The Presence of Ureteral Calculi Upon Supine PCNL Completion: Occlusion Balloon Catheter Versus 5FR Ureteral Catheter
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The Presence of Ureteral Calculi upon supine PCNL Completion: Occlusion Balloon Catheter versus 5FR Ureteral Catheter

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1.1 SYNOPSIS

Title:	The Presence of Ureteral Calculi upon supine PCNL Completion: Occlusion Balloon Catheter versus 5FR Ureteral Catheter
Study Description:	An occlusion balloon catheter provides the ability to occlude the exit of the renal pelvis during percutaneous nephrolithotomy (PCNL), and potentially prevents the migration of stone fragments into the ureter. The necessity for it might be questioned during supine PCNL due to the upward oblique position of the kidney. The objective of the study is to compare the presence of ureteral stone fragments upon completion of supine PCNL with and without using an occlusion balloon catheter (OBC).
Objectives*:	Comparing the rate of ureteral stone fragments upon completion of PCNL while using OBC versus 5FR ureteral catheter (5FR-UC).
Endpoints*:	**Primary**: Endoscopic identification of ureteral stone fragments **Secondary:** Length of procedure, Intraoperative complications, stent placement
Study Population:	An estimated sample size of 98 patients (49 in each arm) will provide sufficient power and significance (a=0.05, power=0.8) to detect a minimal difference of 20% in the primary outcome between the groups. To account for potential dropouts, particularly due to inability to access the kidney with the ureteroscope in patients with a tight ureter, we plan to enroll 12 additional patients (6 in each arm), bringing the total planned enrollment to 110 patients (55 per arm).
Description of Sites/Facilities Enrolling Participants:	All procedures and subject consent will be performed at the following locations: 1070 Park Ave; 5 East 98th street 6th floor, 425 W. 59th. Street, 4th Floor; 625 Madison Avenue, 2nd Floor, and Mount Sinai West which are all Mount Sinai approved sites in which the PI practices and operates.
Description of Study Intervention/Experimental Manipulation:	Patients enrolled will be randomized for OBC arm or 5FR-UC arm. According to randomization the selected catheter will be inserted retrogradely at the beginning of the procedure. The rest of the procedure will be performed according to standard of care. Before the surgeon completes the procedure, an antegrade flexible ureteroscopy will be performed after removing the Occlusion Balloon Catheter / 5FR-UC, and identification of ureteral calculi will be recorded (number, size, location).
Study Duration*:	18-24 months
Participant Duration:	1 day

1.2 SCHEMA

Patient eligibility will be confirmed during initial presentation of urinary tract stone. The patient's provider will determine if surgery will be performed based upon available imaging studies and urologic standard of care. If so, the provider will explain the specifics of the study to the patient and ask if he or she is willing to speak to a member of the research team for more information.

If the patient is willing, a member of the research team will approach the patient after the provider has introduced the study and the patient agrees to learn more.

Once informed consent has been achieved, patients will be enrolled into the study, randomized to OBC or 5FR-UC arms, and undergo the PCNL operation on the scheduled date. Antegrade Flexible ureteroscopy will be performed at the of the procedure through the percutaneous access.

1.3 SCHEDULE OF ACTIVITIES

- Once informed consent has been achieved, patients will be enrolled into the study
- Randomization to OBC or 5FR-UC arms will be performed just before the operation
- OBC or 5FR-UC will be inserted retrogradely at the beginning of the procedure.
- If OBC was placed, the balloon will be inflated under endoscopic/fluoroscopic guidance before the initiation of the nephrolithotomy.
- Rest of the procedure will be performed according to standard of care.
- Antegrade flexible ureteroscopy will be performed after removing the Occlusion Balloon Catheter / 5FR Ureteral Catheter
- Identification of ureteral stone fragments will be recorded, and any identified stone will be removed.

2 INTRODUCTION

2.1 STUDY RATIONALE

PCNL is a procedure to remove renal stones via a small skin incision, providing percutaneous access to the kidney. Before creating the access, a ureteral catheter is inserted retrogradely to allow for optional pyelography for guidance.

Historically, PCNL was performed exclusively in the prone position, where the kidney's orientation increased the likelihood of stone fragments migrating into the ureter, making an occlusion balloon catheter (OBC) necessary. An OBC is a specialized catheter with an inflatable balloon at its tip that can temporarily block the renal pelvis exit, preventing fragment migration into the ureter.

