Article

Application of a Self-Made Negative Pressure Suction-Assisted Device in Micro-Channel Percutaneous Nephrolithotomy

Ann. Ital. Chir., 2026 97, 3: 480–487
https://doi.org/10.62713/aic.4475

Yu Liu[1], Bo Guo[2], Yuanbin Jiang[1]

[1]Department of Urology, Chongqing Traditional Chinese Medicine Hospital, 400021 Chongqing, China
[2]Department of Anesthesiology, Chongqing Traditional Chinese Medicine Hospital, 400021 Chongqing, China

AIM: This study aims to investigate the effect of a self-made negative pressure suction-assisted device on intrarenal pressure (IRP), surgical efficiency, and postoperative complications in micro-channel percutaneous nephrolithotomy (mPCNL).
METHODS: This retrospective study included 97 patients with renal calculi who underwent mPCNL at Chongqing Traditional Chinese Medicine Hospital between January 2023 and August 2025. Patients were divided into two groups: an observation group (n = 50) that received negative pressure suction-assisted mPCNL and a control group (n = 47) that underwent conventional mPCNL. The baseline characteristics, intraoperative IRP-related parameters, operative time, stone-free rate (SFR), and postoperative complications were compared between the two groups.
RESULTS: There were no significant differences between groups in baseline characteristics, including gender, age, body mass index (BMI), and stone parameters ($p > 0.05$). The mean intraoperative IRP was significantly lower in the observation group than in the control group (15.71 $\pm$ 3.62 mmHg vs. 19.19 $\pm$ 5.13 mmHg; $p < 0.001$). The cumulative duration of high IRP (>30 mmHg) was significantly shorter in the observation group (16.68 $\pm$ 2.59 seconds vs. 24.73 $\pm$ 7.53 seconds; $p < 0.001$). However, both the total operative time (46.11 $\pm$ 18.79 minutes) and lithotripsy/stone extraction time (29.57 $\pm$ 14.35 minutes) were significantly shorter in the observation group than in the control group (54.81 $\pm$ 20.78 minutes and 36.98 $\pm$ 16.00 minutes, respectively; $p < 0.05$). Furthermore, both the initial postoperative SFR (88.00% vs. 87.23%; $p > 0.05$) and the final SFR (94.00% vs. 95.74%; $p > 0.05$) did not differ between groups. There was no significant difference in the incidence of postoperative fever and urosepsis among the groups ($p > 0.05$). The decrease in postoperative hemoglobin was also similar between the groups ($p = 0.151$).
CONCLUSIONS: The self-made negative pressure suction-assisted device during mPCNL can effectively reduce intraoperative IRP, shorten operative time, and improve surgical efficiency, without increasing the risk of postoperative complications, demonstrating favorable clinical utility.

Keywords: renal calculi; intrarenal pressure; micro-channel percutaneous nephrolithotomy; negative pressure suction; retrospective study

Introduction

Renal calculi are a common urological condition, with their incidence continuing to increase, posing a significant burden on urinary system health and reducing overall quality of life [1]. Percutaneous nephrolithotomy (PCNL) is the primary surgical option for large-volume or complex renal and upper ureteral stones [2]. However, its complications are still clinically critical, particularly hemorrhage and infection-related events such as fever, systemic inflammatory response syndrome (SIRS), and, in severe cases, sepsis with potentially increased mortality [3,4].

Submitted: 7 December 2025 Revised: 18 December 2025 Accepted: 7 January 2026 Published: 10 March 2026
Correspondence to: Yuanbin Jiang, Department of Urology, Chongqing Traditional Chinese Medicine Hospital, 400021 Chongqing, China (e-mail: YuanbinJ2025@outlook.com).
Editor: Guglielmo Mantica

With the shift toward minimally invasive approaches, micro-channel percutaneous nephrolithotomy (mPCNL) has become an important supplement or even alternative to traditional PCNL due to its advantages in reducing renal parenchymal damage and bleeding risk while maintaining a high stone-free rate [5,6]. However, miniaturizing the access tract leads to new technical challenges. The narrow working channel may limit the irrigation outflow, which can increase intrarenal pressure (IRP) during the procedure [7]. Persistently high IRP is widely recognized as a key determinant of postoperative infectious complications, such as bacteremia and sepsis [8].

