Official Title: Impact of Negative Pressure Suction on Irrigation Fluid Absorption and Postoperative Infection Risk During Flexible Ureteroscopic Lithotripsy: A Prospective Cohort Study

Date: December 1, 2025

Objective:

Based on the precise monitoring of irrigation fluid absorption during retrograde intrarenal surgery (RIRS) using an endoscopic surgical monitor, this study aims to investigate the impact of applying negative pressure suction technology during RIRS on the volume of irrigation fluid absorbed and the incidence of postoperative infections (fever, systemic inflammatory response syndrome [SIRS], and urosepsis).

Significance:

Currently, negative pressure suction technology is increasingly applied in RIRS. However, there are no international reports on whether negative pressure suction affects the volume of intraoperative irrigation fluid absorption. Our study will fill this research gap and provide robust clinical evidence for the rational application of negative pressure suction technology.

Project Implementation:

1. Study Population

All subjects in this study will be patients with kidney stones treated at the Department of Urology, Lanzhou University Second Hospital, who meet both the inclusion and exclusion criteria.

• Inclusion Criteria:

1)Patients aged 18 years and older with kidney stones who meet the surgical indications for RIRS;

2) Patients who have provided informed consent.

• Exclusion Criteria:

1) Concurrent combination with other surgical procedures, such as percutaneous nephrolithotomy (PCNL);

2) Patients with malignancies, urinary tuberculosis, immune system diseases, or hyperthyroidism;

3) Congenital renal anomalies, such as polycystic kidney disease or horseshoe kidney;

4) Presence of untreated urinary tract infections;

5) Inability to tolerate surgery due to severe cardiopulmonary dysfunction, hepatic or renal insufficiency, or coagulation abnormalities.

• Withdrawal/Dropout Criteria:

1) Surgery is not performed or is terminated early due to various reasons;

2) Lack of valid monitoring records or missing key data;

3) Temporary alteration of the surgical approach;

4) Patient requests withdrawal from the study.

2. Exposure and Outcomes

• Exposure: Intraoperative application of negative pressure suction technology.

• Primary Outcome: Volume of irrigation fluid absorption.

• Secondary Outcomes: Postoperative fever (≥38°C), SIRS, urosepsis, postoperative pain requiring opioids, blood transfusion, renal artery embolization, Clavien-Dindo classification, and postoperative length of hospital stay.

3. Study Content

1) Effect of negative pressure suction on irrigation fluid absorption during RIRS: This study will establish a prospective cohort including eligible patients with kidney stones. By utilizing an endoscopic surgical monitor to precisely measure fluid absorption, we will compare the intraoperative irrigation fluid absorption between the exposure group (using a negative pressure suction ureteral access sheath) and the non-exposure group (using a standard ureteral access sheath). We will analyze whether the negative pressure suction device can effectively reduce renal pelvic pressure, thereby

decreasing the intravascular absorption of irrigation fluid, and evaluate its role in maintaining intraoperative hemodynamic balance.

2) Correlation analysis between negative pressure suction and the risk of postoperative infectious complications: We will closely monitor and record infection-related indicators in both groups postoperatively, including the incidence of postoperative fever (≥38°C), SIRS, and urosepsis. Through statistical analysis, we will explore whether the intraoperative application of negative pressure suction significantly reduces the risk of postoperative infectious complications by mitigating bacterial toxin reflux and lowering intrarenal pressure. Concurrently, combined with the patients' preoperative urine culture results, we will analyze the protective efficacy of negative pressure suction under different infectious backgrounds.

3) Comprehensive evaluation of the safety and recovery indicators of negative pressure suction following RIRS: In addition to infection indicators, we will systematically evaluate the impact of negative pressure suction on other postoperative complications and recovery metrics. Specifically, we will compare the two groups regarding postoperative pain severity (opioid requirement), bleeding risk (transfusion rate and incidence of renal artery embolization), overall complication severity (Clavien-Dindo classification), and postoperative length of hospital stay. This aims to comprehensively evaluate the clinical application value of this technology in enhancing surgical safety, alleviating patient suffering, and accelerating postoperative recovery.

