

Analysis of the Clinical Efficacy and Safety of a Single Upper Pole Access (SUPA-PCNL) for Staghorn Calculi: A Prospective Single Center Descriptive Study

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Introduction and Objective: The endoscopic management of staghorn calculi is very challenging owing to its complex anatomical configuration. The authors analyzed the clinical efficacy and safety of a single upper pole access PCNL (SUPA-PCNL) for Guy Stone Score (GSS) 3-4 staghorn calculi.

Methods: Prospective data collection was done on 56 consecutive patients who with GSS 3-4 staghorn calculi. All cases were treated with a standardized technique of a single upper pole access PCNL in the prone position. The patient demographics, stone characteristics, perioperative and postoperative outcomes were analyzed.

Results: The cohort exhibited diversity in age (51.7±12), gender (male to female ratio of 5.5:4.5) comorbidities, and stone burden (4.82±1.96 cm). SUPA-PCNL demonstrated a high median stone-free rate (99.5%, IQR 90-100) with minimal complications, low blood loss with a of 200cc (IQR 100-300), and median hospital stay of 3.5 days (IQR 3-5). Stone characteristics did not significantly influence outcomes. A subset required secondary treatments (12%, n=7), but overall morbidity was low (16%, n=9): (7% n=4) of which required blood transfusion, and (9% n=5) due to sepsis. The following factors were associated with increased odds of perioperative morbidity: preoperative creatinine >3 mg/dl (OR 4.19 95% CI 0.59 – 29.71 p=0.152) and a history of endoscopic surgery (OR 7.33 95% CI 1.20-44.96 p=0.031).

Conclusion: SUPA-PCNL is effective and safe for the treatment of staghorn calculi. In select patients, this approach obviates the need for a multi-tract access or an endoscopically-combined intrarenal surgery (ECIRS).

Key words: Percutaneous Nephrolithotomy, Guy Stone Score, single upper pole access, morbidity, staghorn calculus

Introduction

Staghorn calculi are large branching renal stones that occupy almost the entire renal collecting system. Percutaneous nephrolithotomy (PCNL) is considered the standard treatment for these types of stones. Following its initial introduction in the 1976, the evolution in the operative technique,

vis-à-vis the development of more enhanced high-definition videoendoscopic imaging and more efficient intracorporeal lithotripters, stone clearance rates have increased up to 98.5%.¹ Compared to open stone surgery, PCNL provides comparable stone clearance rates, with reduced bleeding, less postoperative pain, and shorter convalescent period, making it the preferred treatment for staghorn calculi.

Staghorn calculi can be classified using the Guy's Stone Score (GSS) [Appendix]. The classification is defined based on the figure shown below. The authors' focused on patients with GSS 3-4 which encompasses partial and complete staghorn calculi.³ The authors utilized a single upper pole access in the prone position in most PCNL cases unless the renal anatomy precludes access to the stone location such as a bifid renal pelvis and an acute upper-calyx to lower calyceal angle of <90 degrees.

Up to this present however, there is great variability in the approaches to PCNL and there is no single standard technique that is acceptable to the majority.¹ The choice and method of percutaneous varies from one surgeon to another and from patient to patient depending on the physical features and renal anatomical characteristics. Such variance in the techniques is related to patient position (supine vs. prone), choice and size of access (standard vs. mini-), the choice of image-guided technology (ultrasound vs. fluoroscopy), energy source for intracorporeal lithotripters (ultrasonic, pneumatic or laser), and postoperative drainage technique (tubeless, with nephrostomy tube vs. indwelling ureteral stent).

PCNL can be performed in either the supine or prone position. The prone position is advantageous as it allows for wider working space, easier access to the superior pole and greater hydrodistention of the renal collecting system, making it easier to target stones, enhancing visualization and facilitating effective stone fragmentation and removal. On the other hand, the supine approach reduces the risk of certain complications, such as positioning-related injuries, but can limit access to difficult stone locations.