To address this challenge, various intraoperative pressure-control strategies have been proposed, among which negative pressure suction has drawn widely attention. In principle, active suction can efficiently evacuate irrigation fluid and stone fragments, maintain a lower renal pelvic pressure, enhance endoscopic visibility, and potentially reduce operative time. Given these clinical needs, we designed a simple, low-cost negative pressure suction-assisted device that can be connected to a standard peel-away sheath. This retrospective cohort study aims to evaluate the real-world clinical utility of this self-developed device on intraoperative IRP, surgical efficiency, and perioperative safety in patients undergoing mPCNL, providing evidence to support further optimization and broader clinical adoption of this approach.

Methods

Selection of Study Subjects

This study enrolled 97 patients with renal calculi who underwent mPCNL at Chongqing Traditional Chinese Medicine Hospital between January 2023 and August 2025. Patients were assigned to an observation group (n = 50), who underwent negative pressure suction-assisted mPCNL, and a control group (n = 47), who received conventional mPCNL.

Inclusion criteria for patient selection were as follows: ① age 20–70 years; ② unilateral renal calculi, confirmed by pre-operative non-contrast urinary tract CT, with a maximum stone diameter of 2–4 cm; ③ underwent mPCNL in the prone position; ④ complete clinical data available, including surgical records, intraoperative IRP monitoring, postoperative laboratory results, and follow-up information; and ⑤ patients with positive initial urine cultures, a repeat culture became negative after targeted antibiotic treatment.

Exclusion criteria included ① patients with American Society of Anesthesiologists (ASA) physical status classification $\geq$ III; ② uncorrected coagulation disorders; ③ pyonephrosis or severe acute infection (pre-operative body temperature $\geq$38.5 °C, and/or white blood cell count >15 $\times$ 10^9/L); ④ severe obesity (body mass index (BMI) $\geq$35 kg/m^2); ⑤ bilateral renal calculi requiring simultaneous treatment; ⑥ requirement for multiple tracts; ⑦ impaired renal anatomy (transplanted kidney, ectopic kidney, or horseshoe kidney); ⑧ persistent positive initial urine culture despite appropriate treatment; and ⑨ incomplete medical records or loss to follow-up.

This single-center retrospective cohort study was conducted in accordance with the ethical principles outlined in the World Medical Association's Declaration of Helsinki. The study protocol was reviewed and approved by the Ethics Committee of Chongqing Traditional Chinese Medicine Hospital (Approval No.: 2025-KY-HY-77). Written informed consent was obtained from all participants. All medical records were de-identified before analysis.

Surgical Protocol

Review of the surgical records revealed that procedures in both groups were performed by the same team of urologists, each with over 5 years of experience in mPCNL. Consistent with a previous study [9], all patients underwent surgery under general anesthesia and received intravenous antibiotics 30 minutes before the procedure. Patients were placed in the lithotomy position for ureteroscopy, and a 6 Fr ureteral catheter (catalog number: G14430, Cook Medical, Bloomington, IN, USA) was inserted. They were then turned to the prone position.

Under ultrasound guidance, the renal calyx was punctured using an 18 G needle, followed by tract dilation. An 18 Fr peel-away sheath was inserted, and a ureteroscope was advanced through the sheath to complete the procedure. For negative pressure suction-assisted mPCNL, one end of the self-developed connector was fitted to the peel-away sheath (Fig. 1), and the other end was connected to a standard surgical suction unit.

Fig. 1. An illustration of a self-developed negative pressure suction mPCNL device. mPCNL, micro-channel percutaneous nephrolithotomy.

In the observation group, suction was initiated at 0.02–0.04 MPa. During lithotripsy, negative pressure was increased to 0.04 MPa to enhance evacuation of fragments; whereas during calyceal inspection or laser activation, it was reduced to 0.02 MPa to minimize mucosal injury from excessive suction. In cases with brisk bleeding or poor endoscopic visibility, intermittent suction was used. Suction settings were adjusted based on real-time IRP readings and surgical field clarity.

Lithotripsy was conducted using a holmium laser (100 W), typically set at 2~3 J energy and 20 Hz frequency. At the end of surgery, an F5 double-J stent (catalog number: 776624, Bard Medical, Covington, GA, USA), and a nephrostomy tube was placed in all patients. Retrieved stone fragments were collected for composition analysis. Routine postoperative examinations, including complete blood count, electrolytes, and biochemical indicators, were performed on return to the ward and again the next morning. The double-J stent was removed at an outpatient follow-up visit 2–3 weeks after discharge.

