

Study Protocol

Official Title: Triple-Zero Retrograde Intrarenal Surgery (TZ-RIRS) versus Conventional Retrograde Intrarenal Surgery (C-RIRS): Development and Internal Validation of the Novel TZ-STONE Feasibility Score

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1. Background and Rationale

Retrograde intrarenal surgery (RIRS) is a standard minimally invasive treatment for renal stones. Traditionally, it utilizes fluoroscopy, a ureteral access sheath (UAS), and preoperative stenting. However, the risks of ionizing radiation, UAS-related injuries, and stent morbidity have prompted interest in "minimalist" techniques. The Triple-Zero RIRS (TZ-RIRS) approach eliminates all three adjuncts. Because this is technically demanding, we developed the TZ-STONE score to predict which patients are suitable candidates.

2. Objectives

Primary: To develop and internally validate the TZ-STONE score for predicting complete TZ-RIRS success.

Secondary: To compare clinical outcomes (stone-free rate, operative time, complications) between TZ-RIRS and conventional RIRS (C-RIRS).

3. Study Design

This is a single-center observational study. It includes a prospective cohort of 312 patients undergoing TZ-RIRS (Jan 2023 – Dec 2025) and a retrospective cohort of 376 patients undergoing C-RIRS (Jan 2020 – Dec 2022). Propensity score matching (1:1) will be used to compare 250 patients in each group.

4. Patient Population

Inclusion Criteria: Age ≥ 18 ; non-lower calyceal stones ≤ 15 mm or lower calyceal stones ≤ 10 mm; normal renal anatomy; unilateral stones; ASA I–III; no preoperative stent.

Exclusion Criteria: Pregnancy; active UTI; ureteral stricture; staghorn calculi; solitary kidney; severe hydronephrosis; prior ipsilateral RIRS within 6 months.

5. Surgical Technique

TZ-RIRS: No preoperative stent. Direct no-touch visualization using an Olympus URF-V2R digital flexible ureteroscope without a UAS or fluoroscopy. Modified T-tilt positioning, high-frequency laser dusting (30-watt Karl Storz Ho:YAG), and a postoperative stent placed under direct vision.

C-RIRS: Fluoroscopy-guided access, deployment of a 9.5/11.5 Fr UAS, and use of a preoperative and postoperative double-J stent.

6. Outcome Measures

Primary Outcome: Complete TZ-RIRS Success (no fluoroscopy, no rescue UAS, no preoperative stent).

Secondary Outcomes: Stone-free rate (zero fragments, ≤ 2 mm, ≤ 4 mm at 3 months), operative time, Clavien-Dindo complications, reintervention rate.

7. The TZ-STONE Score

A 10-point pre-operative tool derived from five variables: Stone size, Topography, Obstruction (SFU grade), Number of stones, and Estimated density (HU).