4) Subgroup analysis of populations benefiting from negative pressure suction under different clinical characteristics: Based on the collected cohort data, further subgroup analyses will be conducted according to factors such as stone size (e.g., >2cm vs. <2cm), stone CT value, surgical duration, or the presence of preoperative urinary tract infections. We will explore under which specific clinical scenarios the use of negative pressure suction can maximally reduce irrigation fluid absorption and lower infection risk, thereby providing clinicians with more precise surgical instrument selection strategies and individualized treatment recommendations.

4. Data Collection

Preoperative, intraoperative, and postoperative clinical data will be retrieved from the Hospital Information System (HIS) of Lanzhou University Second Hospital.

Preoperative data include imaging and laboratory results, as well as baseline characteristics such as age, gender, and comorbidities. Urological CT or ultrasound results are collected to determine the location, size, and presence of staghorn calculi. Additionally, infection-related laboratory results, including white blood cell (WBC) count, routine urinalysis, and urine culture, will be collected. Intraoperative data include the surgical procedure details and duration. Postoperative data primarily consist of vital signs, nursing records, treatment records, postoperative laboratory and imaging results, and postoperative length of hospital stay. Postoperative complications such as fever, SIRS, urosepsis, blood transfusion, renal artery embolization, and pain requiring opioids will be assessed. SIRS is defined as meeting at least two of the following criteria: (1) Body temperature >38°C or <36°C; (2) Heart rate >90 beats/min; (3) Respiratory rate >20 breaths/min or PaCO2 <4.3 kPa (32 mmHg); (4) WBC count >12×10^9/L or <4×10^9/L, or >10% immature neutrophils.

5. Statistical Analysis

Statistical analyses will be performed using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA). A two-sided P-value < 0.05 will be considered statistically significant. Normality will be assessed using the Shapiro-Wilk test. Categorical variables will be presented as frequencies and percentages and compared using the Chi-square test or Fisher's exact test. Continuous variables will be expressed as medians (interquartile ranges [IQR]) and compared using the Mann-Whitney U test. If there are differences in baseline characteristics between the groups, Propensity Score Matching (PSM) will be employed to adjust for inter-group variables. A logistic regression model will be used to calculate the propensity score for each patient. Variables included in the propensity score model will consist of maximum stone diameter, presence of staghorn calculi, and surgical duration ≥2 hours. Matching will be performed at a 1:1 ratio with a caliper width of 0.02 to maximize execution performance. The balance of variables between the groups before and after matching will be evaluated by comparing statistical significance. Subgroup analyses in the matched cohort will be based on age (<60 years vs. ≥60 years), gender (female vs. male), urine culture (positive vs. negative), and surgical duration (≥2 hours vs. <2 hours). For subgroup analyses, a logistic regression model will be used to calculate the odds ratios (OR) and 95% confidence intervals (CI) for the primary

outcome (postoperative fever ≥38°C), and interaction tests will be conducted across subgroups.

6. Bias Control

A comparative analysis will be conducted to determine if there are statistical differences in baseline data and clinical characteristics. If the baselines are consistent, subsequent statistical analyses will proceed directly; if inconsistent, Propensity Score Matching (PSM) or other statistical methods will be applied to ensure baseline comparability between groups before proceeding with further statistical analysis.

7. Publication Plan

The results of this research project may be published in medical journals. However, we will maintain the confidentiality of patient information as required by law. Unless mandated by relevant laws, patients' personal information will not be disclosed. When necessary, government regulatory authorities, the hospital's Institutional Review Board (IRB), and their authorized personnel may access patient records in accordance with regulations.

Risks:

This is an observational clinical study, and the patients' routine diagnostic and treatment processes will not be affected by this research. The study only involves the collection and statistical analysis of patients' clinical data and will not interfere with or influence patients' treatment choices or processes. Therefore, this study poses no risk of personal injury to the patients.

Compensation for Subjects:

If the leakage of relevant clinical information or medical records causes related losses or adverse effects, and if it is related to this study, the sponsor will bear the corresponding responsibilities and provide financial compensation in accordance with relevant regulations.