, rates of complications were similar. Interestingly, the most common complication in this review was fever but the complications were reported utilizing the modified Clavien-Dindo classification and likely underestimating the true number of complications. Our investigation would add significantly to the current body of literature in both procedure number and by better defining procedure specific complications.

Clavien was the first to propose a reporting system to define and classify surgical complications to allow for standardized reporting throughout the literature.[15] In 2004, Dindo et al. evaluated the reproducibility of the modified Clavien system and found that it correlated well with complexity of surgery and hospital stay. The Clavien system serves as the guideline for classification of postoperative

morbidity and mortality to this day.[16] The creation of a surgical complications reporting system has led to the more objective reporting of patient outcomes in the literature. However, the Clavien system is not specialty specific and thus can lead to inconsistent reporting of the severity of postoperative complications. The limitations in reporting of complications in PCNL was noted in a recent review by Seitz et al. and the authors recommended a modified Clavien system be established.[2] Therefore, de la Rossette and the Clinical Research Office of the Endourology Society (CROES) analyzed the interrater reliability of PCNL complications. After surveying a group of urologists who rated a set of complications the authors found low reliability between individuals with regards to lower Clavien complications. In order to reduce this variability in the future, a proposed categorization of complications based on the Clavien system was constructed based on expert opinion.[11] This CROES procedure-specific grading system was utilized to define all complications within our investigation.

SB-PCNL was first reported nearly 10 years after initial U-PCNL reports; however, [5 17 18] there is limited data comparing the complications associated between SB-PCNL and U-PCNL. Looking only at U-PNCL, the CROES PCNL Global Study database with 5724 patients reported a complication rate of 20.5% using the Clavien complication grading system.[19] Desai et al in 2007 demonstrated a complication rate of 22.2% in 45 patients undergoing SB-PCNL.[20] Holman et al in 2002 compared 150 SB-PCNLs with 300 U-PCNLs.[9] This study found complications rates of 14.3% and 11.3% for patients undergoing

SB-PCNL and UPCNL, respectively. Silverstein et al in 2004 compared 19 patients who underwent staged U-PCNLs to 17 patients who underwent SB-PCNLs.[6] They reported complication rates of 19% and 28% for the staged and simultaneous PCNL groups, respectively. They noted less blood loss in patients undergoing SB-PCNL compared to those in a staged approach. However, transfusion rates while comparable were noted to be considerable between the two groups at 28.6 and 36.8% (p-value=NS) for the SB-PCNL and the asynchronous group, respectively. The transfusion rate of our cohort was not significantly different at 2% and 4.7% for U-PCNL and SB-PCNL respectively. While overall complication rates were not discussed, blood loss may serve as an indicator of the similar morbidity that SB-PCNL has to U-PCNL.

Although multiple reports have indicated similar morbidity between SB-PCNL and U-PCNL, investigators have raised caution in certain circumstances such as complex renal anatomy.[19] Our investigation did find a difference in complex renal anatomy with a significantly higher number of patients undergoing SB-PCNL who had a horseshoe kidney. Nonetheless, there were no statistically significant differences within the cohort even with the added anatomic complexity.

A recent investigation would seem to disagree with the notion of SB-PCNL and U-PCNL having similar rates of complications. Kadlec et al., in an institutional series of 47 patients over 11 years who underwent bilateral PCNL, noted an increase in any complication within the bilateral PCNL group when compared to a matched unilateral cohort, with over 50% having a complication compared to 31% (p=0.01) in the U-PCNL group.[10] Renal access was obtained by a

radiologist the day prior to the planned procedure. While the analysis of Kadlec et al. utilized the Clavien classification, it did not apply the PCNL specific categorization recommended by the CROES group and did not discuss prolonged nephrostomy drainage, the most common complication in our cohort. While the current investigation is over a similar period of time, we report a considerably larger cohort of patients. Also dissimilar to our series was a rather high rate of sepsis in the bilateral cohort (6.4%) of the Kadlec et al study. In our series we noted a sepsis rate of approximately 1% in the entire cohort which may in turn be due to our perioperative antibiotic protocol. This includes a minimum of 7 days pre- and 7 days of post-procedural antibiotics. Overall, we note fewer complications with no difference in the severity of complications within our series.