The Clinical Research Office of the Endourological Society (CROES) Study was done in 2011 showing that PCNL is an effective and safe technique for the management of renal stones, especially staghorn calculus.⁵ The study showed that PCNL was able to yield a stone-free rate of 90% with minimal complications. However, this included stones less than a GSS 4, and only 15% of the study population had a large stone load.

A retrospective study done in 2002 showed that patients treated with a single percutaneous access has a stone-free rate of 95% and those with residual

stone were treated with flexible ureteroscopy and holmium:YAG laser or basket stone extraction.⁶ To the authors' knowledge, this will be the first prospective study in clinically assessing the efficacy of single upper pole access on a staghorn calculus.

The authors determined the outcomes of surgery in patients with staghorn calculus and a GSS of 3-4 who underwent single upper pole access PCNL (SUPA-PCNL). They summarized and analyzed patient demographics, stone characteristics, assess stone-free rates, perioperative and postoperative outcomes, and 30-day surgical morbidity and mortality rates using the Clavien-Dindo Scoring system.

Methods

Subject Population

After IRB and ethics approval, the authors performed prospective data collection of patients who underwent SUPA-PCNL for staghorn calculus with GSS 3-4 in their institution. These included both service and private patients who all signed an informed consent. Enrollment to the procedure was completely voluntary.

All patients with staghorn calculus defined by GSS 3-4, underwent SUPA-PCNL, with an intention to treat all stone fragments. Whenever necessary, additional tracts were used to maximize stone clearance. The primary outcome was stone-free rate defined as absence of stone or stones <4mm postoperatively confirmed via radiologic study and a non-contrast CT on postoperative day 30.

Eligibility criteria was over 18 years old, GSS 3-4. Patients with incomplete data, <18 years of age, with congenital kidney anomalies, GSS less than 3, with spina bifida, or spinal injury were excluded. Patients requiring multiple accesses during the procedure, were still included in the study for further analysis.

Standardized Upper Pole Access Technique

All patients were operated on using a standardized technique which consisted of a preliminary insertion of a ureteral catheter to the posterior upper pole calyx in the lithotomy

position. The patient was repositioned to prone. Under fluoroscopic guidance, an air pyelogram was introduced to visualize the most upper and posterior calyx. This was followed by a “bull’s-eye” (hub-over-tip) technique which was used to advance the percutaneous access needle to the target calyx. Its position was confirmed through a 20 degree oblique view away from the surgeon. Instillation of saline also noted egress of urine through the percutaneous access needle. A guidewire is introduced and advanced into the ureter until it coiled in the urinary bladder. This was duplicated using a dual lumen ureteral catheter or a co-axial guidewire introducer (Desilet-Hoffman). Tract dilation was typically done with graduated silicon Amplatz dilators and occasionally with a renal dilator balloon or telescoping serial metal Alken dilators. Stones were fragmented with either an ultrasonic or pneumatic devices. Immediate postoperative stone burden was confirmed under fluoroscopy. The decision to drain with either an indwelling ureteral stent or a nephrostomy tube depended on the clinical judgment of each surgeon. (Figure 2).

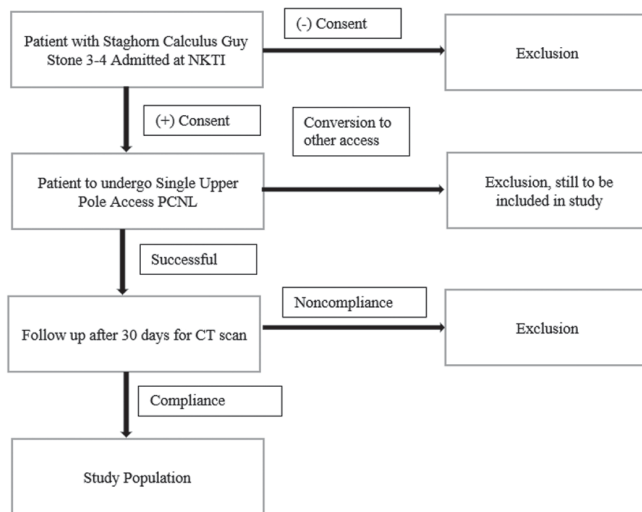


Figure 2. Process flow of patient recruitment.

