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*Review Article*

# Network meta-analysis of clinical efficacy and safety of flexible ureteroscopic holmium laser lithotripsy combined with tip-flexible suction ureteral access sheath for kidney stones

Guo Chen, Bo Wu, Li Xie

*Department of Urology, Pidu District People's Hospital of Chengdu, Chengdu 611730, Sichuan, China*

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**Abstract:** Background: The tip-flexible suction ureteral access sheath is an innovative device designed to reduce intrarenal pressure and improve stone clearance during flexible ureteroscopy. This network meta-analysis compared its efficacy and safety with traditional ureteral access sheath (T-UAS)-assisted flexible ureteroscopy, mini-percutaneous nephrolithotomy (mini-PCNL), and extracorporeal shock wave lithotripsy (ESWL) for 1-3 cm kidney stones. Methods: PubMed, Web of Science, and Cochrane CENTRAL were searched up to December 2025. We included 18 studies (7 RCTs, 3 prospective, 8 retrospective) with a total of 4,987 patients across all study arms. The primary outcome was 1-month stone-free rate (SFR). A frequentist random-effects network meta-analysis was performed. Results: For SFR, SUCRA values were: suction sheath 0.84, mini-PCNL 0.76, traditional UAS 0.31, ESWL 0.07. Suction sheath significantly reduced overall complications (RR=0.35, 95% CI: 0.24-0.50) and postoperative fever (RR=0.35, 95% CI: 0.23-0.52) versus traditional UAS. Operative time did not differ between suction sheath and traditional UAS (MD=-0.31 min, 95% CI: -10.64 to 11.25). Intraoperative blood loss was lower with suction sheath than with PCNL/mPCNL (MD=-3.43 g/L, 95% CI: -5.59 to -1.27). Heterogeneity was low for SFR and complications but high for operative time ($I^2$=98.1%). meta-regression did not identify significant sources, and sensitivity analyses confirmed robustness. Conclusions: The tip-flexible suction ureteral access sheath provides a favorable balance of efficacy and safety for 1-3 cm kidney stones, with SFR comparable to mini-PCNL but with significantly fewer complications and less trauma. It may be preferred for stones ≤2 cm and an alternative for 2-3 cm stones in patients unfit for percutaneous surgery.

**Keywords:** Flexible ureteroscopy, kidney stones, suction ureteral access sheath, ureteral access sheath, network meta-analysis

## Introduction

Kidney stones are a highly prevalent urinary system disease with a global incidence of 7-15%, and their prevalence has shown an increasing annual trend [1-3]. Characterized by clinical manifestations such as abdominal distension, abdominal pain, hematuria, and dysuria, kidney stones can induce renal colic, hematuria, and other symptoms. They may also lead to urinary tract obstruction, hydronephrosis, and even renal function impairment, seriously affecting patients' quality of life and increasing the medical burden [4]. With the development of minimally invasive urological technology, the treatment of kidney stones has shifted from traditional open surgery to minimally invasive modalities dominated by flexible ureteroscopic lithotripsy (FURS), percutaneous nephrolithotomy (PCNL), and extracorporeal shock wave lithotripsy (ESWL) [5, 6]. However, traditional ureteral access sheaths (UAS) have limitations including elevated intrarenal pressure (intraoperative peak pressure often ≥80 mmHg), insufficient efficiency in clearing stone fragments (residual rate 33%-70.6%), and increased risk of complications such as infection (incidence 17.5%-18.6%) and residual stones. Among these minimally invasive techniques, flexible ureteroscopic lithotripsy (FURS)

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using holmium laser is widely used for treating 1-3 cm kidney stones due to its advantages of minimal trauma and rapid recovery, but the aforementioned defects of traditional UAS still limit its efficacy; the tip-bendable vacuum-assisted ureteral access sheath (FV-UAS/FANS), through the design of 'active negative pressure drainage + tip bendability (deflection >90°)', can effectively reduce intrarenal pressure and improve fragment clearance efficiency, further optimizing the clinical effect of FURS. As a novel minimally invasive device, the flexible and navigable suction ureteral access sheath (FANS)/flexible vacuum-assisted suction ureteral access sheath (FV-UAS) can in real-time reduce intrarenal pressure and quickly clear stone fragments through active negative pressure drainage technology [7]. Existing clinical studies have initially confirmed the potential of this device in improving stone-free rates and reducing infectious complications. However, there is a lack of systematic horizontal comparisons with multiple traditional modalities such as conventional UAS, mini-PCNL, and ESWL. Additionally, conclusions regarding efficacy and safety vary across studies, making it difficult to form a unified basis for clinical decision-making. Furthermore, high-quality evidence supporting the comprehensive superiority of suction ureteral access sheaths over other minimally invasive techniques in secondary outcome indicators such as operative time, intraoperative blood loss, and postoperative pain remains insufficient.

## Methodology

### *Study design*

This study was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and its Network Meta-Analysis extension (PRISMA-NMA). The study protocol was registered in PROSPERO (CRD420261401472).

### *Inclusion and exclusion criteria*

<u>*Study types*</u>

Randomized controlled trials (RCTs), prospective non-randomized studies and retrospective cohort studies published in English or Chinese were included, with no publication year restriction (literature search updated to December 2025). Case reports, case series, reviews, meta-analyses, animal experiments, in vitro studies, clinical protocols and studies with insufficient extractable data were excluded.

<u>*Participants*</u>

Adult patients (≥18 years) diagnosed with 1-3 cm kidney stones confirmed by CT, IVP or ultrasound were included, regardless of stone location (renal calyces, pelvis or multiple sites). Patients were excluded if they were under 18 years old, pregnant or lactating, had severe hepatic/renal insufficiency, coagulopathy, urinary malignancy, congenital urinary tract anomalies, uncontrolled urinary tract infection, psychiatric disorders or inability to complete follow-up.

<u>*Intervention*</u>

Experimental group: tip-flexible suction ureteral access sheath (including FANS, FV-UAS, TFS-UAS, S-UAS and NFTS-UAS) combined with flexible ureteroscopic holmium/thulium laser lithotripsy with active negative pressure suction (80-150 mmHg).

<u>*Comparasions*</u>

① Traditional ureteral access sheath (T-UAS)+flexible ureteroscopic laser lithotripsy; ② Mini-percutaneous nephrolithotomy (mini-PCNL) or conventional PCNL; ③ Sheathless retrograde intrarenal surgery (Sheathless RIRS); ④ Extracorporeal shock wave lithotripsy (ESWL).

<u>*Outcomes*</u>

Primary outcome: stone-free rate (SFR) at 1 month postoperatively (no visible stones or residual fragments <4 mm on CT/ultrasound/IVP).

Secondary outcomes: operative time, intraoperative blood loss (hemoglobin drop), postoperative pain (VAS), overall complications, postoperative fever, hospital stay, etc.

### *Outcome indicators*

<u>*Primary outcome*</u>

One-month stone-free rate (SFR): absence of visible stones or residual fragments <4 mm confirmed by CT, ultrasound or IVP at 1 month postoperatively.

*Secondary outcomes*

Surgical indicators: operative time, laser lithotripsy time and length of hospital stay; Safety indicators: postoperative complication rate (including fever, bleeding, infection, ureteral injury and perirenal complications, graded by Clavien-Dindo classification), intraoperative blood loss and 24-hour postoperative VAS pain score; Other indicators: reintervention rate, double-J stent indwelling rate and duration, quality of life (QoL) score and total hospitalization cost.

*Additional exclusion criteria*

① Non-RCT studies, duplicate publications, studies with unavailable or conflicting data; ② Intervention measures inconsistent with the definitions of the experimental or control groups; ③ Studies lacking the primary outcome or with no available data for outcome indicators; ④ Studies involving special populations (e.g., those with severe underlying diseases, urinary tract malformations) where data could not be extracted independently; ⑤ Non-Chinese/English literature and studies with unavailable full texts.

*Search strategy*

A systematic search was conducted in PubMed, Web of Science, and the Cochrane Central Register of Controlled Trials (CENTRAL) databases from their inception to December 2025. English search terms combined MeSH terms and free-text words, including "flexible ureteroscopy", "retrograde intrarenal surgery", "suction ureteral access sheath", "tip-bendable sheath", "renal calculi", "kidney stone", "randomized controlled trial", etc. Reference lists of included studies were also searched to supplement relevant literature.

*Literature screening and data extraction*

EndNote X9 was used for literature management and duplicate removal. Two reviewers (Guo Chen and Bo Wu) independently screened titles/abstracts, evaluated full texts and extracted data. Discrepancies were resolved via discussion or consultation with a third reviewer (Li Xie). A standardized form was used to extract: ① Basic study information (first author, publication year, country of study, sample size, follow-up duration); ② Baseline characteristics of patients (age, gender, BMI (body mass index), stone size, stone location); ③ Details of intervention and control measures (type of access sheath, surgical method, laser type and parameters); ④ Outcome indicator data (specific values, standard deviations/standard errors, confidence intervals for the primary and secondary outcomes); ⑤ Information related to risk of bias assessment (randomization method, allocation concealment, blinding implementation, etc.).

