Study protocol for systematic review and meta-analysis

Objective
To evaluate the impact of previous open renal surgery on the outcomes of subsequent percutaneous nephrolithotomy by systematically comparing the perioperative outcomes of percutaneous nephrolithotomy in patients with or without previous ipsilateral open renal surgery

Database
PubMed, Web of Science, and the Cochrane Library

Search strategy
PubMed
(lumbotomy[Title/Abstract] OR open[Title/Abstract]) AND ("percutaneous nephrolithotomy"[Title/Abstract] OR "percutaneous nephrolithotripsy"[Title/Abstract] OR PCNL[Title/Abstract] OR PNL[Title/Abstract])

Web of Science
Theme: (lumbotomy or open) AND Theme: ("percutaneous nephrolithotomy" OR "percutaneous nephrolithotripsy" OR PCNL OR PNL)

Cochrane Library
"percutaneous nephrolithotomy" OR "percutaneous nephrolithotripsy" OR PCNL OR PNL in Title, Abstract, Keywords and lumbotomy or open in Title, Abstract, Keywords in Trials

Inclusion/exclusion Criteria

Study type
1. Prospective or retrospective controlled clinical trials will be eligible to enter our meta-analysis.
2. We will include studies with two or more than two groups.

Participants
1. We will include studies comparing perioperative outcomes of PCNL in patients with or without previous ipsilateral open surgery.
2. We will include studies in patients younger or older than 18 years old.

Outcome measures
1. Eligible studies should have reported at least one of the following outcomes: Intraoperative complications, postoperative complications, or stone-free rate.
2. Eligible studies should have reported the numbers of included participants of each group.
3. Eligible studies should have reported the outcomes of each groups in patient numbers or the numbers can be acquired by calculating.

Publication type
1. Full-length articles or letters in peer-reviewed journals will be eligible.
2. Conference abstracts will be ineligible.
language restrictions
No language restrictions will be applied

Publication time restriction
No time restrictions will be applied

Data extraction
1. All data from each eligible study will be extracted and entered into a standardised spreadsheet software (Microsoft Excel 2007; Microsoft Corp, Redmond, WA, USA).
2. The following information will be extracted and entered into databases by two investigators independently (Henglong Hu, Yuchao Lu): publication year and journal, authors, countries, study design, study period, inclusion/exclusion criteria, patient number, patients’ characteristics (age, gender, body weight index, stone side, stone size, stone number), operation position, anesthesia method, tract size, tract number, lithotripsy method, fluoroscopic time comparisons, tract establishing time, operative time, analgesic, hemoglobin change, hospital stay, criteria for stone-free, and complications.
3. Disagreements between the two authors will be resolved by discussion. If the disagreement persists, the senior investigator (Shaogang Wang) will be consulted to attain consensus.

Quality Assessment
1. The methodological quality of eligible trials will be evaluated independently by two investigators (Henglong Hu, Yuchao Lu) using Newcastle-Ottawa Scale for nonrandomized controlled trials on three broad perspectives: the selection of the study groups; the comparability of the groups; and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies respectively.
2. Publication bias will be assessed using funnel plots of the outcome comparisons.
3. Disagreements between the two authors will be resolved by discussion. If the disagreement persists, the senior investigator (Shaogang Wang) will be consulted to attain consensus.

Data Synthesis and Analysis
1. We will use Review Manager Software version 5.3 (RevMan v5.3, The Cochrane Collaboration, Oxford, UK) to perform this meta-analysis.
2. The weighted mean difference and relative risk with 95% confidence intervals will be used as the summary statistics for continuous and dichotomous variables, respectively.
3. If studies presenting continuous data as means and ranges, the standard deviations will be calculated using the methodology described by Hozo et al. (Hozo SP, Djulbegovic B, Hozo I. Estimating the mean and variance from the median, range, and the size of a sample. BMC Med Res Methodol 2005;5:13.)
4. Heterogeneity between studies will be assessed using the chi-squared test and I-squared statistics.
5. Pooled estimates will be calculated using a fixed-effects model, but if significant
heterogeneity is detected, the random-effects model will be applied.
6. The pooled effects will be determined by z-test.
7. Funnel plots will be generated in order to screen for potential publication bias.
8. If some there are some studies in which participants of the two groups were not perfectly matched (some important parameters such as stone burden are not matched), then we will conduct additional sensitivity analyses will be performed by ruling out these studies.
9. A two-sided p-value <0.05 will be used to indicate statistical significance.