Secondary outcomes included perioperative parameters such as operative time, number of percutaneous access tracts, estimated blood loss, and type of urinary drainage (ureteral stent, nephrostomy, or totally tubeless). Postoperative parameters such as length of hospital stay,

transfusion requirements and change in hemoglobin and creatinine. The complications were analyzed using the modified Clavien-Dindo classification.

Unenhanced Computed Tomography (CT) of the KUB was done 30 days after PCNL to stone-free status. Whenever necessary, secondary therapies for residual stones may be done utilizing the following options: repeat PCNL, retrograde intrarenal surgery, ureteroscopy or ESWL.

Data Management

All patients signed an informed consent. Preoperative CT was done on all patients to document the stone configuration based on the Guy Stone Classification. Intraoperative data included duration of surgery and estimated blood loss. Postoperative data included stone-free rate, change in serum creatinine and hemoglobin levels, and length of hospital stay. The complications were summarized using the modified Clavien-Dindo classification.

Sample Size

Using G*Power 3.1.9.2, a minimum of 54 patients are required for this study based on desired moderate effect size before and after OR of patients with complete staghorn calculus with GSS 3-4 who will undergo SUPA-PCNL, 5% level of significance and 95% power.

Sample size is computed as follows:

$$n = \left(\frac{1 + \lambda}{\lambda} \right) \frac{(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2} + \frac{z^2_{1-\alpha/2}}{2(1+\lambda)}$$

$$n = \left(\frac{1+1}{1} \right) \frac{(1.96 + 1.645)^2}{0.7^2} + \frac{(1.96)^2}{2(1+1)}$$

$$n = 54.0054 \approx 54$$

Where:

n = sample size

λ = standard

Zα = 5 % of significance

Zβ = 95% of power

Δ = large size effect

Statistical Analysis

Descriptive statistics was used to summarize the demographic and clinical characteristics of the patients. Frequency and proportion were used for categorical variables, median and inter quartile range for non-normally distributed continuous variables and mean and standard deviation for normally distributed continuous variables. Odds ratio and corresponding 95% confidence intervals from binary logistic regression was computed to determine significant predictors for mortality. Shapiro-Wilk test was used to test the normality of the continuous variables. Missing values were neither replaced nor estimated. Null hypotheses were rejected at 0.05 α -level of significance. STATA 13.1 was used for data analysis.

Ethical Considerations

Informed consent was secured from all patients who passed the inclusion criteria. Consent was obtained upon admission prior to the said operation by the principal investigator or his delegate. Information obtained from this study were all confidential. Materials were kept in a safe and locked storage. The recipients were assigned codes,

from the start of the data collection. The names of the patient were anonymized. Only the primary investigator or his designated research assistant may had access to the records.

Results

Fifty six patients were enrolled in this study. The patients who were treated with SUPA-PCNL were predominantly below 60 years old (76.79%). Gender distribution is 55.35% male and 44.64% female. The mean height of patients is 161.38 cm, weight is 65.4 kg and the mean BMI is 25.21. The median preoperative creatinine level is 1.3 mg/dl with a median interquartile range (IQR) of 0.98-1.88. Ninety one percent of the patients have a preoperative creatinine below 3 mg/dl suggesting relatively normal kidney function in the study population. 55.36% of the population had cardiovascular disease, 33.93% had chronic kidney disease and 16.07% had diabetes mellitus. 23.21 % of the patients had previous PCNL, 10.71% had previous cystoscopy/ureteroscopy, 11% of the population had a mix of open stone surgery, ESWL and previous nephrectomy. Majority of the patients were ASA 2 patients (67.86%), followed by ASA 1 (21.43%) and ASA 3 (10.71%).

Table 1. Patient demographics (n=56).