Outcome Measures and Data Collection

IRP Measurement and Monitoring

Intraoperative IRP was recorded continuously using a standardized monitoring protocol. After induction of general anesthesia, and while the patient was in the lithotomy position, a 6 Fr ureteral catheter was inserted into the renal collecting system under ureteroscopic guidance. The catheter was connected through an extension line to a pressure transducer, which was fixed at the level of the renal pelvis to ensure a stable reference point throughout the procedure. The transducer was then connected with a bedside monitor (measurement range 0–200 mmHg). Zero calibration was performed before the procedure began to establish the baseline IRP. During surgery, real-time IRP was continuously recorded. The following IRP-related outcomes were extracted for analysis: (a) mean intraoperative IRP (mmHg), (b) the number of patients experiencing high IRP episodes, defined as IRP >30 mmHg, (c) the cumulative duration (seconds) spent above the 30 mmHg threshold.

Surgical and Postoperative Outcomes

The following outcome measures were collected from surgical records and postoperative follow-up:
(1) Operative time: it included total operative time, defined by the interval from the start of renal puncture to completion of nephrostomy tube placement and lithotripsy/stone extraction time, defined by the interval from initiation of holmium laser lithotripsy to complete clearance of stone fragments.
(2) Stone-free rate (SFR): SFR was assessed by urinary ultrasound on postoperative day 1 (initial SFR) and again at the 1-month follow-up (final SFR). Stone-free status was defined as the absence of residual stones or the presence of only clinically insignificant residual fragments (≤3 mm).
(3) Postoperative complications: these outcomes included postoperative fever, urosepsis, and hemoglobin decrease. Urosepsis was defined as sepsis secondary to a urinary tract infection, diagnosed based on the Sepsis-3 criteria: suspected or confirmed urinary tract infection with an acute increase of ≥2 points in the Sequential Organ Failure Assessment [SOFA] score. Postoperative complications were graded using the modified Clavien-Dindo classification system to standardize assessment of adverse event severity [10].

Statistical Analysis

Data were analyzed using SPSS (version 26.0, IBM Corp., Armonk, NY, USA). Normality of continuous variables was assessed using the Shapiro-Wilk test ($p > 0.05$). Normally distributed continuous variables were expressed as mean ± standard deviation, and between-group comparisons were performed using an independent-sample *t*-test. Non-normally distributed data were presented as median (interquartile range) and were analyzed using the Mann-Whitney U test. Count data (categorical variables) were reported as number (percentages) [*n* (%)], and comparisons between groups were performed using the χ^2 test or Fisher's exact test, as appropriate. A *p*-value of <0.05 was considered statistically significant.

Results

Comparison of Baseline Characteristics Between Groups

This study included 97 patients in the final analysis: 50 patients in the observation group and 47 in the control group. Baseline characteristics were comparable between the two groups, with no statistically significant differences in gender, age, BMI, comorbidities (hypertension and diabetes), maximum stone diameter, stone attenuation (HU), or the rate of positive initial urine culture ($p > 0.05$), indicating comparability (Table 1).

Comparison of IRP Between Groups

As shown in Table 2, baseline IRP was measured before the procedure and was comparable between the two groups: 9.51 ± 2.31 mmHg in the observation group versus 9.48 ± 2.35 mmHg in the control group ($p = 0.951$). During continuous intraoperative IRP monitoring, the observation group demonstrated a significantly lower mean IRP (15.71 ± 3.62 mmHg) compared to the control group (19.19 ± 5.13 mmHg; $p < 0.001$).
High IRP (>30 mmHg) was observed in 8 out of 50 patients in the observation group, compared with 16 of 47 patients in the control group, indicating a statistically significant difference ($p = 0.040$). However, the cumulative time spent at high IRP (IRP >30 mmHg) was significantly shorter in the observation group (16.68 ± 2.59) than in the control group (24.73 ± 7.53 seconds, $p < 0.001$).

Comparison of Operative Time Between Groups

As shown in Table 3, the observation group had a significantly shorter mean total operative time than the control group (46.11 ± 18.79 minutes vs. 54.81 ± 20.78 minutes; $p = 0.033$). Similarly, the mean lithotripsy time was substantially lower in the observation group (29.57 ± 14.35 minutes) compared with the control group (36.98 ± 16.00 minutes; $p = 0.018$).

Comparison of Stone-Free Rate Between Groups

As shown in Table 4, the SFR on postoperative day 1 was 88% (44/50 cases) in the observation group and 87.23% (41/47 cases) in the control group. Although the SFR was slightly higher in the observation group, the difference was not statistically significant ($p = 0.909$). At 1-month follow-up, the final SFR, defined as the proportion of patients with no residual stones or clinically insignificant fragments ≤3 mm, was similarly high in both groups: 94% (47/50 patients) in the observation group and 95.74% (45/47 cases) in the control group, with no statistically significant between-group difference ($p = 1.000$).