In supine PCNL, the patient lies on their back with the flank elevated, causing the kidney to tilt obliquely with the upper pole lower and more posterior. This positioning may naturally retain small fragments

within the kidney, reducing the need for an OBC. A 5FR ureteral catheter (5FR-UC), without an inflatable balloon, may suffice, offering cost savings and a shorter procedure time.

2.2 BACKGROUND

Kidney stones are a prevalent urological condition, affecting approximately 1 in 11 individuals in the United States and causing significant morbidity due to pain, obstruction, and infection [1]. Percutaneous nephrolithotomy (PCNL) is a common surgical procedure for the removal of large or complex kidney stones [2]. During the procedure, stone fragments may migrate from the kidney into the ureter during fragmentation. These migrations might be missed by surgeons, placing patients at risk of obstructing uropathy.

The 5FR ureteral catheter (5FR-UC) is an open-ended small-caliber tube inserted at the beginning of PCNL to facilitate visualization of the collecting system using fluoroscopy and assist with renal access. The occlusion balloon catheter (OBC) is a type of ureteral catheter equipped with a small inflatable balloon at its tip. When inflated, the balloon can help prevent the migration of stone fragments [3,4]. While most surgeons retrogradely insert a 5FR-UC, primarily for percutaneous access, at our institution, OBCs are used in most PCNLs.

During PCNL, if the OBC is placed retrogradely into the renal pelvis and inflated, it occludes the pelvic exit, potentially preventing stone fragments from entering the ureter. The adoption of OBCs is evolving, including their use in ureteroscopy and PCNL, with theoretical benefits for stone-free rates and complication prevention. However, there is no supporting data, and no established guidelines currently exist for their use.

In supine PCNL, patients are positioned such that the upper pole of the kidney is oriented more medially, caudally, and posteriorly, which may make it a favorable site for fragment migration. Our aim is to compare the use of OBCs and 5FR-UCs during PCNL and assess their roles in minimizing stone fragment migration into the ureter.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

There will be no risk of physical harm to subjects due to study interventions. Both the OBC and 5FR-UC are approved tools commonly used during stone surgeries, and both are FDA-approved. The PCNL procedure will be performed according to standard care protocols, with antegrade flexible ureteroscopy considered an acceptable adjunct procedure during PCNL if needed. In this study, antegrade ureteroscopy will be performed for all patients to assess and clear any ureteral fragments.

All patients will have the associated risk of increased operative time due to antegrade ureteroscopy.

2.3.2 KNOWN POTENTIAL BENEFITS

No benefits are expected to participation.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Other than the extremely small risk of compromising protected health information and minimal prolongation of the surgery (by 5-10 minutes), we do not foresee any unusual risks other than PCNL's regular known risks.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
Compare rate of ureteral stone fragments upon completion of PCNL while using OBC versus 5FR-UC	Endoscopic identification of ureteral stone fragments	Endoscopic identification is the gold standard for ureteral stone identification.	*N/A*
Secondary			
Compare procedural outcomes of OBC and 5FR-UC	1) Length of procedure 2) Intraoperative complications 3) stent placement	Common procedural outcomes of endourologic procedures	*N/A*

4 STUDY DESIGN

4.1 OVERALL DESIGN

Once informed consent has been achieved, patients will be enrolled into the study, and randomization to OBC or 5FR-UC arms will be performed just before the operation. OBC or 5FR-UC will be inserted retrogradely at the beginning of the procedure. The rest of the procedure will be performed according to the standard of care. Upon completion of the procedure, antegrade flexible ureteroscopy will be performed after removing the ureteral catheter (which ever was inserted) and identification of ureteral stone fragments will be recorded. Length of procedure, intraoperative complications and stent placement would also be recorded during the procedure.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

- Randomization is performed to create equal groups of OBC and 5FR-UC
- Antegrade flexible ureteroscopy is performed since it is the gold standard for ureteral stone identification.

4.3 JUSTIFICATION FOR INTERVENTION

Surgical interventions for kidney stones will be performed regardless of participation in this study.

4.4 END-OF-STUDY DEFINITION

This investigation will finish once all participants are enrolled. Follow up is not part of the protocol, so as the last enrolled patient completes his procedure, the study ends.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

- Adults aged 18 years and older.
- Diagnosed with kidney stones and scheduled for PCNL.
- Able and willing to provide informed consent.