	Frequency (%); Mean $\pm$ SD; Median (IQR)
Age in years	51.66 $\pm$ 12.02
< 60	43 (76.79)
$\geq$ 60	13 (23.21)
Sex	
Male	31 (55.36)
Female	25 (44.64)
Height, cm	161.38 $\pm$ 7.67
Weight, kg	65.4 $\pm$ 9.61
BMI	25.21 $\pm$ 4.25
Preop Creatinine, mg/dl	1.3 (0.98 to 1.88)
< 3	51 (91.07)
$\geq$ 3	5 (8.93)
Comorbidities	
Cardiovascular Disease	31 (55.36)
Chronic Kidney Disease	19 (33.93)
Diabetes Mellitus	9 (16.07)
History of Anticoagulant use	6 (10.71)
Previous PCNL	13 (23.21)
Previous ESWL	1 (1.79)
Previous Open Stone Surgery	4 (7.14)
Previous URS	6 (10.71)
Previous nephrectomy	2 (3.57)
ASA Class	
ASA 1	12 (21.43)
ASA 2	38 (67.86)
ASA 3	6 (10.71)
ASA 4	0

The mean HU of the patients was 1234, with a range from 653-1415. 39.29% had HU <1000, while 60.71% had HU >1000. The mean stone burden was 4.82 with an SD of 1.96. Sixty four percent of patients had stones less than 5 cm and 35.71 had stone burden from 5-10 cm. (Table 2)

Table 3 shows the perioperative outcomes. while Table 4 shows the postoperative outcome.

Table 5 shows patients with morbidities are grouped together to make an analysis of which of the factors may predispose them to have intraoperative morbidities. Age, sex, BMI, comorbidities and ASA Class did not show any statistical significance for perioperative morbidity. There is a trend towards an increase Odds ratio for higher preoperative creatinine levels but was not statistically significant. It should be noted that patients with cystoscopy, ureteroscopy are 7.3333 times more likely to have morbidity based on Clavien-Dindo morbidity scoring.

Preoperative and post-operative hemoglobin levels do not show statistically significant associations with patient morbidity. A longer hospital stay is significantly associated with increased odds of morbidity. Patients with secondary PCNL treatment are 13.143 times more likely to have morbidity based on Clavien-Dindo morbidity scoring (Table 6).

Discussion

SUPA-PCNL provides the following advantages: 1) shortest skin to calyceal distance, 2) a panoramic view of the entire renal collecting system, 3) a straight line to the ureteropelvic junction and the lower pole resulting to 4) less torquing of the nephroscope for navigation of all the major and minor calyces, and 5) easier antegrade insertion of an indwelling ureteral stent.

Table 2. Stone demographics (n=56)

	Frequency (%); Mean $\pm$ SD; Median (IQR)
Hounsfield Units	1234 (653 to 1415)
< 1000	22 (39.29)
$\geq$ 1000	34 (60.71)
Stone burden, cm	4.82 $\pm$ 1.96
< 5 cm	36 (64.29)
5 to 10 cm	20 (35.71)
> 10 cm	0

Table 3. Perioperative outcomes (n=56).

	Frequency (%); Median (IQR)
Intraoperative time, minutes	100 (60 to 130)
< 60	8 (14.29)
60 to 120	32 (57.14)
> 120	16 (28.57)
Intraoperative blood loss, ml	200 (100 to 300)
< 100	5 (8.93)
100 to 500	46 (82.14)
> 500 to 1000	5 (8.93)
> 1000	0
Conversion to Multi-access PCNL	
1 access	50 (89.29)
> 1 access	6 (10.71)
Location	
Upper	50 (89.29)
Upper + Middle	4 (7.14)
Upper + Inferior	2 (3.57)
Need for intraoperative Blood Transfusion	
1 unit given	3 (5.36)
No blood given	53 (94.64)
Post-operative Stenting	53 (94.64)
Post-operative Nephrostomy Tube	51 (91.07)

Table 4. Postoperative outcomes (n=56).

