Research Square

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Comparative Efficacy and Safety of Suction-Assisted Retrograde Intrarenal Surgery (S-RIRS) versus Mini Percutaneous Nephrolithotomy (mPCNL) for Large Renal Stones (2-3.5cm): A Retrospective Cohort Study

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Research Article

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Abstract

Background: Retrograde intrarenal surgery with a tip-bendable suction ureteral access sheath (S-UAS) may offer an alternative to mini percutaneous nephrolithotomy (mPCNL) for renal stones larger than 2 cm. This study compared S-RIRS with mPCNL for renal stones measuring 2-3.5 cm.

Methods: We retrospectively analyzed patients treated by a single surgical team (2018 to 2025). After propensity score matching (PSM), 42 matched patient pairs were retained. We evaluated the immediate stone-free rate (SFR) by CT within 72 h, with non-inferiority tested against a -8% margin (one-sided $p < 0.025$). Secondary outcomes included operative time, hospital stay, postoperative changes in biochemical marker changes and in-hospital complications.

Results: Immediate SFR was 57.1% in S-RIRS vs 73.8% in mPCNL (risk difference, RD, -16.7%; 95% CI -36.7% to 3.4%; one-sided non-inferiority $p = 0.802$). S-RIRS had shorter operative time ($p < 0.001$) and shorter hospital stays ($p < 0.001$). Hemoglobin drop was smaller in S-RIRS ($p = 0.001$), and the white blood cell rise was attenuated ($p < 0.001$). Renal function changes were comparable between groups (all $p > 0.4$). On postoperative day 1, 47.6% patients in the S-RIRS group were discharged, compared with none in the mPCNL group. Larger prospective RCTs are warranted across stratified stone burden subgroups.

Conclusion: For 2–3.5 cm renal stones, S-RIRS and mPCNL had similar immediate stone-free rates, but S-RIRS offered faster recovery and less bleeding. S-RIRS may be considered when rapid recovery is prioritized, accepting lower immediate stone clearance.

Introduction

Kidney stones account for a large proportion of urolithiasis [1]. Renal stones make up most urinary tract calculi. Global prevalence ranges from approximately 1% to 13%, and the incidence is rising. It exceeds 10% in several developed countries, including Sweden, Canada, and the USA [2–5], and some regions report increases of more than 37% over the past 20 years [5]. In China, prevalence is estimated at 5.8% [3]. Beyond their economic burden, nephrolithiasis is linked to a higher risk of chronic kidney disease [6–8].

Minimally invasive surgery is the mainstay of stone management, primarily retrograde intrarenal surgery (RIRS) and minimally invasive percutaneous nephrolithotomy (mPCNL) [9]. The European Association of Urology (EAU) Guidelines recommend RIRS as a first-line treatment for renal stones ≤ 2 cm, citing its low invasiveness, favorable safety profile, and high patient acceptance [10]. For larger stones (> 2 cm), mPCNL remains the standard of care because of its higher stone clearance rate [11]. As a percutaneous procedure, mPCNL carries risks of bleeding (occasionally requiring transfusion), adjacent-organ injury, sepsis, and postoperative pain [12]. It is unsuitable for patients with uncorrected coagulopathy, significant cardiopulmonary comorbidity, uncontrolled diabetes or hypertension, or ongoing anticoagulation [13]. Its invasiveness may also contribute to perioperative anxiety. RIRS is less invasive

and better tolerated [14], making it an option for elder or frail patients with reduced surgical tolerance. For stones > 2 cm, however, RIRS is technically demanding, particularly for complete fragment extraction after laser lithotripsy [15], and often requires multiple sessions to achieve satisfactory stone-free rates (SFR). These repeat procedures prolong treatment and increase costs [16]. Continuous irrigation during RIRS can raise intrarenal pressure and facilitate the retrograde migration of bacteria or endotoxins, increasing the risk of postoperative infection [17].