5.2 EXCLUSION CRITERIA

- Pregnant women
- Urinary tract anomalies such as urinary diversion, previous ureteral reconstruction surgeries, horseshoe kidney, solitary kidney, duplicated system, urinary stricture disease, ureteropelvic junction obstruction, pelvic kidney, stone in calyceal diverticulum.
- Prone procedure

5.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Patients will be recruited from the practice of Dr. Mantu Gupta and Dr. William Atallah. Together, they have one of the busiest kidney stone practices in the area providing ample patients to recruit into the study. We do not anticipate any issues with retention as patient involvement occurs for one day, which is the day of surgery.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

OBC or 5FR-UC will be inserted retrogradely at the beginning of the procedure, and both are considered standard of care either way. The rest of the procedure will be performed according to the standard of care. Upon completion of the procedure, antegrade flexible ureteroscopy will be performed after removing the ureteral catheter (which ever was inserted) and identification of ureteral stone fragments will be recorded. Any identified stone will be removed. Antegrade flexible ureteroscopy is considered an acceptable adjunct procedure during PCNL if needed.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Dr. Mantu Gupta, professor of urology at Mount Sinai West Hospital will be performing the procedures. Dr. Gupta is a world-renowned expert in these operative techniques.

Dr. William Atallah will also be performing the procedures. He is assistant Professor of Urology at the Kidney Stone Center of Mount Sinai, director of Quality Improvement and Patient Relations at Mount Sinai West & Morningside Hospital, Chief of Endourology at Elmhurst Hospital.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

There will be randomization to minimize bias. There will be no blinding.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

No discontinuation will take place as the surgical procedures being performed are part of subjects' standard clinical care.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Patients will be considered enrolled in the study once consent has been signed. Participants may discontinue or withdraw from the study for any reason and at any point in time through the conclusion of the study.

7.3 LOST TO FOLLOW-UP

There is no follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.1.1 DEFINITION OF ADVERSE EVENTS

Any untoward medical occurrence, unintended sign, symptom, illness or disease temporally associated with the study protocol regardless of the suspected cause.

8.1.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An Adverse Event that is considered "serious" if it meets at minimum one of the three Seriousness reporting criterions below:

1. Led to death,
2. Led to a serious injury which:
    a. Resulted in a life-threatening illness or injury, or
    b. Resulted in a permanent impairment of a body structure or a body function, or
    c. Resulted in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function

8.1.2.1 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All AEs will be assessed for relationship to the study protocol based on the following definitions:

Not Related: There is no clear evidence that the AE has a relationship to the study protocol and can be attributed to an underlying or concurrent illness/clinical condition or an effect of another device, drug or treatment.

Related: There is a clear causal relationship of the AE to the marketed device or procedure beyond reasonable doubt.

8.1.3 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

There is no follow-up.

8.1.4 ADVERSE EVENT REPORTING

Adverse events must be reported to the IRB as soon as possible and no later than **2 working days** after the PI first becomes aware of the event. The PI or designee must record all AE information that can be gathered within the reporting timeframe and enter it onto the AE eCRF.
Relevant follow-up information should be submitted to the IRB as soon as it becomes available and/or upon request.

8.1.5 SERIOUS ADVERSE EVENT REPORTING

See section 7.1.4

8.1.6 REPORTING EVENTS TO PARTICIPANTS

All SAE's or AE's will be reported to affected participants by the principal investigator directly.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

9.2 SAMPLE SIZE DETERMINATION

An estimated sample size of 98 patients (49 in each arm) will provide sufficient power and significance (a=0.05, power=0.8) to detect a minimal difference of 20% in the primary outcome between the groups. To account for potential dropouts, particularly due to inability to access the kidney with the ureteroscope in patients with a tight ureter, we plan to enroll 12 additional patients (6 in each arm), bringing the total planned enrollment to 110 patients (55 per arm).