	Frequency (%); Mean $\pm$ SD; Median (IQR)
Stone Free Rate, %	99.5 (90 to 100)
100%	28 (50)
90% to 99%	24 (42.86)
50% to 89%	4 (7.14)
< 49%	0
Preoperative hemoglobin	12.66 $\pm$ 2.01
Post-operative hemoglobin	11.59 $\pm$ 1.90
Post-operative Hemoglobin Decrease, mg/dl	0.95 (0.3 to 1.75)
< 1	28 (50)
$\geq$ 1	28 (50)
Length of Hospital Stay, <u>days</u>	3.5 (3 to 5)
< 4	28 (50)
$\geq$ 4	28 (50)
Secondary ESWL treatment	11 (19.64)
Secondary Ureteroscopy treatment	4 (7.14)
Secondary PCNL treatment	3 (5.36)
Clavien Dindo morbidity scoring	
None	47 (83.93)
II	4 (7.14)
IVB	5 (8.93)

Table 5. Association of demographic profile to patient's morbidity.

	Crude odds ratio	95% CI	P-value
Age in years			
< 60	(reference)	-	-
$\geq$ 60	0.3646	0.0412 to 3.2246	0.364
Sex			
Male	0.5926	0.1409 to 2.4920	0.475
Female	(reference)	-	-
Height, cm	1.0150	0.9255 to 1.1133	0.751
Weight, kg	0.8931	0.8092 to 0.9857	0.025
BMI	0.6897	0.5073 to 0.9376	0.018
Preop Creatinine, mg/dl			
< 3	(reference)	-	-
$\geq$ 3	4.1905	0.5909 to 29.717	0.152
Comorbidities			
Cardiovascular disease	1.7600	0.3928 to 7.8851	0.460
Chronic kidney disease	0.9688	0.2137 to 4.3920	0.967
Diabetes mellitus	-	-	-
History of Anticoagulant use	1.0500	0.1078 to 10.227	0.966
Previous PCNL	3.3778	0.7520 to 15.171	0.112
Previous ESWL	-	-	-
Previous Open Stone Surgery	-	-	-
Previous URS	7.3333	1.1960 to 44.964	0.031
Previous nephrectomy	-	-	-
ASA Class			
ASA 1	(reference)	-	-
ASA 2	2.0625	0.2228 to 19.087	0.524
ASA 3	5.5000	0.3850 to 78.573	0.209
ASA 4	-	-	-

Table 6. Association of postoperative outcomes to patient's morbidity.

	Crude odds ratio	95% CI	P-value
Preoperative hemoglobin	1.1058	0.7728 to 1.5823	0.582
Post-operative hemoglobin	0.8003	0.5212 to 1.2288	0.309
Post-operative Hemoglobin Decrease, mg/dl			
< 1	(reference)	-	-
$\geq$ 1	2.2727	0.5073 to 10.182	0.283
Length of Hospital Stay, <u>days</u>			
< 4	(reference)	-	-
$\geq$ 4	10.800	1.2483 to 93.440	0.031
Secondary ESWL treatment	1.2063	0.2136 to 6.8135	0.832
Secondary Ureteroscopy treatment	-	-	-
Secondary PCNL treatment	13.143	1.0483 to 164.77	0.046

A multi-tract puncture may typically be avoided even for complex large volume stones. However, this upper pole access is avoided by many due to the increased propensity for pleural injury and pulmonary complications. The authors still prefer to use the upper posterior calyx as a preferential approach unless there are contraindications. They recently published their experience which showed that the incidence of serious pulmonary complications resulting from this approach was rare.²

The study population was diverse, reflecting the complexities often encountered in managing staghorn calculi. The presence of various comorbidities, such as cardiovascular disease chronic kidney disease and diabetes mellitus, highlights the importance of careful patient selection and pre-operative optimization. While the prevalence of these comorbidities might suggest a higher risk profile, this study's overall success aligns with the established safety of PCNL when performed in appropriately selected and managed patients.⁷⁻⁹ The varied history of prior stone interventions further underscores the recurrent nature of stone disease and the challenges in achieving long-term stone-free status in this population

The observation that a substantial proportion of patients presented with high Hounsfield Units suggests a predominance of certain stone compositions, potentially impacting the effectiveness of lithotripsy and overall operative time. Further analysis correlating stone composition with HU and surgical outcomes could provide valuable insights for pre-operative planning.