*Risk of bias assessment*

Two reviewers (Guo Chen and Li Xie) independently assessed risk of bias using design-specific tools.

For RCTs: the Cochrane Risk of Bias 2.0 (RoB 2.0) tool was used to evaluate randomization process, deviations from interventions, missing outcome data, outcome measurement and selective reporting. Each domain was rated as low risk, some concerns or high risk.

For non-randomized studies: the ROBINS-I tool was used to assess confounding, participant selection, intervention classification, intervention deviations, missing data, outcome measurement and selective reporting. Overall risk was classified as low, moderate, serious or critical.

Discrepancies were resolved by discussion or a third reviewer (Bo Wu) [9].

*Statistical analysis*

All analyses were performed using Stata 17.0 with a significance level of $\alpha$=0.05.

*Pairwise meta-analysis*

Standard pairwise meta-analysis was conducted for direct comparisons. Heterogeneity was quantified using the $I^2$ statistic and Cochrane's Q test: $I^2 \leq 25\%$ (low), 25%-50% (moderate), ≥50% (high). A fixed-effects model was used for $I^2<50\%$ and $P>0.05$; otherwise, a random-effects model was applied. Dichotomous outcomes were reported as relative risk (RR) with 95% confidence interval (CI); continuous out-

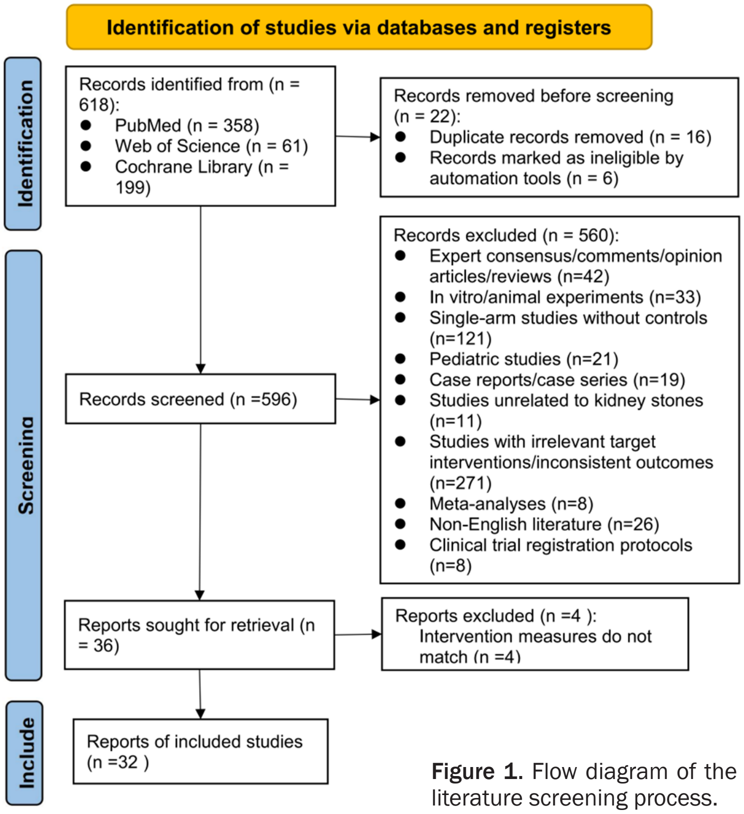


**Figure 1.** Flow diagram of the literature screening process.

comes were reported as mean difference (MD) or standardized mean difference (SMD) with 95% CI.

*Network meta-analysis*

A frequentist random-effects model was used to account for clinical and methodological heterogeneity. Network structure was visualized graphically. Global inconsistency was tested using the node-splitting model (P>0.05 indicated consistency). The surface under the cumulative ranking curve (SUCRA) was used to rank interventions based on the primary outcome (1-month SFR). Higher SUCRA values indicated a higher likelihood of being the optimal intervention. SUCRA rankings were unadjusted for confounders.

*Convergence and model diagnostics*

A supplementary Bayesian analysis with MCMC (non-informative priors, 20,000 iterations, 5,000 burn-in) was performed to verify model stability. Convergence was confirmed by a potential scale reduction factor <1.05 (Brooks-Gelman-Rubin diagnostic).

*Subgroup and sensitivity analyses*

Preplanned subgroup analyses were conducted by study design (RCT vs. non-RCT), stone size (<2 cm vs. ≥2 cm) and suction sheath type (FANS/FV-UAS vs.TFS-UAS/others). Leave-one-out sensitivity analysis was performed by sequentially excluding each study to assess result robustness.

*Publication bias*

Publication bias was assessed using funnel plots, Egger's test and Begg's test (P>0.05 indicated no significant bias). Meta-regression was conducted for operative time (13 studies) using stone size and study design as covariates. Meta-regression was not performed for other outcomes due to limited studies (n≤4). High heterogeneity was discussed qualitatively in the Discussion section.

## Results

*Literature screening process and results*

The literature screening process strictly followed the PRISMA guidelines. A total of 612 relevant records were initially retrieved, and 596 remained after removing duplicates. After title and abstract screening, 560 records were excluded. The full texts of the remaining 36 studies were reviewed, and a further 21 studies were excluded. Finally, 18 studies [10-27] were included in the network meta-analysis, including 7 randomized controlled trials, 3 prospective non-randomized studies, and 8 retrospective studies. The literature screening process is shown in **Figure 1**.

*Characteristics of included studies*

Eighteen studies [10-27] with 4,987 patients were included, consisting of 7 randomized controlled trials, 3 prospective non-randomized studies, and 8 retrospective studies. All participants were patients with kidney stones, with stone locations covering the renal pelvis and calyces, and stone sizes ranging from 1 cm to 3.5 cm.

In all included studies, the experimental intervention was tip-flexible suction ureteral access sheath combined with flexible ureteroscopic holmium laser lithotripsy. Suction sheath types included flexible vacuum-assisted ureteral access sheath, flexible and navigable suction ureteral access sheath, tip-flexible suction ureteral access sheath, and new-type tip-flexible suction ureteral access sheath.

Control interventions included traditional ureteral access sheath (10 studies), mini-percutaneous nephrolithotomy (4 studies), standard percutaneous nephrolithotomy (1 study), extracorporeal shock wave lithotripsy (1 study), sheathless retrograde intrarenal surgery (1 study), and suction mini-percutaneous nephrolithotomy (1 study).

The primary outcome was 1-month stone-free rate, and secondary outcomes included operative time and postoperative fever. Baseline characteristics of each study are detailed in **Table 1**.

*Risk of bias assessment results of included studies*

Seven RCTs were assessed using the RoB 2.0 tool, and 11 non-randomized studies (3 prospective, 8 retrospective) were evaluated with the ROBINS-I tool.

For RCTs, 4 (57.1%) had low risk in random sequence generation. Allocation concealment and participant blinding were difficult to implement due to surgical characteristics, and were rated as high risk or with some concerns. Outcome assessment blinding was mostly at low risk, as stone-free rate was evaluated by blinded assessors using CT. Overall risk of bias was low in 2 studies, moderate in 3 studies, and high in 2 studies (mainly due to insufficient allocation concealment).

For non-randomized studies, bias mainly derived from confounding control and outcome measurement. Based on ROBINS-I, 4 studies (36.4%) had moderate risk of bias, 5 (45.5%) had serious risk, and 2 (18.2%) had critical risk. Studies using matching or weighting showed relatively lower risk of bias, as shown in **Table 2**.

*Results of meta-analysis for clinical efficacy and safety comparison*

*Evidence network structure*

Five interventions were included to establish the evidence network. In the network plot, node size is proportional to the cumulative sample size of each intervention, and edge width is positively correlated with the number of direct comparative studies between two interventions.

The overall network showed a star-shaped structure. The suction ureteral access sheath had direct pairwise comparisons with all other interventions. Specifically, there were 11 direct comparative studies between suction sheath and traditional ureteral access sheath (the most frequent pairwise comparison), and 5 direct comparative studies between suction sheath and mPCNL/PCNL. The suction sheath had one direct comparative study with ESWL and one with SM-PCNL, providing limited direct evidence.

No direct comparisons were identified among traditional UAS, mPCNL/PCNL, ESWL, and SM-PCNL. All interventions could be indirectly compared via the suction sheath as a common node. The full connectivity and stable structure of the evidence network are displayed in **Figure 2**.