A recent advance is the tip-bendable suction ureteral access sheath (S-UAS), designed to address some limitations of T-UAS. Unlike rigid T-UAS, the S-UAS has a tip-bendable segment and continuous negative-pressure suction [18]. Its maneuverability allows synchronous passive bending with the flexible ureteroscope (angle > 180°), which improves access to the renal pelvis and calyces and enhancing visibility and stone retrieval [19]. The suction function helps evacuate stone fragments and maintain low, stable intrarenal pressure (IRP), reducing the risk of infection and other pressure-related complications [20]. For 2–3 cm renal stones, the RCT by Zeng et al confirmed S-RIRS as a non-inferior alternative to mPCNL, with similar immediate SFR, fewer bleeding events, and shorter hospital stay [21]. These findings suggest that S-UAS-enhanced RIRS may extend the indications of RIRS to stones traditionally managed by mPCNL. The efficacy and safety boundaries of S-RIRS for higher-burden stones (e.g., > 3 cm) remain unclear, however, and real-world evidence for S-RIRS in 2-3.5 cm stones is still limited.

Although preliminary studies have shown the minimally invasive benefits of RIRS, rigorously controlled comparisons with mPCNL in patients with larger calculi are lacking. We therefore conducted a retrospective cohort study with propensity score matching (PSM) to control for stone size and number. The aim was to evaluate the efficacy and safety of S-RIRS versus mPCNL for renal calculi measuring 2-3.5 cm, with a focus on SFR and rapid recovery outcomes, including postoperative day 1 discharge rate, and to provide an evidence basis for individualized treatment decisions.

Material and Methods

Trial Design and Participants

This study retrospectively analyzed patients with large renal stones (2-3.5 cm) who underwent RIRS with S-UAS or mPCNL at our hospital between January 2018 and December 2025. Inclusion and exclusion criteria are listed in Table S1. To reduce selection bias, all consecutive patients who met the inclusion criteria during the study period were considered for analysis. After PSM with stone length, width, and count as covariates, 42 pairs were retained. Patient composition, case numbers, and exclusion criteria are presented in Figure S1.

Procedures and Quality Control

All patients underwent preoperative non-contrast CT. Laboratory tests comprised complete blood count, renal function tests, and urine cultures. All procedures were performed by the same surgical team.

Postoperatively, CT imaging was repeated within 24 hours to assess immediate stone clearance. Follow-up blood tests, including white blood cell count and hemoglobin, were also performed. Stone composition analysis was also performed. Patients without complications were discharged on the following day.

Operative Procedures

S-RIRS

After administration of general anesthesia and positioning, a semi-rigid ureteroscope was introduced to assess the ureteral anatomy. A guide wire was inserted into the renal pelvis, followed by the placement of a 12/14F or 11/13F S-UAS. In cases of ureteral narrowing, a smaller 10/12F S-UAS was used. The S-UAS (Guangzhou Weili Medical Equipment Co., LTD., Guangzhou, China) features an outer hydrophilic coating to facilitate passage through the ureter. The sheath is manufactured in lengths of 46 cm for males and 40 cm for females. A disposable flexible ureteroscope (either 7.5F or 8.5F depending on sheath size) was then introduced (Figure S2a). A 200 μm holmium:YAG laser fiber was utilized for stone fragmentation. Fragment removal was facilitated with negative-pressure irrigation through an endoscopic irrigation pump(Figure S2b, Figure S2c). After confirming stone clearance, a 6F double-J stent was placed and retained for 2–4 weeks. A Foley catheter was also inserted postoperatively.

mPCNL

With the patient under general anesthesia in the prone position, a 5F ureteral catheter was placed, followed by fluoroscopy-guided percutaneous renal access with an 18G needle (Figure S3a). Fascial dilators were used to establish an access tract (16F-20F), into which a Y-shaped sheath with suction was placed. Stones were fragmented by either pneumatic ballistic or holmium laser lithotripsy (550 μm fiber) via a 12F Wolf nephroscope. Residual stones were assessed with KUB or CT (Figure S3b). A 6F double-J stent was inserted for 2–4 weeks, and a nephrostomy tube (12F–16F) was left in place postoperatively and removed before discharge.