Current study demonstrates the potential of SUPA-PCNL to achieve favorable outcomes in the management of complex staghorn calculi, particularly when considering the trifecta goals of PCNL. The high stone-free rate achieved with SUPA-PCNL in this series is particularly encouraging. While a stone-free rate of 99.5% was achieved, it is important to acknowledge that 50% of the population had stone clearance of 100%, while 42.86% had a stone-free rate of 90-99%. This is higher compared to a study which reported as high as 92.18% but the majority of patients dealt with solitary stones¹¹ and another study with a stone clearance of 56% dealing with staghorn calculi.¹⁰

This suggests that SUPA-PCNL can be a highly effective approach for achieving complete or near-complete stone removal in this challenging patient population.

The low transfusion rate observed in the current study is another important indicator of the safety and efficacy of SUPA-PCNL. This compares favorably to other studies in which transfusion rates was 11.5%¹⁰ when it comes to tackling PCNL on full staghorn calculi, suggesting that the single upper pole access may minimize blood loss by possible potential mechanisms, e.g., avoiding multiple punctures and strategic access to vascularly less dense areas.

Furthermore, the minimal post-operative complications observed, as reflected in the Clavien-Dindo morbidity scoring, underscore the potential of SUPA-PCNL to facilitate rapid recovery. The absence of pulmonary complications in this series is particularly noteworthy, given concerns about pleural injury with upper pole access. This finding supports the growing evidence that, with careful technique and appropriate patient selection, upper pole access can be performed safely without increasing the risk of pulmonary complications.^{2,4}

The need for secondary treatments in a subset of patients highlights the inherent challenges in achieving complete stone clearance in all cases of complex staghorn calculi. These patients often presented with a larger stone burden, suggesting that stone size and complexity may be predictors of the need for additional interventions.

The association between previous endoscopic surgery (cystoscopy, ureteroscopy) and increased morbidity warrants further investigation. It is possible that these patients had pre-existing conditions, such as AKI secondary to obstructing lithiasis, that predisposed them to complications. Similarly, the association between secondary PCNL and higher morbidity may reflect the challenges encountered during the initial procedure, such as sepsis or increased blood loss, necessitating a staged approach.

The current study acknowledges limitations, including the impact of the pandemic on patient recruitment and follow-up, which may have affected the generalizability of current findings. The expanded inclusion criteria to GSS 3-4, instead of solely GSS 4, may have introduced variability.

Future studies with larger sample sizes and longer follow-up periods are needed to validate our findings and identify predictive factors for success with SUPA-PCNL.

Conclusion

SUPA-PCNL demonstrated favorable outcomes, with a median Stone Free Rate of 99.5% and minimal postoperative complications. The patient's comorbidities, stone demographics, did not significantly correlate with outcomes, emphasizing the efficacy of the single upper pole access approach. Urologists may consider this approach as a primary choice for patients with staghorn calculi GSS 3-4. While the majority of patients underwent SUPA-PCNL with a single upper pole access, a subset required additional access. Urologists should be prepared for potential variations in stone complexity, considering additional access points as needed. Patients requiring secondary treatments, such as ESWL, ureteroscopy, or PCNL, should be closely monitored. Future research may delve into predictive factors for the need for secondary interventions.

Given the challenges posed by the pandemic leading to dropouts, future studies should aim for longer timelines and robust follow-up strategies to enhance the reliability of the findings and provide a more comprehensive understanding of outcomes over time.

Appendix. Guy's Stone Score Classification³

- (i) Guy's stone score 1 (GSS1): a solitary stone in the mid/and or lower pole or in the renal pelvis with a normal anatomy and simple collecting system
- (ii) Guy's stone score 2 (GSS2): a solitary stone in the upper pole; multiple stones in patients with simple anatomy; or a solitary stone in a patient with abnormal anatomy
- (iii) Guy's stone score 3 (GSS3): multiple stones in a patient with abnormal anatomy or in a calyceal diverticulum or partial staghorn calculus
- (iv) Guy's stone score 4 (GSS4): a complete staghorn calculus or any stone in a patient with spinal bifida or a spinal injury, calculus in patients with clinical neurological alternations (spinal cord injury, myelomeningocele)

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