*Network meta-analysis*

*Stone-free rate:* (1) Pairwise meta-analysis of direct comparisons: Direct comparisons were analyzed using random-effects models (Supplementary Figures 1, 2, 3). Suction sheath vs. traditional UAS: Suction sheath yielded higher SFR (OR=2.65, 95% CI 1.77-3.97, $P<0.001$, $I^2=48.0\%$). Suction sheath vs. mPCNL/PCNL: SFR was comparable (OR=1.02, 95% CI 0.75-1.38, P=0.922, $I^2=0.0\%$). Suction sheath vs. ESWL: Suction sheath was superior (OR=3.87, 95% CI 1.71-8.77, P=0.001). Suction sheath improves SFR vs. traditional UAS and ESWL, with similar efficacy to mPCNL/PCNL.

**Table 1.** Basic characteristics of the included studies

| No. | First author (year) | Country | Sample size (E/C) | Control group (age, stone size) | Experimental group (age, stone size) | Control intervention | Experimental intervention | Operative time (min, E vs. C) | Outcome codes | Complications (control) | Complications (experimental) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Men C (2024) [10] | China | 76/73 | 48.7±9.0 y, 16.1±3.4 mm | 49.2±8.6 y, 15.4±3.2 mm | ESWL | RIRS + FV-UAS + Ho:YAG laser | 65.3±6.4 vs. 25.3±7.8 | ①, ⑫, ②, ⑧ | A(4), B(1), G(2), ⑫ (2) | A(2), B(1) |
| 2 | Wang DJ (2024) [11] | China | 80/80 | 48.3±7.2 y, 2.5±0.5 cm | 49.7±8.3 y, 2.4±0.4 cm | MPCNL + Ho:YAG laser | RIRS + FV-UAS + Ho:YAG laser | 66.7±5.2 vs. 65.3±5.6 | ①, ②, ⑦, ③ | A(2), J(2) | A(4), B(5), J(13), C(2) |
| 3 | Zhu W (2024) [12] | China, Malaysia, Philippines, Turkey | 160/160 | 52.0 (40.0-61.8) y, 11.0 (9.0-16.0) mm | 53.0 (45.0-64.0) y, 14.0 (10.0-20.0) mm | Traditional UAS + basket | S-UAS + suction | 45.0±23.2 vs. 40.9±19.1 | ①, ②, ③, ⑬, ⑭ | A(28), B(1), G(2), C(1) | A(9), G(1) |
| 4 | Arikan O (2025) [13] | Turkey | 105/102 | 49.1±15.0 y, 12 (6-20) mm | 46.6±15.0 y, 13 (7-20) mm | Traditional UAS | FV-UAS + suction | 50 (15-90) vs. 57.5 (25-90) | ①, ②, spec | B(4), D(2), A(19) | B(4), D(2), A(4) |
| 5 | Cacciatore L (2025) [14] | Italy | 62/70 | 57.1 (47.5-68.3) y, 13.5 (10.8-20.0) mm | 63.3 (48.7-71.5) y, 13.5 (10.0-24.3) mm | Traditional UAS + basket | FANS + suction | 55.3 (43.7-118.4) vs. 61.4 (46.7-125.4) | ①, ②, ⑥, ⑫, ⑧, ③ | B(14), A(4), D(1) | B(5), A(1) |
| 6 | Chen Y (2025) [15] | China | 49/53 | 55.7±12.3 y, 2.54±0.38 cm | 54.2±10.4 y, 2.42±0.52 cm | mPCNL + Ho:YAG laser | SUAS + f-URL + Ho:YAG laser | 58.6±27.8 vs. 44.3±18.4 | ①, ⑤, ②, ⑧, ⑦, ③, ④ | Mostly Clavien I, few II | Similar |
| 7 | Cormio A (2025) [16] | Italy, Russia, India, Mexico, Philippines, Bulgaria, Japan, Morocco, Turkey, Spain, Greece, Egypt, Chile, Saudi Arabia, Brazil, UK, Switzerland, South Africa, Singapore (21 countries) | 686/686 | 49 (38-60) y, 1.4 (0.8-2.1) $cm^3$ | 50 (36-61) y, 1.4 (0.8-2.1) $cm^3$ | SM-PCNL | FANS + laser | 46 (37-61) vs. 40 (27-66) | ①, ②, ⑧, ③, ⑫ | A (obs 3.2%/ AB 6.0%), B (0.3%) | A (obs 2.1%/ AB 3.1%), B (0.1%) |
| 8 | Gao JG (2025) [17] | China | 167/170 | 56.3±11.0 y, 2-3.5 cm | 54.3±12.3 y, 2-3.5 cm | PCNL | NFTS-UAS + FURS | 80.0±29.4 vs. 98.9±28.8 | ②, ③, ①, ⑨ | A(91), G(6), C(1), I(1) | A(10), E(11), F(10) |
| 9 | Hu HY (2025) [18] | China | 71/119* | 54 (47-60) y, 16 (13-18) mm | 55 (38-61) y, 16 (14-19) mm | 9.2 Fr + Traditional UAS | 7.5 Fr + TFS-UAS | 48 (40-55) vs. 74 (56-94) | ②, ⑥, ① | A(18), J(19), C(5), F(3), K(7) | A(4), J(3), D(5) |
| 10 | Liu GQ (2025) [19] | China | 35/41 | 54.7±10.0 y, 30.8±4.3 mm | 52.7±9.1 y, 30.1±4.1 mm | PCNL | FANS + su-fURS | 135.5±39.8 vs. 99.4±27.5 | ①, ②, ⑧, ⑦, ③, ④ | K (2 grade II, 1 grade III) | K (1 grade II) |
| 11 | Liu YQ (2025) [20] | China | 101/102 | 43.2±5.7 y, 1.5±0.5 cm | 44.5±6.1 y, 1.6±0.4 cm | Traditional UAS + RIRS | FV-UAS + RIRS | 53.7±4.9 vs. 54.8±5.1 | ①, ②, ③, ④ | A(9), G(5), C(8) | A(2), C(1) |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 12 | Luo DX (2025) [21] | China | 33/33 | 53.4±14.5 y, <2 cm | 50.6±13.9 y, <2 cm | Traditional UAS + NAES | FANS + NAES | 100.8±25.3 vs. 116.2±35.6 | ①, ②, ⑦, ③, ⑩, ⑫ | B(1), I(1) | A(1) |
| 13 | Mazzon G (2025) [22] | UK, Italy, Singapore, Canada, Turkey, Egypt, India, Hong Kong (China) | 184/184 | 57 (50-67) y, 1.40 (1.09-1.70) cm³ | 56 (48-66) y, 1.40 (0.70-2.30) cm³ | CUAS + Ho:YAG laser | FANS + TFL | 49.99 (23.56) vs. 50.02 (15.71) | ①, ⑥, spec, ②, ⑯, ⑬, ⑫, ③ | B(2), J(26) | D(5), A(1) |
| 14 | Rico L (2025) [23] | Argentina | 48/48 | 57 (48-67) y, 805 (550-1073) mm³ | 54 (41-67) y, 895 (627-1100) mm³ | c-UAS + TFL | FANS + TFL | 33.5 (26.3-44.5) vs. 57.5 (40-65) | ⑮, ②, ⑥, ①, ⑯ | K (3, ≤ grade 2) | K (2, ≤ grade 2) |
| 15 | Wu CL (2025) [24] | China | 136/132 | Balanced, 2.68±0.24 cm | Balanced, 2.71±0.22 cm | Traditional UAS | F-UAS | 51.0±13.9 vs. 59.8±18.2 | ①, ②, ⑦, ③, spec | A(11), spec(9), B(4) | A(6), spec(4), B(7) |
| 16 | Zeng GH (2026) [25] | China, Turkey, Russia, India, Malaysia | 360/360 | 55 (48-62) y, 25 (22-29) mm | 53 (47-62) y, 25 (23-28) mm | mPCNL | FANS + f-URS | 88 (median) vs. 59 (median) | ①, ②, ③, ⑫, ⑭ | B(9), G(5), I(3), C(15), spec(1) | B(1), C(12), spec(1) |
| 17 | Zhao JY (2025) [26] | China | 69/83 | 44.8±12.6 y, 1.3±0.45 cm | 45.7±12.3 y, 1.4±0.49 cm | Traditional UAS + basket | Bendable suction sheath | 119.8±10.4 vs. 93.2±9.8 | ②, ①, ④, ⑦, ③ | 8 cases | 5 cases |
| 18 | Zhu ZJ (2025) [27] | China | 36/33 | Balanced, 1.64±0.24 cm | Balanced, 1.64±0.24 cm | Traditional UAS + FURS | FANS + FURS | 63.0±8.2 vs. 73.9±15.6 | ①, ②, ③ | - | - |

Note: E = experimental group (suction UAS); C = control group. Outcome codes: ① = 1-month SFR, ② = operative time, ③ = complications, ④ = hospital stay, ⑤ = anesthesia time, ⑥ = postoperative pain/fever, ⑦ = hospitalization cost, ⑧ = hemoglobin drop, ⑨ = infection markers, ⑩ = retreatment rate, ⑪ = intrarenal pressure, ⑫ = stone-free rate (immediate or other), ⑬ = basket use, ⑭ = quality of life, ⑮ = laser efficiency, ⑯ = stenting duration, ⑰ = irrigation volume, ⑱ = systemic inflammatory response syndrome (SIRS), ⑲ = surgical success rate, spec = study-specific outcome. Complication codes: A = fever, B = hematuria/bleeding, C = urosepsis, D = ureteral injury, E = steinstrasse, F = stricture, G = perirenal hematoma, H = urine leakage, I = embolization, J = pain, K = other (infection or minor complications). *For Hu HY (2025), the effective sample size after excluding conversions is shown.