Table 1. Comparison of baseline characteristics between the two groups [mean ± SD, *n* (%)].

Indicator	Control group (*n* = 47)	Observation group (*n* = 50)	*p*-value
Gender			
Male	27 (57.45%)	35 (70.00%)	0.198
Female	20 (42.55%)	15 (30.00%)	
Age (years)	44.64 ± 15.09	48.12 ± 14.62	0.251
BMI (kg/m^2)	26.27 ± 3.20	26.76 ± 4.02	0.515
Comorbidities			
Hypertension	12 (25.53%)	15 (30.00%)	0.624
Diabetes	3 (6.38%)	8 (16.00%)	0.135
Other	7 (14.89%)	12 (24.00%)	0.259
Maximum stone Diameter (mm)	29.31 ± 5.73	31.25 ± 5.90	0.104
Stone attenuation (HU)	987.62 ± 292.58	936.58 ± 315.06	0.411
Positive initial urine culture	10 (21.28%)	12 (24.00%)	0.749

BMI, body mass index.

Table 2. Comparison of intrarenal pressure between the two groups [mean ± SD, *n* (%)].

Indicator	Control group (*n* = 47)	Observation group (*n* = 50)	*p*-value
Baseline IRP (mmHg)	9.48 ± 2.35	9.51 ± 2.31	0.951
Intraoperative IRP (mmHg)	19.19 ± 5.13	15.71 ± 3.62	<0.001
Number of cases with high IRP (>30 mmHg)	16 (34.04%)	8 (16.00%)	0.040
Duration of high IRP (s) (>30 mmHg)	24.73 ± 7.53	16.68 ± 2.59	<0.001

IRP, intrarenal pressure.

Table 3. Comparison of operative time between the two groups (mean ± SD).

Indicator	Control group (*n* = 47)	Observation group (*n* = 50)	*p*-value
Total operative time (minutes)	54.81 ± 20.78	46.11 ± 18.79	0.033
Lithotripsy/stone removal Time (minutes)	36.98 ± 16.00	29.57 ± 14.35	0.018

Table 4. Comparison of stone-free rates between the two groups [*n* (%)].

Indicator	Control group (*n* = 47)	Observation group (*n* = 50)	*p*-value
Initial SFR	41 (87.23%)	44 (88.00%)	0.909
Final SFR	45 (95.74%)	47 (94.00%)	1.000

SFR, stone-free rate.

Comparison of Postoperative Outcomes Between Groups

The incidence of postoperative events was uncommon in both groups. The rates of fever (≥38 °C) and urosepsis were low and did not differ substantially between the two groups ($p > 0.05$). Postoperative hemoglobin reduction was also comparable between groups: the mean change was 15.59 ± 6.63 g/L in the observation group and 13.53 ± 7.35 g/L in the control group, with no statistically significant difference ($p = 0.151$). Complication severity, determined using the Clavien-Dindo classification, was predominantly Grade I–II in both groups and showed no between-group difference ($p = 1.000$). No Grade III or IV complications occurred in either group (Table 5).

Discussion

This retrospective analyzed 97 patients with renal stone who underwent mPCNL to systematically evaluate the impact of a self-developed negative pressure suction-assisted device on intraoperative IRP control, surgical efficiency, and perioperative safety. Patients in the observation group had a significantly lower mean intraoperative IRP and spent less cumulative duration at a high IRP than the control group. Furthermore, both total operative time and lithotripsy/stone extraction time were significantly shorter in the observation group. Notably, SFR and postoperative complication rates were comparable between the two groups, with no statistically significant differences. These results validate the practical value of negative pressure suction in mPCNL, and highlight that the low-cost, self-made device is clinically feasible for improving pressure management and procedural efficiency without limiting efficacy or safety. It also provides evidence to support further optimization and broader adoption of minimally invasive approaches for renal stone surgery.

Increased IRP is one of the most critical intraoperative risk factors during mPCNL. Because the access tract is narrow, resistance to irrigation fluid outflow increases, lead-

Table 5. Comparison of postoperative outcomes between the two groups [mean ± SD, *n* (%)].

