INPLASY PROTOCOL

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None declared.

Efficacy and safety of surgery for kidney stones larger than 2cm: a systematic review and net meta-analysis

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Review question / Objective: **To systematically evaluate the clinical efficacy and safety of PCNL, mPCNL, eSMP, RP, and RIRS for the treatment of > 2 cm kidney stones.**
Eligibility criteria: **Literature Inclusion Criteria1) Study type: RCTs with >2 cm kidney stones treated surgically and stone-free rate or complications reported in the study (clavien-dindo classification); 2) Study population: age >18 years, no gender, race, or etiology restrictions; 3) Interventions: percutaneous nephrolithotomy (PCNL), mini-PCNL (mPCNL), Enhanced super-mini-PCNL (eSMP), retroperitoneal pelvic dissection for stone extraction (RP), retrograde intrarenal surgery (RIRS). exclusion criteria1) types of studies such as reviews, retrospective studies, cohort studies, etc.; 2) literature other than English, repeated publications or conference abstracts, etc.; 3) Article on percutaneous nephrolithotomy regarding lithotripsy machines, dilation methods, and puncture sites; 4) animal experiments.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 July 2022 and was last updated on 24 July 2022 (registration number INPLASY202270106).

INTRODUCTION

Review question / Objective: **To systematically evaluate the clinical efficacy and safety of PCNL, mPCNL, eSMP, RP, and RIRS for the treatment of > 2 cm kidney stones.**

Condition being studied: **The global incidence of kidney stones has been on the rise over the past few decades, ranging from 7-13% in North America, 5-9% in Europe, and 1-5% in Asia. According to the EAU guidelines, the surgical procedures for kidney stones are PCNL, RIRS and RP, while PCNL is recommended for >2 cm kidney stones. With the advancement of medical knowledge and technological innovation, PCNL began to change from the traditional working channel (inner**

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diameter >22F) to mPCNL (inner diameter 14-22F) , and there are even studies proposing eSMP (11F), which can effectively reduce postoperative complications while maintaining a higher SFR. For PCNL, mPCNL, and eSMP, the most critical procedure for surgery is the establishment of the working channel, moreover, the body position and the puncture guidance system are essential for the establishment of the working channel. Positions mainly include supine and prone positions. The prone position has a larger puncture field, but there are significant intraoperative changes in cardiovascular function, and the supine position has less impact on cardiovascular function, however, it is more difficult for the establishment of working channels . Fluoroscopy and ultrasound are the traditional puncture guidance modalities for PCNL, but the use of ultrasound-guided after 3D modeling and retrograde ureterography followed by ultrasound-guided puncture is gradually increasing in PCNL. However, the efficacy of PCNL in combination with guidance modalities and positions in the surgical treatment of >2 cm kidney stones is still unknown. With the large number of different surgical interventions in published studies, traditional meta-analyses no longer yield the best clinical guidance. The purpose of this study was to conduct an exploratory network meta-analysis of randomized controlled trials to systematically compare direct and indirect evidence to determine the best treatment option for >2 cm kidney stones.

METHODS

Participant or population: Age >18 years, no gender, race, or etiology restrictions.

Intervention: Percutaneous nephrolithotomy (PCNL), mini-PCNL (mPCNL), Enhanced super-mini-PCNL (eSMP), retroperitoneal pelvic dissection for stone extraction (RP), retrograde intrarenal surgery (RIRS).

Comparator: None.

Study designs to be included: RCTs.

Eligibility criteria: Literature Inclusion Criteria1) Study type: RCTs with >2 cm kidney stones treated surgically and stone-free rate or complications reported in the study (clavien-dindo classification); 2) Study population: age >18 years, no gender, race, or etiology restrictions; 3) Interventions: percutaneous nephrolithotomy (PCNL), mini-PCNL (mPCNL), Enhanced super-mini-PCNL (eSMP), retroperitoneal pelvic dissection for stone extraction (RP), retrograde intrarenal surgery (RIRS). exclusion criteria1) types of studies such as reviews, retrospective studies, cohort studies, etc.; 2) literature other than English, repeated publications or conference abstracts, etc.; 3) Article on percutaneous nephrolithotomy regarding lithotripsy machines, dilation methods, and puncture sites; 4) animal experiments.

Information sources: PubMed, Cochrane Library, and Embase.

Main outcome(s): The primary outcome was the SFR, Short-term SFR was defined as no residual stone larger than 4 mm in diameter found on imaging within one week after operation. Long-term SFR was defined as no residual stone larger than 4 mm in diameter on imaging at 1-3 months of follow-up. stone-free rate

Additional outcome(s): The secondary outcome was the incidence of complications. We classified complications based on the Clavien-dindo classification, with mild defined as Clavien-dindo I-II and severe defined as Clavien-dindo III and above.

Data management: None.

Quality assessment / Risk of bias analysis: The risk assessment tool ROB 2.0 (https://www.riskofbias.info/) was used to assess bias in the RCTs. Judgement of the risk of bias was assessed in the following areas: bias due to either the randomization process, expected intervention bias, or missing outcome data; bias in outcome

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measures; and bias in selective reporting of outcomes. Based on the results of this assessment, the overall risk of bias was described as "low risk of bias," "some concern," or "high risk of bias."

Strategy of data synthesis: The NMA used a Bayesian framework to calculate the odds ratio (OR) and 95% confidence intervals (CI) for the random or fixed effects models. Heterogeneity between effect sizes for individual studies was assessed using the statistic I2 and defined as low (25-50%), medium (50-75%), or high (>75%). When obvious heterogeneity was observed, the causes were analyzed, and after excluding clinical heterogeneity, a random effect model NMA was applied. We insured clinical similarity (intervention, similar population, and outcomes) as well as methodological similarity between treatments by including RCTs with strict subject inclusion and exclusion criteria in order to achieve balance between the treatments. Another prerequisite assumption was consistency that referred to the degree of similarity of results between direct and indirect comparisons. The more similar the results were, the better the consistency, and if there was a significant difference, this indicated that inconsistency existed and that the source of this inconsistency needed to be explored. Convergence diagnostics and trajectory density plots were used to evaluate the validity of the model. The consistency model was calculated using a Markov chain with an initial value scaling of 2.5, tuning iterations of 5000, simulation iterations of 20000, and thinning interval of 1. If no inconsistency was observed, the results were presented using a forest plot of the consistency model and a probability ranking plot to report the intervention efficacy ranking of the preventive drug. The larger area of the box tending towards 1 indicated a better treatment effect. R 4.0.3 ('gemtc' package, 'rjags' package) and MCMC (Markov Chain Monte Carlo, MCMC) simulation techniques in J.A.G.S 4.2.0 were used for the statistical analyses. This study was reported according to the list of entries in the Systematic Evaluation and Network Meta-Analysis Report.

Subgroup analysis: None.

Sensitivity analysis: None.

Language: English.

Country(ies) involved: China.

Keywords: kidney stone, stone-free rate, complication.

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