Study outcomes

Immediate SFR, assessed by noncontrast CT within 24 h of surgery, served as the primary outcome. SFR was defined as the complete absence of residual fragments > 2 mm. Secondary outcomes included operative time, postoperative and total hospital stay, postoperative changes in biochemical markers (hemoglobin, white blood cell count, serum creatinine; measured preoperatively and within 24–48 h after surgery, with both absolute change and postoperative-to-preoperative ratio calculated), and in-hospital complications graded by Clavien-Dindo classification [22]. Operative time was measured from endoscope insertion to ureteral stent placement in the S-RIRS group, and from retrograde ureteral catheter to nephrostomy tube placement in the mPCNL group.

Statistical analysis

PSM was estimated with a nonparsimonious logistic regression model (stone length, width, and count as covariates), followed by 1:1 nearest-neighbor matching without replacement (caliper = 0.25 SD of the propensity score logit). Covariate balance was assessed using SMDs, with SMD ≤ 0.1 indicating adequate balance. All analyses were restricted to the matched cohort. Noninferiority of S-RIRS to mPCNL was assessed by the RD with a 95% CI (Wald method) against a prespecified margin of − 8% (one-sided $p < 0.025$). Secondary comparisons used two-sided tests ($p < 0.05$).

Continuous variables are presented as mean ± SD (Student's t-test) or median (IQR) (Mann-Whitney U test) according to distribution; categorical variables as n (%) (chi-square or Fisher's exact test). Effect measures (mean difference, Hodges-Lehmann median difference, RD) are reported with 95% CIs. Analyses were performed using R 4.6.0 (MatchIt v4.5.0, tableone v1.9.3, ggplot2 v3.5.2).

Results

Patient characteristics and propensity score matching

Between January 2018 and December 2025, 615 patients who initially underwent S-RIRS or mPCNL for urinary tract stones were assessed for eligibility. Of these, 471 were excluded because the maximum stone size was outside the 20–35 mm range, leaving 144 eligible patients (S-RIRS, n = 77; mPCNL, n = 67). All 144 patients entered propensity score matching using stone length, stone width, and stone count as covariates. One-to-one nearest-neighbor matching within a caliper of 0.25 standard deviations of the logit yielded 42 matched pairs (84 patients), with 60 patients discarded due to failure to match. Matching diagnostics are shown in Supplementary Figures S4 and S5, and absolute standardized mean differences are presented in Figure S6. Before matching, significant between-group differences were observed in stone length (23.73 ± 3.31 vs 27.00 ± 4.17 mm; $p < 0.001$), stone width (15.06 ± 3.97 vs 17.78 ± 4.34 mm; $p < 0.001$), stone count ($p = 0.008$), comorbidity profile ($p < 0.001$), preoperative stent placement (23.4% vs 4.5%; $p = 0.003$), stone side ($p = 0.049$), stone composition ($p = 0.001$), stone location ($p < 0.001$), hydronephrosis grade ($p = 0.030$), and preoperative white blood cell count (7.78 (6.40, 10.18) vs 6.92 (5.88, 8.55) ×109/L; $p = 0.011$; Table 1).

After matching, stone length (24.85 ± 3.21 vs 25.10 ± 3.74 mm; $p = 0.750$), stone width (16.04 ± 4.08 vs 16.19 ± 3.84 mm; $p = 0.865$), and stone count ($p = 0.826$). Age, sex, BMI, urine culture positivity, stone side, stone composition, hydronephrosis grade, CT value, preoperative hemoglobin, and preoperative serum creatinine also showed no significant between-group differences (Table 1).

Operative outcomes

The S-RIRS group did not demonstrate noninferiority to mPCNL for the primary endpoint of immediate SFR (24/42, 57.1% vs 31/42, 73.8%; RD − 16.7%; 95% CI − 36.7% to 3.4%; one-sided noninferiority $p = 0.802$; margin − 8%; Table 2, Fig. 1). The lower bound of the 95% CI (− 36.7%) was well below the

prespecified noninferiority margin, and the two-sided chi-square comparison did not reach statistical significance ($p = 0.169$).