**Table 2.** Risk of bias assessment results for the 18 included studies

| No. | First author (year) | Study design | Assessment tool | Random sequence generation | Allocation concealment | Blinding of participants | Blinding of outcome assessment | Incomplete outcome data | Selective reporting | Confounding control | Overall risk of bias |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Men C (2024) [10] | RCT | RoB 2.0 | Low | High | High | Low | Low | Low | - | Moderate |
| 2 | Wang DJ (2024) [11] | RCT | RoB 2.0 | Low | High | High | Low | Low | Low | - | Moderate |
| 3 | Zhu W (2024) [12] | RCT | RoB 2.0 | Low | Moderate | High | Low | Low | Low | - | Moderate |
| 4 | Arikan O (2025) [13] | RCT | RoB 2.0 | Low | Moderate | High | Low | Low | Low | - | Moderate |
| 5 | Cacciatore L (2025) [14] | RCT | RoB 2.0 | Low | High | High | Low | Low | Low | - | Moderate |
| 6 | Chen Y (2025) [15] | RCT | RoB 2.0 | Low | High | High | Low | Low | Low | - | Moderate |
| 7 | Cormio A (2025) [16] | RCT | RoB 2.0 | Low | Low | High | Low | Low | Low | - | Low |
| 8 | Gao JG (2025) [17] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 9 | Hu HY (2025) [18] | Prospective | ROBINS-I | - | - | - | Moderate | - | - | Moderate | Moderate |
| 10 | Liu GQ (2025) [19] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 11 | Liu YQ (2025) [20] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 12 | Luo DX (2025) [21] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 13 | Mazzon G (2025) [22] | Retrospective (PSM) | ROBINS-I | - | - | - | Moderate | - | - | Moderate | Moderate |
| 14 | Rico L (2025) [23] | Prospective | ROBINS-I | - | - | - | Moderate | - | - | Moderate | Moderate |
| 15 | Wu CL (2025) [24] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 16 | Zeng GH (2026) [25] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 17 | Zhao JY (2025) [26] | Retrospective | ROBINS-I | - | - | - | Serious | - | - | Serious | Serious |
| 18 | Zhu ZJ (2025) [27] | Retrospective (IPTW) | ROBINS-I | - | - | - | Moderate | - | - | Moderate | Moderate |

Notes: "-" indicates not applicable for that domain. PSM = propensity score matching; IPTW = inverse probability of treatment weighting.

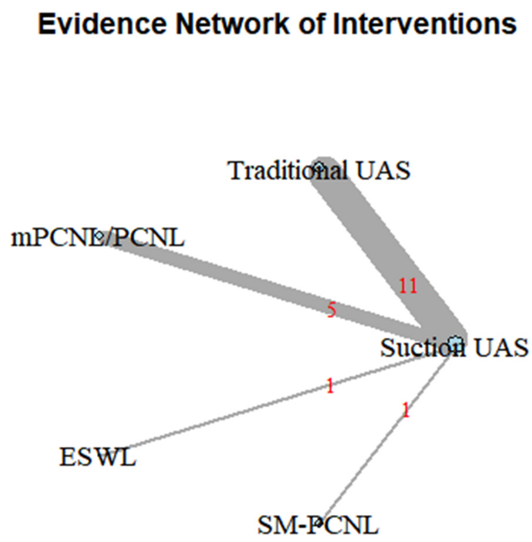


**Figure 2.** Evidence network of included interventions. Node size is proportional to the total sample size of each intervention; edge width is proportional to the number of direct comparison studies between two interventions.

(2) Network meta-analysis: Network meta-analysis was performed with traditional UAS as reference (**Figure 3A**). Global heterogeneity supported random-effects model ($\tau^2$=0.2038, $I^2$=48.0%, P=0.038). Indirect comparison showed similar SFR between traditional UAS and mPCNL/PCNL (OR=1.02, 95% CI 0.75-1.38), while ESWL had lower SFR (OR=0.38, 95% CI 0.21-0.69). Suction sheath had lower SFR than SM-PCNL (OR=0.23, 95% CI 0.18-0.29). SUCRA ranking: suction sheath (0.84) > mPCNL/PCNL (0.76) > traditional UAS (0.31) >ESWL (0.07) (**Figure 3B**). Funnel plot and Egger's test suggested potential small-study effects (P=0.005) (**Figure 3C**). Trim-and-fill analysis (Supplementary Figure 4) confirmed the robustness of suction sheath superiority (corrected OR=2.129, P=0.0015). Exclusion of Cacciatore (2025) or Mazzon (2025) did not alter the conclusion.

*Operative time:* Network meta-analysis included 13 studies with traditional UAS as reference (**Figure 4A**). Indirect comparison showed longer operative time for traditional UAS vs. ESWL (MD=40.31 min, 95% CI 9.93-70.69, P=0.009). No differences were found between traditional UAS and MPCNL/PCNL, or between suction sheath and traditional UAS (MD=0.31 min, 95% CI -10.64 to 11.25, P=0.956). Extreme heterogeneity was observed ($I^2$=98.1%). Meta-regression with stone size and study design failed to explain heterogeneity (residual $I^2$>99%, Supplementary Figure 5). Variation may stem from stone burden, operative definition, devices, or experience. SUCRA ranking: ESWL (0.974) >MPCNL (0.676) >PCNL (0.415) > suction sheath (0.218) > traditional UAS (0.217) (**Figure 4B**). Funnel plot showed no publication bias (**Figure 4C**). Leave-one-out analysis confirmed

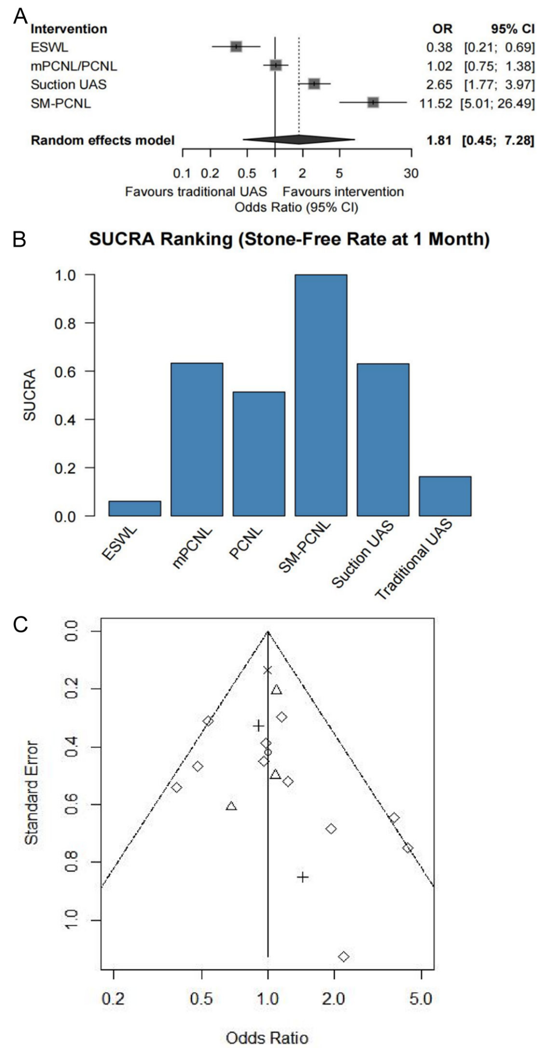


**Figure 3.** Network meta-analysis of stone-free rate. A. Forest plot of suction sheath versus traditional UAS (reference) for stone-free rate. Squares represent individual studies; the diamond represents the pooled effect size; horizontal lines indicate 95% confidence intervals; the dashed vertical line indicates the line of no effect (OR=1). B. SUCRA ranking of five interventions based on 1-month stone-free rate. C. Funnel plot for publication bias of direct comparisons between suction sheath and traditional UAS.