While our study represents the largest single series in the literature, it is not without limitations. Our survey results are prone to response bias and may not represent the entirety of the Endourological society. Although our rates of complications are similar to that of the reported literature, we are the first to utilize the CROES categorization of complications and thus, may have a higher rate of Clavien grade 1 and 2 complications. Our medical center serves as a high volume tertiary referral center for stone disease and therefore, the generalizability of our patients and outcomes may not reflect that of a smaller referral practice. Finally, although the series represents that of an experienced surgeon, it should be noted that as a tertiary teaching hospital residents and fellows participated in all aspects of the cases including percutaneous access.

Conclusion

Although U-PCNL and SB-PCNL did have significant differences in certain reported metrics including total operative time, likelihood for a secondary procedure, and length of hospital stay, rates of complications and severity of complications were similar between the two groups. Thus, SB-PCNL should be considered an acceptable treatment alternative for patients with bilateral stone burden warranting percutaneous management. We also identified that a majority of endourologists surveyed do not perform bilateral PCNL but would perform bilateral URS, citing the duration of the procedure and concern for bilateral renal injury representing the most common reasons.

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Figure 1. Graph of Survey results regarding respondents who do not offer B/L PCNL

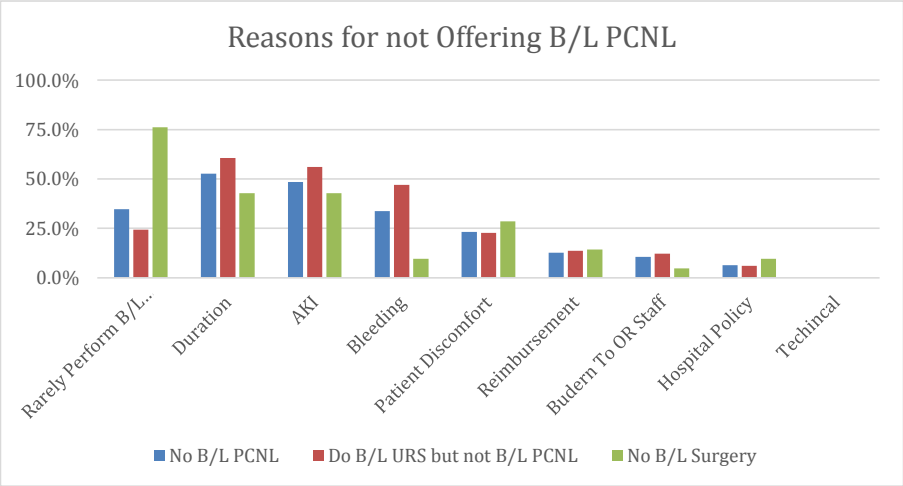

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Table 1. Preoperative demographics of patients who underwent unilateral or simultaneous bilateral percutaneous nephrolithotomy
n = number of patients

	Unilateral (n=434)	Bilateral (n=129)	*P* value
Years of age (mean ± SD)	53.4 (15.7)	54.3 (15.3)	0.60
Male gender (%)	45	49	0.42
BMI (mean ± SD)	32.0	32.1	0.89
Pre-operative serum Creatinine (mg/dl, mean ± SD)	1.02 (0.4)	1.13 (0.5)	**0.02**
Pre-operative Hb (g/dl, mean ± SD)	13.7 (1.69)	13.8 (1.79)	0.69
UTI (%)	48%	52%	0.37
Hypertension (%)	47%	45%	0.61
Diabetes (%)	23%	24%	0.81
Gout (%)	3%	9%	**0.01**
Hyperparathyroidism (%)	4%	4%	1.0
Horseshoe Kidney (%)	2%	6%	**0.04**
Staghorn Calculus (%)	45%	40%	0.31
Calyceal diverticulum (%)	5%	2%	0.09
Left Stone Burden >2cm (%)	82%	79%	0.50
Right Stone Burden >2cm (%)	77%	70%	0.24
Urinary Diversion (%)	2%	2%	1.0
Paresis (%)	3%	6%	0.11