In comparison with mPCNL, S-RIRS was associated with a shorter operative time (MD − 57.9 min; 95% CI − 79.3 to − 36.5; $p < 0.001$), shorter postoperative hospital stay (MD − 3.0 d; 95% CI − 4.0 to − 2.0; $p < 0.001$), and shorter total hospital stay (MD − 5.0 d; 95% CI − 6.0 to − 4.0; $p < 0.001$; Table 2, Fig. 2). Notably, 47.6% (20/42) of S-RIRS patients achieved postoperative hospital stay of 1 d, whereas no mPCNL patient met this criterion.

Postoperative biochemical marker changes

S-RIRS was associated with a smaller hemoglobin drop than mPCNL (Delta HGB − 0.1 ± 18.5 g/L vs − 11.2 ± 10.9 g/L; MD 11.0 g/L; 95% CI 4.4–17.7; $p = 0.001$), a higher postoperative hemoglobin (133.2 ± 18.0 vs 124.2 ± 18.4 g/L; MD 9.0 g/L; 95% CI 1.1–17.0; $p = 0.026$), and a borderline difference in post/preoperative hemoglobin ratio (1.1 ± 0.5 vs 0.9 ± 0.1; MD 0.1; 95% CI − 0.0 to 0.3; $p = 0.065$; Table 2, Fig. 2).

For white blood cell count, although the postoperative value did not differ significantly between groups (9.6 (7.2, 12.3) vs 10.3 (7.8, 14.5) ×109/L; $p = 0.253$), S-RIRS had a smaller Delta WBC (0.0 (− 2.0, 2.8) vs 2.4 (0.6, 6.7) ×109/L; MD − 2.8; 95% CI − 4.7 to − 1.2; $p < 0.001$) and a lower post/preoperative WBC ratio (1.0 (0.8, 1.4) vs 1.3 (1.1, 1.9); MD − 0.3; 95% CI − 0.6 to − 0.2; $p < 0.001$).

We did not observe differences in postoperative serum creatinine (89.5 (72.0, 121.5) vs 91.5 (68.2, 123.5) μmol/L; $p = 0.690$), Delta SCr (2.0 (− 4.8, 10.8) vs 0.0 (− 19.0, 22.5) μmol/L; $p = 0.426$), or post/preoperative SCr ratio (1.0 (0.9, 1.1) vs 1.0 (0.8, 1.2); $p = 0.429$).

Postoperative complications

The overall postoperative complication rate did not differ between the groups (0/42, 0.0% vs 1/42, 2.4%; RD − 2.4%; 95% CI − 7.0% to 2.2%; $p = 1.000$; Fisher's exact test; Table 2). Given the low event rate, subgroup analyses by Clavien-Dindo grade were not performed.

Discussion

In this propensity score-matched study of 2-3.5 cm renal stones, noninferiority of S-RIRS to mPCNL for immediate stone-free rate was not established (one-sided p = 0.802). The absolute between-group difference was not statistically significant on two-sided testing (p = 0.169), so inferiority cannot be concluded either. S-RIRS was associated with shorter operative time (126.0 vs. 183.9 min), smaller hemoglobin drop (ΔHb − 0.1 vs. −11.2 g/L), smaller white blood cell rise (ΔWBC 0.0 vs. 2.4 ×10⁹/L), and discharge on postoperative day 1 in 47.6% of patients versus 0% in the mPCNL group.

The failure to establish non-inferiority for immediate SFR does not mean S-RIRS is inferior to mPCNL for 2-3.5 cm stones; several factors contributed. First, our cohort included upper-limit cases of 30–35 mm, and RIRS is at an intrinsic clearance disadvantage as stone volume and calyceal complexity increase [1,

23, 24]. Second, the single-center retrospective design with only 42 matched pairs per group produced a 95% CI half-width of approximately 18–19% for the SFR difference, giving a lower bound of − 36.7% and a non-inferiority p value of 0.802; a larger sample or a prospective design restricted to 2–3 cm stones would narrow this interval. The international multicenter RCT by Zeng et al., using FANS f-URS, established non-inferiority in strictly defined 2–3 cm stones [21].