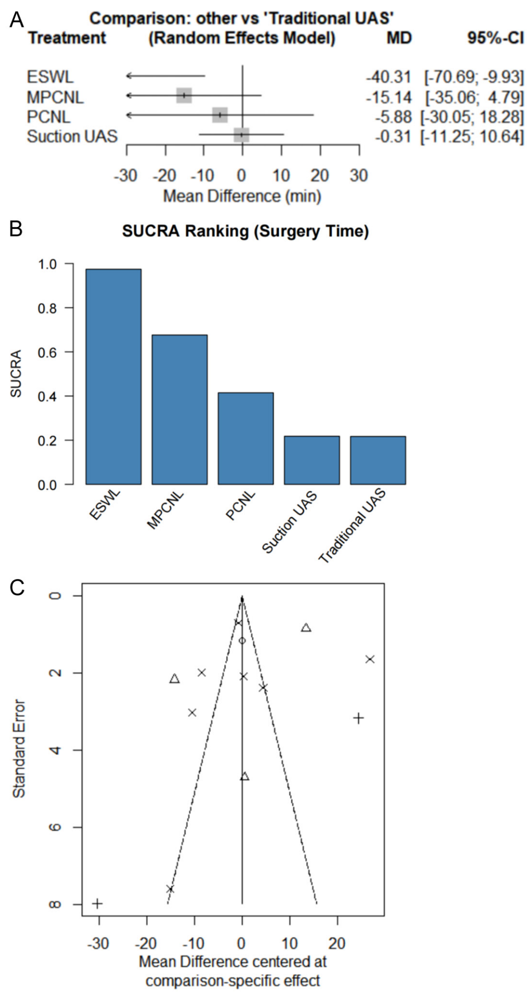


**Figure 4.** Network meta-analysis of operative time. A. Forest plot of operative time comparisons with traditional UAS as reference. B. SUCRA ranking of five interventions based on operative time. C. Funnel plot for publication bias of direct comparisons between suction sheath and traditional UAS. Each dot represents an individual study; the vertical dashed line indicates the pooled effect size; the diagonal dashed lines represent pseudo-95% confidence intervals around the summary effect.

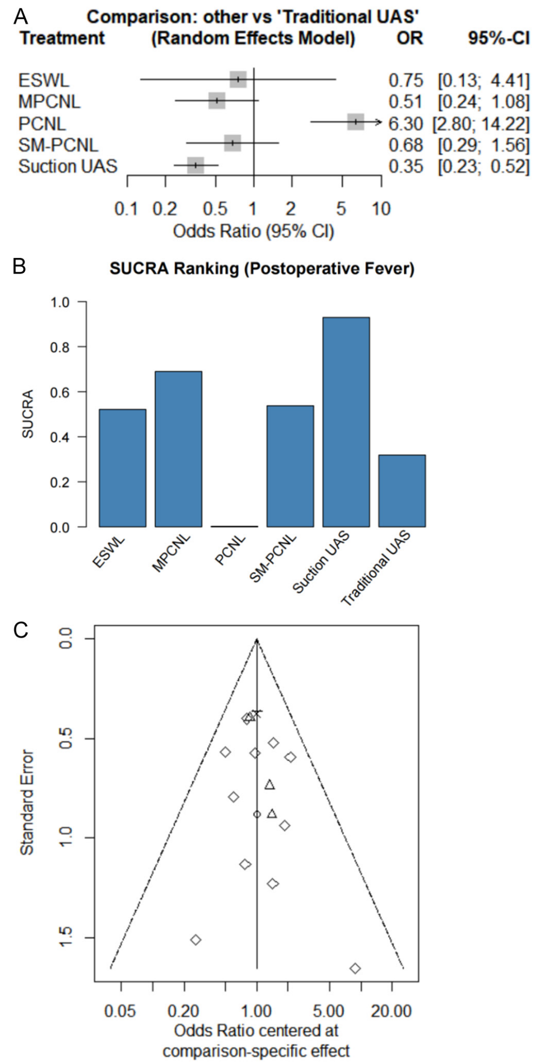


**Figure 5.** Network meta-analysis of postoperative fever. A. Forest plot of fever risk with traditional UAS as reference. B. SUCRA ranking of five interventions based on fever risk. C. Funnel plot for publication bias of direct comparisons between suction sheath and traditional UAS.

no single study drove heterogeneity; the non-inferiority conclusion was stable (Supplementary Figure 6).

*Postoperative complications:* Seventeen studies (4,911 patients) were analyzed with traditional UAS as reference (**Figure 5A**). Suction sheath reduced fever risk (OR=0.35, 95% CI 0.23-0.52, P<0.001). PCNL increased fever risk (OR=6.30, 95% CI 2.80-14.22, P<0.001). MPCNL, ESWL, and SM-PCNL showed no differences. Network heterogeneity was negligible ($I^2$=0.0%). SUCRA ranked suction sheath first in fever reduction (P-score=0.93), PCNL last (0.0025) (**Figure 5B**). Funnel plot and Egger's test confirmed no publication bias (**Figure 5C**).

## Pairwise meta-analysis

*Intraoperative blood loss:* Four studies (1,058 patients) compared suction sheath with PCNL/mPCNL (**Figure 6**). Suction sheath reduced hemoglobin drop (MD=-3.43 g/L, 95% CI -5.59 to -1.27, P=0.0018, $I^2$=81.5%). Heterogeneity may relate to PCNL tract size, operative time, or irrigation pressure. Leave-one-out analysis veri-

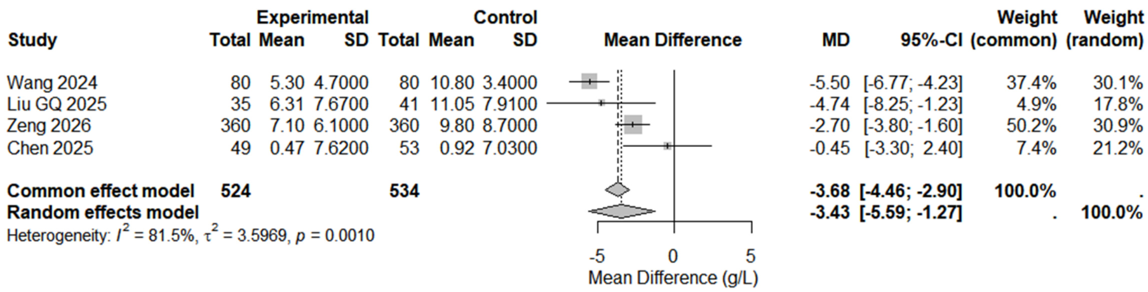


**Figure 6.** Pairwise meta-analysis of intraoperative blood loss (hemoglobin decrease) between suction sheath and PCNL/mPCNL groups.

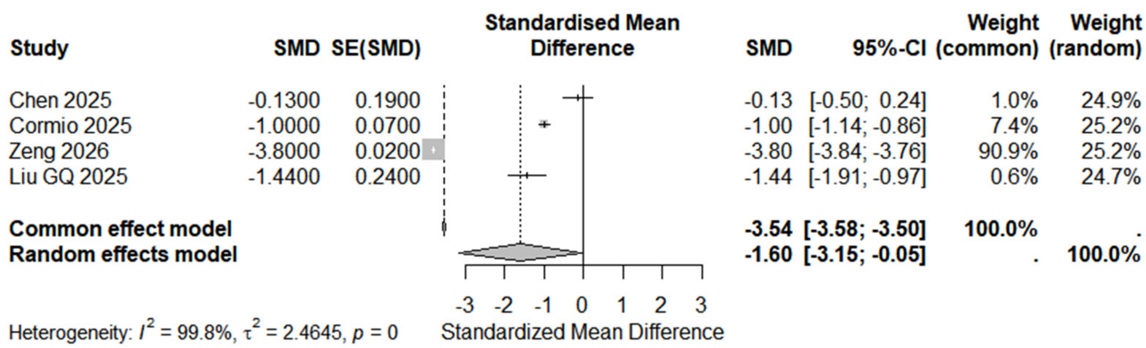


**Figure 7.** Pairwise meta-analysis of postoperative pain (VAS) between suction sheath and PCNL-related procedures.

fied the conclusion was robust; no single study caused heterogeneity.

*Postoperative pain comparison:* Four studies (1,425 patients) were analyzed (**Figure 7**). Suction sheath reduced pain (SMD=-1.60, 95% CI -3.15 to -0.05, P=0.0427), with extreme heterogeneity ($I^2$=99.8%) driven by Zeng (2026). Excluding this study rendered the result non-significant (SMD=-0.84, P>0.05). Leave-one-out analysis confirmed inconsistent evidence; pain reduction should be interpreted cautiously.

*Overall safety analysis:* Eighteen studies (4,987 patients) were included (**Figure 8A**). Suction sheath reduced complications (RR=0.35, 95% CI 0.24-0.50, P<0.001, $I^2$=57.6%). Sensitivity analysis confirmed stable results. Subgroup analysis (**Figure 8B**): traditional UAS (RR=0.38), PCNL (RR=0.12), mPCNL (RR=0.67), MPCNL (RR=0.11), SM-PCNL (RR=0.22), ESWL (RR=1.34). The pronounced benefit in the PCNL subgroup should be interpreted cautiously, as it may be influenced by between-study differences in baseline complication rates or stone complexity. Subgroup difference was significant (P<0.001). Suction sheath reduced complications vs. traditional UAS, PCNL, MPCNL, and SM-PCNL, but not ESWL. Suction sheath provides a safer profile than traditional procedures, especially vs. PCNL and conventional flexible ureteroscopy.