Indicator	Control group (n = 47)	Observation group (n = 50)	p-value
Postoperative fever (n, %)	6 (12.77%)	3 (6.00%)	0.425
Urosepsis (n, %)	2 (4.26%)	1 (2.00%)	0.610
Hemoglobin drop (g/L)	13.53 ± 7.35	15.59 ± 6.63	0.151
Clavien-Dindo grade			
Grade I	6 (12.77%)	5 (10.00%)	1.000
Grade II	1 (2.13%)	1 (2.00%)	
Grade III	0	0	
Grade IV	0	0	

ing to pressure accumulation within the renal pelvis [11]. Sustained or repeated high IRP (>30 mmHg) can disrupt the integrity of the renal collecting system mucosal barrier [12]. It causes irrigation fluid and potentially existing bacteria and toxins to extravasate into the bloodstream via renal veins, lymphatic vessels, or the renal parenchyma, significantly increasing the risk of severe postoperative complications such as urosepsis and systemic inflammatory response syndrome (SIRS) [13,14]. In our study, the observation group used a self-developed negative pressure suction device to actively evacuate irrigation fluid and stone fragments. Hence, the observation group showed a significantly reduced mean intraoperative IRP than the control group (15.71 ± 3.62 mmHg vs. 19.19 ± 5.13 mmHg; $p < 0.001$), and the cumulative duration of high IRP in the observation group was significantly shorter than that in the control group (16.68 ± 2.59 vs. 24.73 ± 7.53; $p < 0.001$). These results are consistent with Lai *et al*. [15], who reported that an 18F negative pressure-assisted access sheath reduces mean IRP in mPCNL from 17.8 ± 5.1 mmHg to 10.3 ± 4.3 mmHg ($p < 0.001$). Similarly, Xu *et al*. [16] observed in 20F negative pressure-assisted PCNL that the mean intraoperative IRP in mid-calyceal puncture cases could be controlled at 8.6 ± 1.9 mmHg, significantly lower than in conventional surgeries. These findings suggest that negative pressure suction establishes an active drainage pathway that breaks the vicious cycle of fluid retention within a miniaturized tract, maintaining a reliable low-pressure environment in the renal pelvis.

Notably, the number of high IRP events was also less frequent in the observation group (8/50, 16.00%) than in the control group (16/47, 34.04%), with a statistically significant difference (p = 0.040). This reduction is consistent with the decrease in mean IRP and shorter high-pressure exposure time, further supporting the effectiveness of the negative pressure suction device in controlling intrarenal pressure peaks. Furthermore, it highlights the potential of the device to reduce transient pressure peaks that may increase infection risk. Nonetheless, because IRP is affected by factors such as stone burden, anatomy, and surgical complexity, larger, multi-center studies would be valuable to confirm these findings across diverse clinical settings.

The improvement in surgical efficiency was another key finding in this study. Compared with the control group, the observation group demonstrated a decrease of 8.7 minutes in total operative time and 7.41 minutes in lithotripsy/stone extraction time (both $p < 0.05$). This advantage stems from the optimization of the surgical workflow by the negative pressure suction technology.

In conventional mPCNL, surgeons often need to interrupt lithotripsy to evacuate fragments using irrigation, flushing, or mechanical extraction. These repeated pauses can prolong the procedure and may increase the risk of tract loss or renal parenchymal injury, particularly when visibility is limited by bleeding or debris [17]. In contrast, the self-made negative pressure device enabled continuous, real-time removal of irrigation fluid and clear stone fragments, maintaining a clear surgical field and reducing time spent on repeated scope positioning and waiting for sufficient flushing. Furthermore, larger stone fragments can be evacuated directly through suction, minimizing the need for additional stone retrieval maneuvers. Fan *et al*. [18] reported similar findings, indicating that negative pressure-assisted mPCNL reduced lithotripsy and stone removal time from 50 to 37 minutes, consistent with our findings. Furthermore, shortening operative time has multiple clinical implications. Shorter procedures decrease exposure to general anesthesia, potentially lowering anesthesia-related complications, including pulmonary infection and postoperative cognitive effects. It can also reduce surgeon fatigue, improve surgical precision, and increase operating room efficiency by elevating case turnover and optimizing medical resource allocation, which is particularly important in resource-limited or primary hospital settings.

Stone-free rates were comparable between the two groups. Neither the initial postoperative SFR (88.00% vs. 87.23%) nor the final SFR at follow-up (94.00% vs. 95.74%) differed considerably ($p > 0.05$), indicating that the self-made negative pressure suction device improved surgical efficiency without compromising the effectiveness of stone removal. These results align with the findings of Agrawal *et al*. [19], who similarly reported that suction-assisted mPCNL could maintain stone-free rates comparable to conventional surgery while supporting better IRP control. A possible explanation is that the active drainage during negative pressure-assisted suction limits fragment migration into remote calyces or down the ureter, thereby preventing a decrease in SFR associated with residual fragments. Simultaneously, improved surgical field visibility may help the surgeon localize stones more accurately, ensuring more thorough lithotripsy [20]. The patients included in this study had maximum stones measuring 2–4 cm, representing a moderate stone burden, suggesting the device provides stable stone removal within this range. However, its efficacy in larger burden or more complex renal stones, such as staghorn calculi, requires further exploration. Although stone recurrence was not assessed in this short-term study, future investigations should incorporate long-term follow-up to evaluate recurrence rates, which is crucial for understanding sustained clinical benefit.