The immediate SFR gap tends to close over time. Gao et al., found that for stones measuring 2–3.5 cm, despite a lower immediate SFR between the two groups (68.26% in S-RIRS versus 83.53% in mPCNL), the 30-day SFR was comparable between S-RIRS and mPCNL (88.62% vs. 85.29%; p = 0.42) [25]. Xu et al. similarly observed that the initial difference (81.5% vs. 89.5%) had largely disappeared by 3 months (92.6% vs. 94.7%) [26]. Pooled analyses also indicate that final SFRs of the two procedures converge, particularly after auxiliary procedures [27]. Three mechanisms may account for this. First, residual fragments < 4 mm after S-RIRS can pass spontaneously. Second, access characteristics differ: the 16–18 Fr tract of mPCNL allows direct removal of larger fragments, giving a higher immediate SFR (e.g., 89.8% vs. 83.3% in the study by Tang et al.) [28], whereas S-RIRS with a vacuum-assisted sheath preferentially aspirates fine fragments and stone dust; these smaller residuals are more likely to pass, and reported final SFRs converge (95.6% vs. 96.6%) [28, 29]. Third, auxiliary procedure rates are similar (11% vs. 9.2% in Zeng et al.)[21], and final SFRs after auxiliary procedures converge at 90% vs. 92%. Improvements in pressure control and continuous suction may further reduce the effect of intrarenal pressure surges on stone clearance [30].

The secondary outcomes consistently favored S-RIRS. Operative time was shorter (126.0 vs. 183.9 min), consistent with simultaneous fragmentation and aspiration, which reduces repeated scope insertions [25]; the theoretical efficiency advantage of direct percutaneous access with mPCNL is offset by tract dilation and establishment [31]. Hemoglobin change was near zero (− 0.1 vs. −11.2 g/L), with no postoperative leucocyte rise (ΔWBC 0.0 vs. 2.4 ×109/L). These findings are compatible with maintenance of low intrarenal pressure throughout S-RIRS, which may limit pyelovenous backflow and bacterial translocation [32, 33], and with avoidance of the parenchymal injury and bleeding inherent to a percutaneous tract [34]. Discharge on postoperative day 1 occurred in 47.6% of S-RIRS patients versus 0% after mPCNL, consistent with ambulatory S-RIRS pathways and the usual 24–48 h observation after mPCNL [33, 35].

These data do not support replacing mPCNL as the default approach for 2-3.5 cm stones, but they support S-RIRS as an alternative when minimizing bleeding and achieving rapid recovery are priorities. The trade-off in immediate clearance should be discussed with patients, alongside the evidence that residual fragments commonly pass or are cleared by auxiliary procedures and that mid-term SFRs appear comparable [25–27].

Our study has several limitations. The single-center retrospective design and relatively small sample may affect the reliability of our estimates. Intrarenal pressure was not measured directly, so the mechanistic interpretation of the bleeding and inflammatory findings relies on prior experimental and clinical

evidence [32, 33]. Long-term outcomes, including stone recurrence, renal function, and the severity and resolution of complications, were not assessed. Larger multicenter prospective studies are needed to define the role of S-RIRS across stone-burden subgroups.

Conclusion

While S-RIRS failed to demonstrate non-inferiority to mPCNL in immediate SFR for 2-3.5 cm stones, it offers significant benefits in operative time, blood conservation, and early discharge. S-RIRS is a viable option for patients prioritizing rapid recovery or at high bleeding risk, though stone clearance versus minimally invasive gains must be balanced. Larger prospective randomized trials are needed to confirm these findings across stone burden subgroups.

Declarations

Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Ethics Approval

This retrospective study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the Institutional Review Board of Guangzhou Liwan Central Hospital (2025023).

Author Contribution

W.G. conceived and designed the study, and acquired data. C.L. and D.L. acquired and analyzed/interpreted the data, and drafted the manuscript. S.L. analyzed/interpreted the data and critically revised the manuscript for scientific and factual content. M.H. and J.Z. acquired and analyzed/interpreted the data. G.C. acquired data, drafted the manuscript, and critically revised it for scientific and factual content. C.X. critically revised the manuscript for scientific and factual content and provided supervision. All authors reviewed and approved the final manuscript.

Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request

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Figures

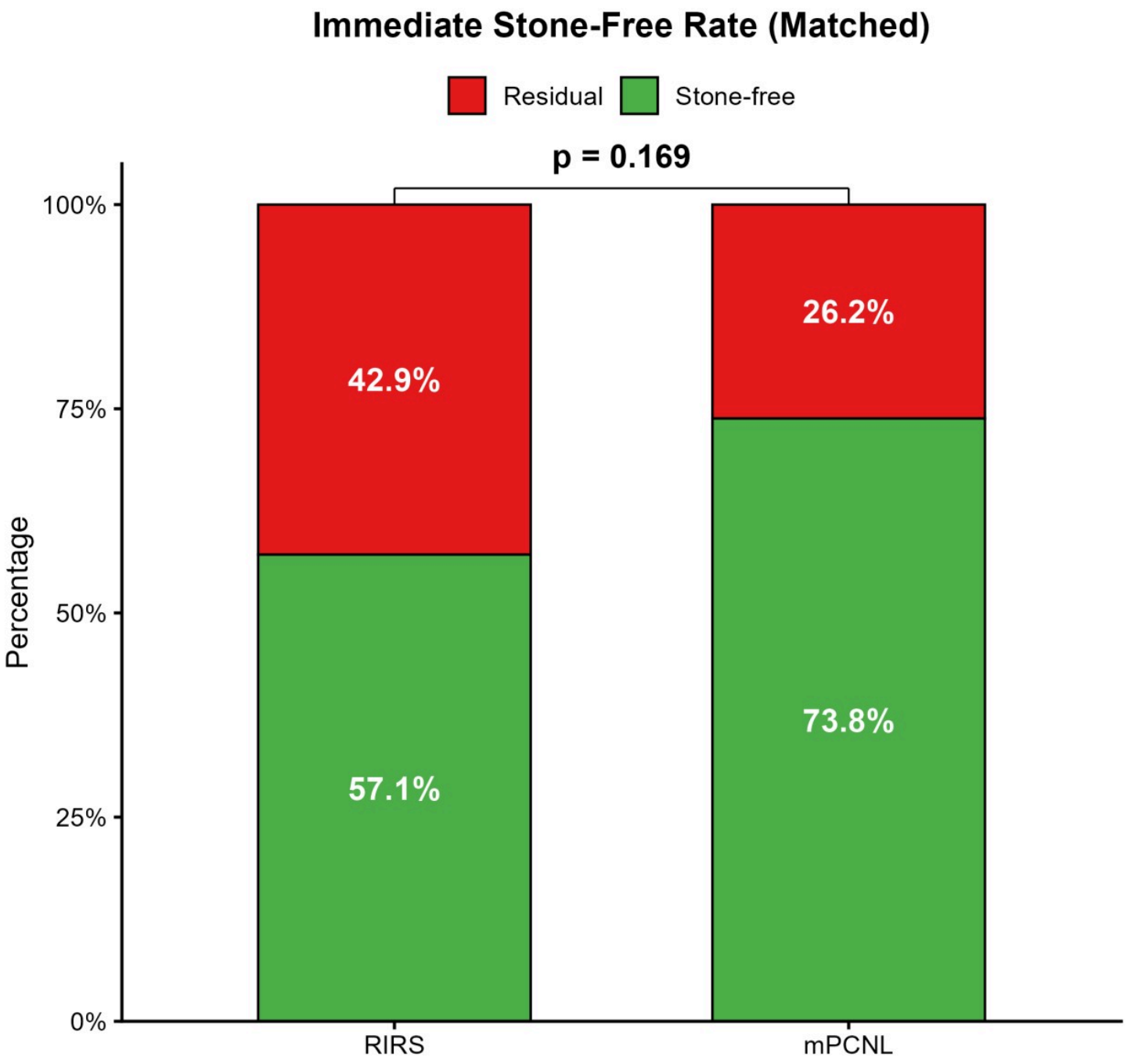


Figure 1

Immediate stone-free rates in the S-RIRS and mPCNL groups.