## Discussion

Kidney stones are solid crystals formed in the kidney due to excessive precipitation of urinary solutes. Multiple factors contribute to their formation, including genetics, dietary habits, fluid intake, and metabolic abnormalities [28]. The global prevalence of kidney stones has increased [29], and symptoms such as renal colic and urinary tract obstruction impair patients' quality of life. Treatment has shifted toward minimally invasive techniques, with flexible ureteroscopic lithotripsy and percutaneous nephrolithotomy as mainstream options. However, traditional procedures have limitations, including incomplete stone clearance and a considerable risk of complications [24]. The present network meta-analysis evaluated the clinical efficacy and safety of flexible ureteroscopic holmium laser lithotripsy assisted by a tip-flexible

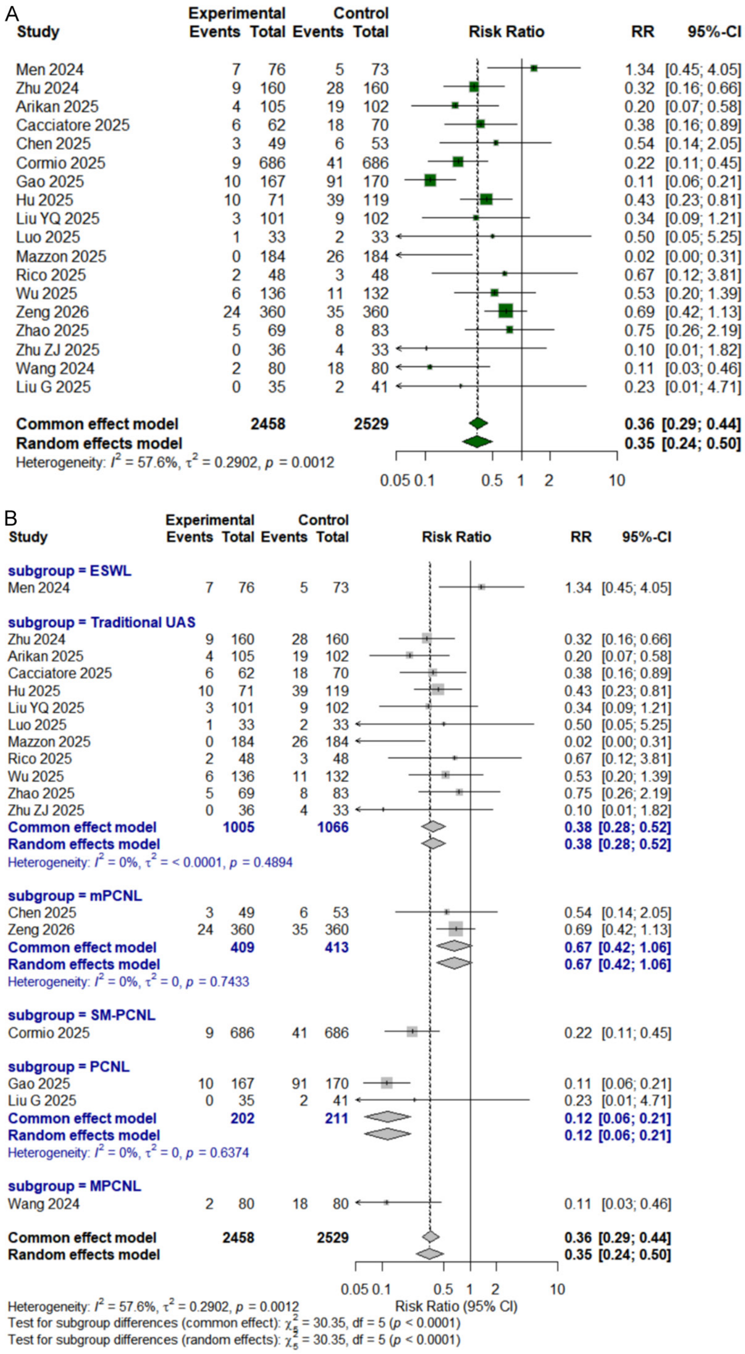


**Figure 8.** Pairwise meta-analysis of overall complications. A. Forest plot of overall complication risk between suction sheath and traditional modalities. B. Subgroup analysis by type of control intervention.

suction ureteral access sheath. This technique was compared with traditional ureteral access sheath, mini-percutaneous nephrolithotomy, and extracorporeal shock wave lithotripsy for kidney stones of 1-3 cm. The analysis included 18 studies: 7 randomized controlled trials, 3 prospective studies, and 8 retrospective studies.

*Stone-free rate*

The suction sheath group achieved a higher stone-free rate than the traditional ureteral access sheath group. This finding is consistent with previous studies showing that negative pressure suction improves stone clearance by actively removing debris and reducing residual fragments [7, 8, 12]. The pooled odds ratio from 11 direct comparisons was 2.65 in favor of the suction sheath. No statistically significant difference in stone-free rate was observed between the suction sheath group and the mini-percutaneous nephrolithotomy or percutaneous nephrolithotomy group. Similarly, an international multicenter randomized trial by Zeng and colleagues [30] reported comparable 30-day stone-free rates between flexible ureteroscopy with a navigable suction sheath and mini-percutaneous nephrolithotomy for 2-3 cm stones. The surface under the cumulative ranking curve for stone-free rate ranked suction sheath at 0.84, higher than traditional ureteral access sheath at 0.31 and extracorporeal shock wave lithotripsy at 0.07, while mini-percutaneous nephrolithotomy ranked at 0.76. Percutaneous nephrolithotomy is associated with a higher stone-free rate for larger stones [5, 24].

*Complications and safety*

The suction sheath group had a lower overall complication rate than the traditional ureteral access sheath group, with a pooled relative risk of 0.35. The incidence of postoperative fever was also reduced, with a relative risk of 0.35. These findings are supported by studies demonstrating that active suction reduces intrarenal pressure, thereby decreasing the risk of bacterial translocation and systemic inflammatory response [31]. In subgroup analyses, the advantage of the suction sheath was maintained in both the traditional flexible ureteroscopy subgroup and the percutaneous nephrolithotomy subgroup. For the percutaneous nephrolithotomy subgroup, the pooled relative risk was 0.288, indicating a reduction in complications when suction technology was applied. A prospective study by Wang and colleagues [32] compared flexible vacuum-assisted ureteral access sheath with mini-percutaneous nephrolithotomy for 2-3 cm stones and also found lower bleeding and pain rates in the suction sheath group.

*Intraoperative blood loss and postoperative pain*

Intraoperative blood loss, measured by hemoglobin decrease, was lower in the suction sheath group than in the percutaneous nephrolithotomy or mini-percutaneous nephrolithotomy group, with a mean difference of -3.43 g/L. This difference is expected because percutaneous nephrolithotomy requires a renal parenchymal puncture, which is typically associated with greater blood loss than a purely endoscopic procedure [19, 35]. Postoperative pain, assessed by the visual analog scale, was also lower in the suction sheath group compared with percutaneous nephrolithotomy-related procedures. A randomized controlled trial by Chen and colleagues [14] compared tip-bendable suction sheath-assisted flexible ureteroscopic lithotripsy with mini-percutaneous nephrolithotomy for 1-3 cm lower calyceal stones and reported lower pain scores and shorter hospital stays in the suction sheath group.

*Operative time*

Operative time did not differ significantly between the suction sheath group and the traditional ureteral access sheath group, with a mean difference of 0.31 minutes. This finding suggests that the addition of negative pressure suction and sheath tip flexibility does not prolong the procedure compared with conventional sheaths. In contrast, operative time was longer in the suction sheath group than in the mini-percutaneous nephrolithotomy group, with a standardized mean difference of 0.581. This difference reflects the higher fragmentation efficiency of direct percutaneous access, which allows faster stone disintegration and removal [19, 25]. High heterogeneity was observed for operative time across studies, with an $I^2$ value of 98.1%. Potential sources of this heterogeneity include variations in the definition of operative time, differences in stone burden and location, and differences in surgeon experience [20, 27, 28].

High heterogeneity was observed for operative time ($I^2$=98.1%) and postoperative pain ($I^2$=92.6%). For operative time, we performed a random-effects meta-regression with mean stone size and study design as covariates. Neither covariate was statistically significant, and the residual $I^2$ exceeded 99% in all models, indicating that these factors did not explain the substantial between-study variation. Other potential contributors include differences in the definition of operative time [12, 18], stone hardness [22], suction sheath models and negative pressure settings [31, 32], and surgeon experience. Subgroup and leave-one-out sensitivity analyses confirmed that no single study dominated the results.