Table 2. Postoperative characteristics and complications of patients who underwent unilateral or bilateral percutaneous nephrolithotomy

	Unilateral (n=434)	Bilateral (n=129)	*P* value
Creatinine, 24hrs post-operative (mg/dl, mean ± SD)	1.23 (0.67)	1.43 (0.62)	**0.002**
Creatinine, 48hrs post-operative (mg/dl, mean ± SD)	1.37 (0.89)	1.62 (0.90)	0.15
Hb@24hrs (g/dl, mean ± SD)	11.7 (1.74)	11.2 (1.76)	**0.007**
Transfusion (%)	2.0%	4.7%	0.11
Length of stay (days; mean, range)	2.3 (1-23)	3.2 (1-21)	**<0.001**
Total surgery time (min) (SD)	115.6 (42.9)	176.9 (54.1)	**<0.0001**
Secondary procedures (%)	44	73	**<0.0001**
Renal units undergoing secondary (%)	44	62	**<0.0001**
Complications			
Clavien % (n) (overall)	27 (116)	33 (43)	0.15
Clavien I	17.8 (77)	19.4 (25)	0.36
Clavien II	3.5 (15)	7.8 (10)	0.14
Clavien IIIa	0.9 (4)	3.1 (4)	0.83
Clavien IIIb	2.5 (11)	0.8 (1)	
Clavien IVa	1.2 (5)	0.8 (1)	
Clavien IVb	0.7 (3)	1.6 (2)	
Clavien V	0.2 (1)	0	

Most frequent Clavien I complication: Delayed removal of nephrostomy tube
Most frequent Clavien II complication: Blood loss requiring blood transfusion
Most frequent Clavien III complication: Edema/clot retention requiring stent placement
Most frequent Clavien IV complication: Sepsis

Table 3. Detailed list of complications by Clavien classification

Clavien grade	Complications (U-PCNL/SB-PCNL)
Grade I (n*)	Delayed removal or displacement of nephrostomy tube (32/9) Blood loss anemia without need for transfusion (10/2) Elevated postoperative temperature (> 38ºC) managed without antibiotics (8/7) Subcapsular hematoma and/or perinephric hematoma (6/0) Small collecting system perforation (6/0) Post-operative pain managed with adjunct opioid analgesics (5/4) Urinary retention (4/0) Hypotension (3/1) Electrolyte derangement managed conservatively (1/0) Hydrothorax managed expectantly (1/0) Desaturation responding to conservative management (1/0) Pneumothorax managed with watchful waiting (0/1)
Grade II (n*)	Bleeding requiring transfusions or receipt of blood product (5/6) Fever managed with antibiotics (4/1) Deep vein thrombosis (3/0) Cardiac arrhythmia (2/0) Hyposaturation managed by oxygen therapy (1/1) Ileus with conservative management (0/1)
Grade IIIa (n*)	Embolization for pseudoaneurysm and arteriovenous fistula (2/1) Hydro/pneumothorax managed by drain/tube placement (1/1) Renal abscess treated with aspiration (0/1) UTI without organ failure requiring advanced monitoring (1/1)

Grade IIIb (n*)	Stent placement for edema/clot (6/1) Bladder clot evacuation (3/0) Colonic injury (2/0)
Grade IVa (n*)	Respiratory failure (3/1) Acute Renal Failure requiring ICU management (2/0)
Grade IVb (n*)	Sepsis and multi-organ failure (3/2)
Grade V	Death (1/0)