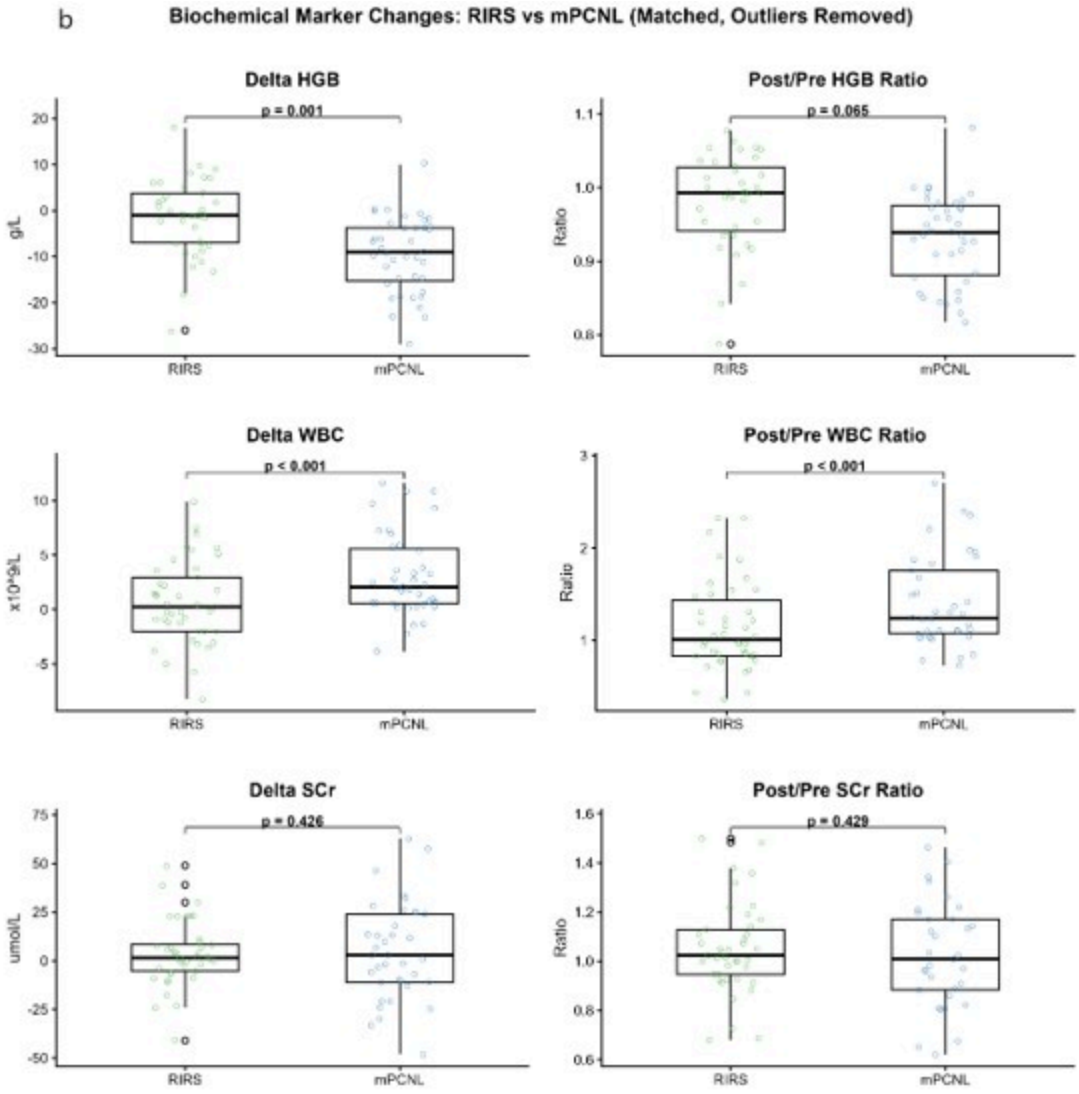


Figure 2

Box plots of primary outcomes and biochemical marker changes for S-RIRS versus mPCNL after propensity score matching. (a) Primary clinical outcomes, including hospital stay, stone-free rate. (b) Biochemical marker changes:

Supplementary Files

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