For postoperative pain, meta-regression was not feasible because only four studies reported this outcome. The extreme heterogeneity was largely driven by a single study conducted by Zeng in 2026 that adopted FANS, which reported an effect size much larger than the others (SMD=-3.80). Excluding this study in a sensitivity analysis reduced $I^2$ to 84.7% and yielded a non-significant pooled estimate (SMD=-0.84, 95% CI -1.97 to 0.29), suggesting that the evidence for reduced postoperative pain with suction sheaths is not robust. Other potential sources include differences in analgesic protocols, pain assessment timing, and the degree of surgical trauma across comparator procedures.

Overall, despite the unexplained heterogeneity for operative time, subgroup and sensitivity analyses confirmed that the main conclusions remained stable across different study designs and stone sizes: improved stone-free rate, reduced complications, and comparable operative time.

*Clinical implications*

Based on the available evidence, suction sheath-assisted flexible ureteroscopic lithotripsy may be considered a valid option for kidney stones equal to or smaller than 2 cm. This technique achieves a stone-free rate comparable to mini-percutaneous nephrolithotomy but with fewer complications and less trauma than percutaneous approaches [15, 21, 33]. For stones of 2 to 3 cm, suction sheath-assisted flexible ureteroscopic lithotripsy provides an alternative for patients who are unsuitable for or decline percutaneous nephrolithotomy, such as those receiving anticoagulant therapy, those with thin renal parenchyma, or those with anomalous kidneys [18]. Reduced intraoperative blood loss and a lower postoperative fever rate further support this choice. For patients with very hard stones or complex lower calyceal anatomy, percutaneous nephrolithotomy may still achieve a shorter operative time, and the choice of procedure should be individualized [19, 25, 34].

*Limitations*

Several limitations should be acknowledged. First, the inclusion of non-randomized studies may have introduced selection and confounding bias. These studies include three prospective and eight retrospective studies. However, sensitivity analyses restricted to randomized controlled trials showed the same direction of effect. This suggests that the overall conclusions are not solely driven by study design. Second, blinding of participants and personnel was not feasible due to the nature of the surgical procedures. This may have introduced performance bias. This issue is common in surgical trials and has been recognized in previous urological meta-analyses [8, 29]. Third, the high heterogeneity for operative time could not be fully explained by the available subgroup analyses. Therefore, the operative time results should be interpreted with caution. Fourth, follow-up durations were short. Most studies reported only the one-month stone-free rate. Long-term outcomes such as stone recurrence and preservation of renal function remain unknown [35]. Fifth, the surface under the cumulative ranking curve rankings reflect relative probabilities. They were not adjusted for potential confounders. Sixth, publication bias was suggested by Egger's test for stone-free rate. However, trim-and-fill sensitivity analysis confirmed that the conclusion regarding the superiority of the suction sheath remained statistically significant. Finally, meta-regression for operative time was performed but did not explain the high heterogeneity (residual $I^2 >$ 99%). Meta-regression for postoperative pain was not feasible due to the limited number of studies (n=4). Some sources of heterogeneity were explored only qualitatively.

*Strengths*

This study has several strengths. It is the first network meta-analysis to specifically compare tip-flexible suction sheaths with multiple treatment comparisons. The comparators include traditional ureteral access sheath, mini-percutaneous nephrolithotomy, percutaneous nephrolithotomy, and extracorporeal shock wave lithotripsy. The analysis exclusively targeted pure renal stones of 1 to 3 cm using rigorous eligibility criteria. Appropriate risk of bias tools were used: RoB 2.0 for randomized controlled trials and ROBINS-I for non-randomized studies. Extensive sensitivity and subgroup analyses were performed to test the robustness of the findings. The low heterogeneity for the primary efficacy and safety outcomes supports the main conclusions.

## Conclusions

This network meta-analysis, based on 18 studies, compared the efficacy and safety of five minimally invasive modalities for 1-3 cm kidney stones. The tip-flexible suction ureteral access sheath-assisted flexible ureteroscopic holmium laser lithotripsy achieved a stone-free rate comparable to mini-percutaneous nephrolithotomy. It also had a lower overall complication rate and reduced intraoperative blood loss. Operative time did not differ from that of traditional ureteral access sheath-assisted procedures. However, it was longer than that of mini-percutaneous nephrolithotomy.

For kidney stones ≤2 cm, suction sheath-assisted flexible ureteroscopic lithotripsy may be considered a preferred option based on its stone-free rate and safety profile. For stones of 2-3 cm, it represents an alternative for patients who are not candidates for percutaneous nephrolithotomy. Such patients include those with coagulation disorders or thin renal parenchyma.

The present study has limitations, including the inclusion of non-randomized studies, lack of blinding, high heterogeneity for operative time, and short follow-up durations. Sensitivity analyses and publication bias assessment supported the robustness of the main findings. Future large-sample, long-term, multicenter randomized controlled trials are needed to further evaluate the role of this technique in special populations and complex stone cases.

## Disclosure of conflict of interest

None.

**Address correspondence to:** Guo Chen, Department of Urology, Pidu District People's Hospital of Chengdu, No. 666 North Deyuan 2nd Road, Pidu District, Chengdu 611730, Sichuan, China. Tel: +86-28-87883582-8310; E-mail: chenguo121747@163.com

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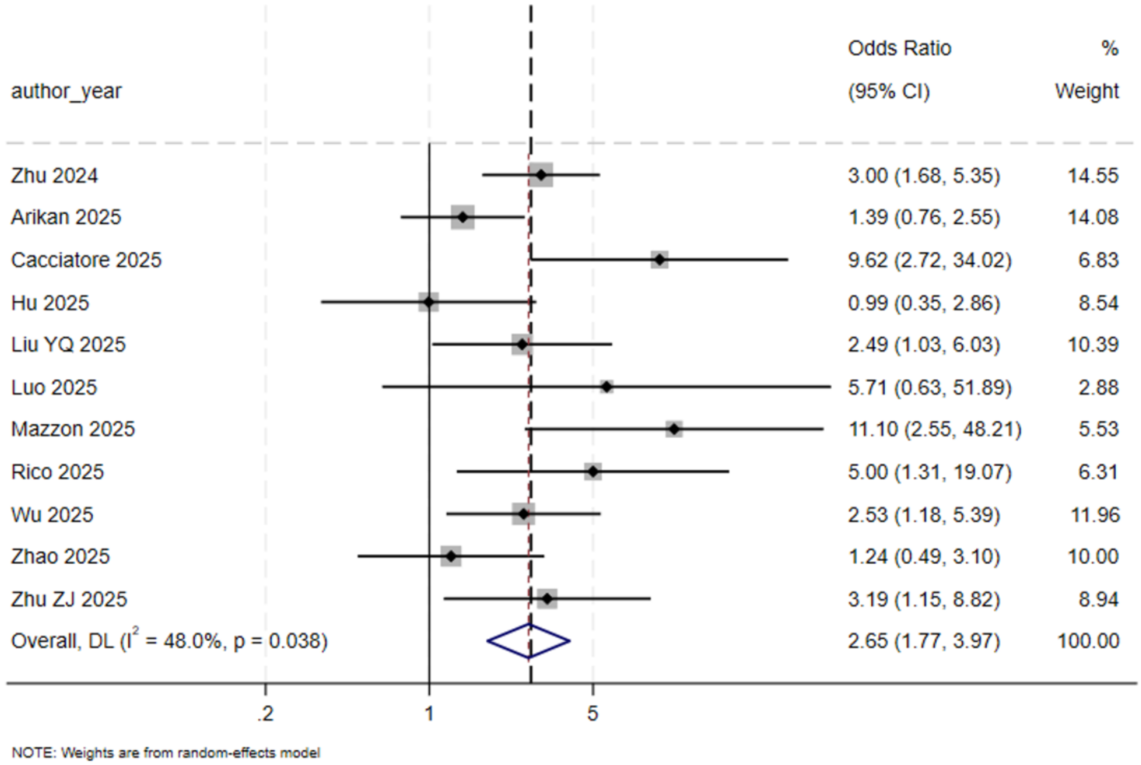
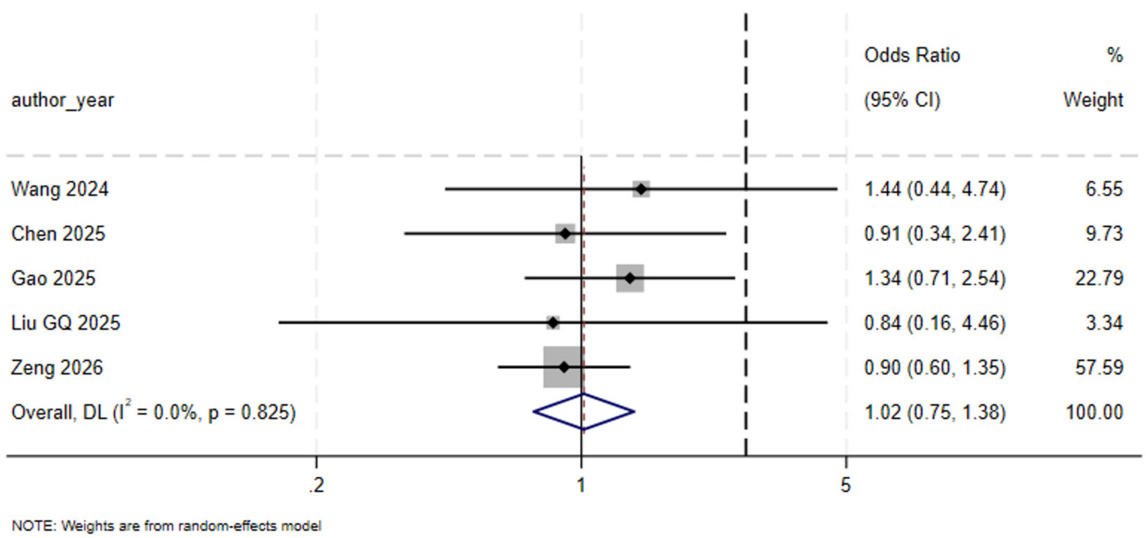
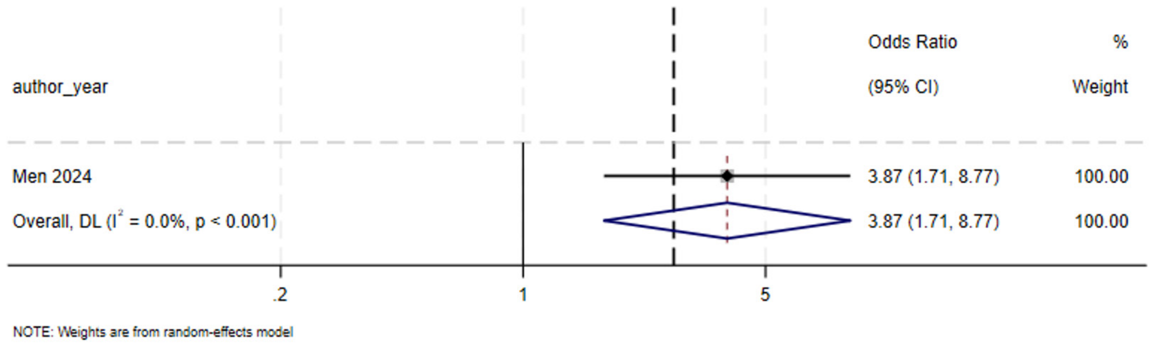