Perioperative safety is a key indicator when evaluating any new surgical adjunct. In this study, there were no statistical differences between the two groups in the incidence of postoperative fever, urosepsis, or the amount of hemoglobin drop ($p > 0.05$). Furthermore, complications in both groups were predominantly mild (Clavien-Dindo grade I–II), and no severe adverse events occurred, supporting the overall safety of self-made negative pressure suction-assisted mPCNL. In principle, although negative pressure suction might reduce the risk of infectious complications by lowering IRP, infection-related complications in the observation group showed only a slight decreasing trend (fever: 6% vs. 13%; urosepsis: 2% vs. 4%), without reaching statistical significance. These outcomes may be due to several factors. First, this study included only patients with positive initial urine cultures that turned negative after treatment, excluding those with severe pre-operative infection, thereby lowering the baseline risk of postoperative infection. Second, the relatively limited sample size (97 cases) may lack sufficient statistical power to detect modest differences in relatively infrequent complications. Third, even in conventional mPCNL, surgeons can partially control IRP by managing irrigation pressure and intermittently venting the tract, potentially narrowing the observable gap between groups.

A meta-analysis by Zhou *et al*. [21] reported that a cumulative duration of IRP >30 mmHg exceeding 20 seconds is an independent risk factor for postoperative infectious complications. In our study, the high-IRP exposure time was significantly shorter in the observation group (16.68 ± 2.59 seconds), with a statistically significant difference and clinical implications for reducing the risk of severe infections. This observation requires further validation through larger samples and adequately powered studies. Finally, the lack of difference in hemoglobin decline between groups indicates that negative pressure suction did not increase intraoperative bleeding risk. This is likely related to the fact that the device does not alter tract caliber and that suction settings were applied in a controlled manner within a standardized surgical technique, avoiding mucosal or vascular injury from excessive negative pressure.

The innovation of this study is the development of a simple, low-cost negative pressure suction-assisted device. This device can be fitted directly onto a standard 18 Fr peel-away sheath without modifying existing surgical instruments. Suction intensity can be adjusted flexibly within 0.02–0.04 MPa to match different intraoperative scenarios. Compared with commercially available negative pressure access sheaths, the self-made device uses readily accessible materials, is simple to assemble, and may potentially significantly reduce upfront capital costs for medical institutions. Its preliminary economic benefit likely extends beyond the minimal material cost, as shorter operative times, which may lead to indirect savings through reduced anesthesia exposure and operating room utilization, while also minimizing the recurring costs of proprietary disposable sheaths. However, this study did not conduct a formal cost-effectiveness assessment against commercial systems. Furthermore, it did not evaluate whether outcomes differ by surgeon experience level, especially among junior physicians, and the learning curve associated with adopting the device remains unclear.

This study has several limitations that should be acknowledged. First, the single-center, retrospective, non-randomized design introduces potential selection bias. In routine practice, surgeons may have been more likely to use the negative pressure device in cases perceived as being technically more challenging (for example, larger or higher-density stones). Even though baseline characteristics are comparable, this type of case selection can still influence outcomes and limit causal inferences regarding efficacy. Second, the sample size was relatively small (97 cases), and postoperative complication events were infrequent. Consequently, the analysis may be statistically underpowered to detect small but clinically relevant differences in complication rates, potentially leading to a Type II error. Third, the inclusion criteria focused on unilateral stones measuring 2–4 cm, excluding more complex scenarios such as staghorn calculi, multi-tract procedures, and atypical renal anatomies. Thus, the findings may not be generalizable to patients with higher stone burden or more challenging surgical anatomy. Fourth, the follow-up period was limited to 1 month and primarily captured short-term perioperative outcomes. Long-term outcomes, including kidney function, stone recurrence, and delayed chronic complications, were not evaluated, which limits our observations about persistent efficacy and safety. Fifth, the negative pressure range (0.02–0.04 MPa) was selected empirically; optimal suction parameters may vary by stone characteristics, bleeding, and renal anatomy and should be investigated in future studies. Finally, because the self-developed device was not directly compared with commercially available negative pressure systems, its relative performance and cost-effectiveness cannot be fully established from the current data.