9.3 POPULATIONS FOR ANALYSES

All enrolled subjects will be included for analyses.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

After sufficient patient enrollment, we will analyze our data:

- We will calculate mean, median, IQR and standard deviation for continuous variables; frequencies and percentages for categorical variables.
- We will compare the baseline characteristics between the groups (OBC vs. 5FR-UC) using chi square test, Fischer exact test, t-test and Mann-Whitney test.
- We will evaluate the endpoints and compare them between the groups using regression models.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Identification of ureteral calculi:

- Rates of ureteral calculi identification will be calculated for each group
- Using Fischer exact/Chi square tests we will compare those rates between the groups
- Using regression models, we will estimate any association between the type of ureteral catheter and ureteral calculi, and with multivariate analysis we will adjust for competing factors.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Length of procedure: we will compare the median/mean procedure time between the groups using Mann-Whitney test/T-test.

Intraoperative complications: we will compare the rates between the groups using Fischer exact/Chi-square test.

Stent placement: we will compare the rates between the groups using Fischer exact/Chi-square test.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

The standard informed consent process for research outlined in SOP HRP-090 will be followed.

10.1.1.1 CONSENT PROCEDURES AND DOCUMENTATION

Subjects will be recruited from Dr. Mantu Gupta's and Dr. William Atallah's practice. Patients will be recruited during the initial presentation to the operative room.

Potential subjects will be informed of the study at their preoperative visit and may sign the consent at that time if they feel comfortable. If subjects require time for further contemplation, the consent may be signed on the day of surgery in the preoperative area (prior to administration of any anesthesia). This gives potential subjects at least 24 hours to consider the study and review the consent form.

Given the simplicity of the nature of subject involvement, we anticipate that no more than 5 minutes will generally be required to explain the consent form. However, longer and more extensive discussions will be available to those who request or require. All potential subjects will be verbally informed that their participation is completely optional and that their decision of whether or not to participate does not impact their care in any manner. Subjects will be asked to verbally repeat and summarize their involvement in the study. A copy of the consent form will be provided to the subject directly after signing the form.

10.1.2 CONFIDENTIALITY AND PRIVACY

The data will be housed in Mount Sinai's REDCap database. The data includes identifiers (name, MRN, phone number, email address, elements of dates) and will be stored with protected passwords. The data will be stored with protected passwords. The data will be reported in aggregate and anonymized.

10.1.3 FUTURE USE OF STORED SPECIMENS AND DATA

The data will be retained for at least 6 years after publication, per regulations.

10.1.3.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the research staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant consented/enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents will be consistent with the data recorded on the source documents.

Clinical data (including adverse events (AEs), concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into the electronic data capture (EDC) system, a 21 CFR Part 11-compliant data capture system. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

The data safety will be monitored by the PI

10.1.3.2 STUDY RECORDS RETENTION

Study documents will be retained until at least 6 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the principal investigator.

The data will be kept until its publication at most six years.

10.1.4 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

The PI will be responsible for any vigilance and monitoring of the data.

11 FUNDING

None

12 REFERENCES

Include a list of relevant literature and citations for all publications referenced in the text of the protocol. Use a consistent, standard, modern format, which might be dependent upon the required format for the anticipated journal for publication (e.g., N Engl J Med, JAMA, etc.). The preferred format is International Committee of Medical Journal Editors (ICMJE).

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2. Assimos D, Krambeck A, Miller NL, Monga M, Murad MH, Nelson CP, Pace KT, Pais VM Jr, Pearle MS, Preminger GM, Razvi H, Shah O, Turk TM, Wei JT. Surgical management of stones: American Urological Association/Endourological Society guideline, PART I. J Urol. 2016 Oct;196(4):1153-60. doi: 10.1016/j.juro.2016.05.090. PMID: 27238619.

3. Dirim A, Tekin MI, Aytekin C, Peskircioglu L, Boyvat F, Ozkardes H. Ureteroscopic treatment of proximal ureter stones with the aid of an antegrade occlusion balloon catheter. Acta Radiol. 2006 Feb;47(1):103-6. doi: 10.1080/02841850500335028. PMID: 16498941.

4. Qi S, Li Y, Liu X, Zhang C, Zhang H, Zhang Z, Xu Y. Clinical efficacy, safety, and costs of percutaneous occlusive balloon catheter-assisted ureteroscopic lithotripsy for large impacted proximal ureteral calculi: a prospective, randomized study. J Endourol. 2014 Sep;28(9):1064-70. doi: 10.1089/end.2014.0167. Epub 2014 Jun 3. PMID: 24786613.