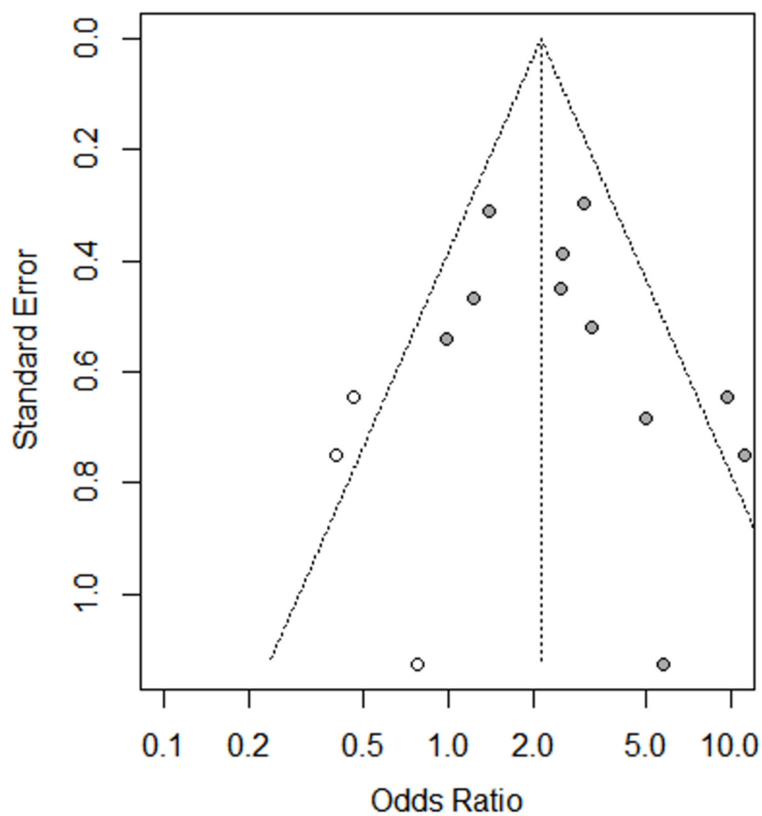

**Supplementary Figure 1.** Forest plot of direct comparison for stone-free rate between suction sheath and traditional UAS.



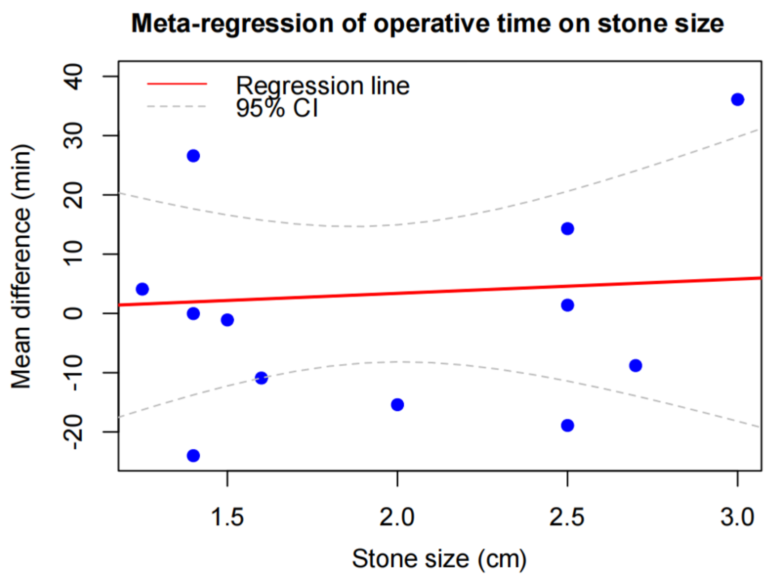

**Supplementary Figure 2.** Forest plot of direct comparison for stone-free rate between suction sheath and mPCNL/PCNL.



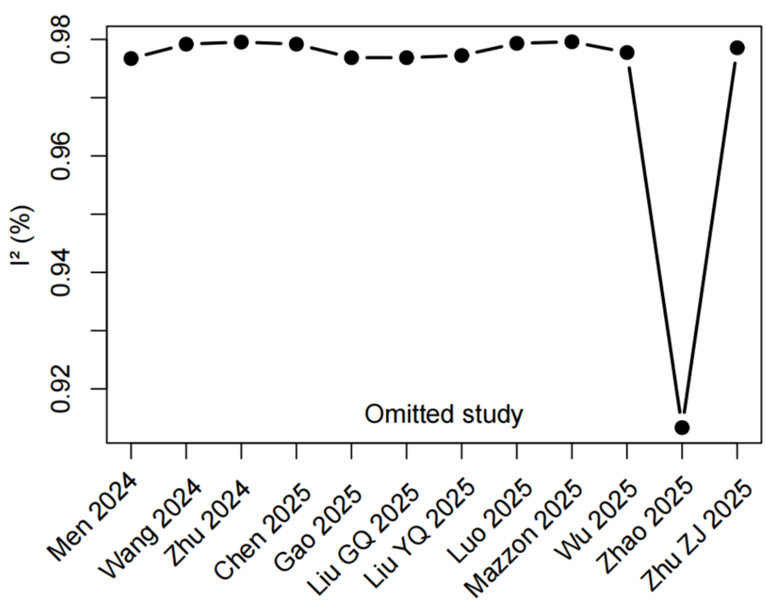

**Supplementary Figure 3.** Forest plot of direct comparison for stone-free rate between suction sheath and ESWL (single study: Men 2024).




**Supplementary Figure 4.** Trim-and-fill sensitivity analysis for stone-free rate between suction sheath and traditional UAS.




**Supplementary Figure 5.** Bubble plot of the meta-regression examining the association between mean stone size (cm) and mean difference in operative time (suction sheath minus traditional sheath). Each circle's area is proportional to the study's weight (inverse variance). The solid red line represents the predicted regression line, and the dashed gray lines show the 95% confidence interval. The high residual heterogeneity ($I^2$=99.2%, p for residual heterogeneity <0.001) indicates that stone size does not significantly explain the between-study variance.




**Supplementary Figure 6.** Leave-one-study-out network meta-analysis for operative time. The plot shows the global $I^2$ statistic after sequentially omitting each study that reported operative time as mean±SD. The dashed red line indicates the upper threshold for moderate heterogeneity ($I^2$=75%). $I^2$ remained above 91% in all iterations, with no single study reducing it below the threshold, indicating that the high heterogeneity ($I^2$=98.1% in the full network) is not driven by any individual study.