Based on these findings and the study's limitations, several priorities emerge for future research. First, multi-center, large-sample randomized controlled trials (RCTs) are required to provide robust evidence, minimize selection bias, and rigorously confirm the efficacy and safety of the self-made negative pressure device. Such trials should also include predetermined subgroup analyses across different stone burdens, stone compositions/densities and anatomical variations. Second, future studies should develop and test an individualized suction protocol, defining how negative pressure settings should be adjusted according to the operative phase, bleeding, visibility and real-time IRP patterns. Third, extended follow-up is critical to assess long-term outcomes beyond the perioperative period, such as stone recurrence rates, renal function preservation, and the need for secondary interventions, which indicate long-term clinical relevance. Fourth, optimizing device design and conducting a formal, comprehensive cost-effective analysis comparing the self-made device with commercial alternatives, accounting for material costs, training requirements, maintenance, and potential savings linked to improved outcomes. Finally, studies involving more complex stone cases and directly compare self-develop device with established commercial suction systems would help elucidate relative performance and define the most appropriate indications, providing more precise guidance for technology adoption.

Conclusions

The self-made negative pressure suction-assisted device can be a safe and effective adjunct for mPCNL, significantly reducing intraoperative IRP and improving surgical efficiency without affecting stone-free rates or increasing postoperative complications. Utilizing existing medical resources for modification, the approach is low-cost, simple to operate, and highly feasible for wider adoption, particularly in primary or resource-limited hospitals to optimize mPCNL. Although the retrospective design limits causal interpretation, the results still provide meaningful clinical evidence supporting the value of negative pressure suction for intraoperative pressure control. Future studies should prioritize large-scale RCTs and technological innovation to support individualized pressure-management strategies, ultimately improving outcomes and enhancing safety in minimally invasive urologic surgery.

Availability of Data and Materials

The anonymized data analyzed are available from the corresponding author upon reasonable request.

Author Contributions

YL: conceptualization, data curation, formal analysis, investigation, methodology, writing – original draft; BG: conceptualization and design the study, investigation, resources, validation, writing – review & editing; YJ: conceptualization, project administration, supervision, validation, writing – review & editing, funding acquisition. All authors have been involved in revising the manuscript critically for important intellectual content. All authors gave final approval of the version to be published. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. The study protocol was reviewed and approved by the Ethics Committee of Chongqing Traditional Chinese Medicine Hospital (Approval No.: 2025-KY-HY-77). Written informed consent was obtained from all individual participants included in this retrospective study. All patient data were anonymized and de-identified prior to analysis to ensure confidentiality and privacy.

Acknowledgment

We would like to express gratitude to all those colleagues who contributed to this study.

Funding

This study was supported by the Chongqing Medical Scientific Research Project (Joint project of Chongqing Health Commission and Science and Technology Bureau) (Grant ID: 2023MSXM083).

Conflict of Interest

The authors declare no conflict of interest.

References

[1] Stamatelou K, Goldfarb DS. Epidemiology of Kidney Stones. Healthcare (Basel, Switzerland). 2023; 11: 424. https://doi.org/10.3390/healthcare11030424.

[2] Zeng G, Zhong W, Mazzon G, Choong S, Pearle M, Agrawal M, *et al*. International Alliance of Urolithiasis (IAU) Guideline on percutaneous nephrolithotomy. Minerva Urology and Nephrology. 2022; 74: 653–668. https://doi.org/10.23736/S2724-6051.22.04752-8.

[3] Kumar GM, Nirmal KP, Kumar GS. Postoperative infective complications following percutaneous nephrolithotomy. Urology Annals. 2021; 13: 340–345. https://doi.org/10.4103/UA.UA_153_20.

[4] Poudyal S. Current insights on haemorrhagic complications in percutaneous nephrolithotomy. Asian Journal of Urology. 2022; 9: 81–93. https://doi.org/10.1016/j.ajur.2021.05.007.

[5] Sharma G, Sharma A, Devana SK, Singh SK. Mini Versus Standard Percutaneous Nephrolithotomy for the Management of Renal Stone Disease: Systematic Review and Meta-analysis of Randomized Controlled Trials. European Urology Focus. 2022; 8: 1376–1385. https://doi.org/10.1016/j.euf.2021.07.014.

[6] Jiao B, Luo Z, Huang T, Zhang G, Yu J. A systematic review and meta-analysis of minimally invasive vs. standard percutaneous nephrolithotomy in the surgical management of renal stones. Experimental and Therapeutic Medicine. 2021; 21: 213. https://doi.org/10.3892/etm.2021.9645.

[7] Riedinger E, Osther PJS, Knudsen B. Intra-renal Pressure. In Per-

cutaneous renal surgery. Springer: Cham. 2023. https://doi.org/10.1007/978-3-031-40542-6_29.

[8] Hong A, Leroi M, Alberto M, Bolton D, Jack G. The exponential relationship between raised intrarenal pressure and bacteraemia. BJU International. 2025. https://doi.org/10.1111/bju.16856. (online ahead of print)

[9] Xu XJ, Zhang J, Li M, Hou JQ. Clinical study on the minimally invasive percutaneous nephrolithotomy treatment of upper urinary calculi. World Journal of Clinical Cases. 2022; 10: 1198–1205. https://doi.org/10.12998/wjcc.v10.i4.1198.

[10] Iqbal MD, Ahmed M, Waleed A, Gazder TUR, Rabiullah S, Saad HM. Frequency of complications in ultrasound-guided percutaneous nephrostomy: An analysis using the modified clavien classification system. JPMA. the Journal of the Pakistan Medical Association. 2025; 75: 447–450. https://doi.org/10.47391/JPMA.21201.

[11] Liang ZJ, Liu WW, Wang J, Du CC. Research progress of renal pelvic pressure monitor and control during percutaneous nephrolithotomy. Journal of Clinical Urology. 2021; 36: 583–586. https://doi.org/10.13201/j.issn.1001-1420.2021.07.016. (In Chinese)

[12] Yuen SKK, Zhong W, Chan YS, Castellani D, Bhojani N, Agarwal MS, *et al*. Current utility, instruments, and future directions for intra-renal pressure management during ureteroscopy: scoping review by global research in intra-renal pressure collaborative group initiative. Therapeutic Advances in Urology. 2025; 17: 17562872251314809. https://doi.org/10.1177/17562872251314809.

[13] John J, Wisniewski P, Fieggen G, Kaestner L, Lazarus J. Intrarenal Pressure in Retrograde Intrarenal Surgery: A Narrative Review. Urology. 2025; 195: 201–209. https://doi.org/10.1016/j.urology.2024.09.026.

[14] Ramala SR, Chandak SR, Avula HS, Annareddy S. Prevention and Management of Infectious Complications in Retrograde Intrarenal Surgery: A Comprehensive Review. Cureus. 2024; 16: e69335. https://doi.org/10.7759/cureus.69335.

[15] Lai D, Chen M, Sheng M, Liu Y, Xu G, He Y, *et al*. Use of a Novel Vacuum-Assisted Access Sheath in Minimally Invasive Percutaneous Nephrolithotomy: A Feasibility Study. Journal of Endourology. 2020; 34: 339–344. https://doi.org/10.1089/end.2019.0652.

[16] Xu G, Liang J, He Y, Li X, Yang W, Lai D, *et al*. Comparison of two different minimally invasive percutaneous nephrostomy sheaths for the treatment of staghorn stones. BJU International. 2020; 125: 898–904. https://doi.org/10.1111/bju.15031.

[17] Gao J, Tang J, Shen Y. Efficacy and Safety of Tip-Flexible Suctioning Ureteral Access in Renal Stone Treatment. Medical Science Monitor: International Medical Journal of Experimental and Clinical Research. 2025; 31: e947055. https://doi.org/10.12659/MSM.947055.

[18] Fan HG, Liu C, Hong JH, Lin YY, Lin SQ. The application of negative pressure suction sheath in minimally invasive percutaneous nephrolithotomy. Chinese Journal of Endourology, 2023; 17: 140–143. https://doi.org/10.3877/cma.j.issn.1674-3253.2023.02.008. (In Chinese)

[19] Agrawal MS, Kumar N, Mishra D, Yadav A, Sharma LK, Sharma G, *et al*. Does suction in Mini PCNL mitigate rise in intrarenal pressure? A prospective randomised study. Urolithiasis. 2025; 53: 132. https://doi.org/10.1007/s00240-025-01804-2.

[20] Geavlete P, Multescu R, Mares C, Buzescu B, Iordache V, Geavlete B. Retrograde Intrarenal Surgery for Lithiasis Using Suctioning Devices: A Shift in Paradigm? Journal of Clinical Medicine. 2024; 13: 2493. https://doi.org/10.3390/jcm13092493.

[21] Zhou G, Zhou Y, Chen R, Wang D, Zhou S, Zhong J, *et al*. The influencing factors of infectious complications after percutaneous nephrolithotomy: a systematic review and meta-analysis. Urolithiasis. 2022; 51: 17. https://doi.org/10.1007/s00240-022-01376-5.