# Comparison of Vacuum-Assisted Sheath and Normal Sheath in Minimally Invasive Percutaneous Nephrolithotomy: A Systematic Review and Meta-Analysis

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## Abstract

# Background

A systematic review and meta-analysis was conducted to compare the safety and efficacy between the vacuum-assisted sheath and conventional sheath in minimally invasive percutaneous nephrolithotomy (MPCNL) in the treatment of nephrolithiasis.

# Methods

PubMed, Web of Science, Embase, EBSCO, and Cochrane library databases (updated March 2021) were searched for studies assessing the effect of vacuum-assisted sheath in patients who underwent MPCNL. The search strategy and study selection processes were managed according to the PRISMA statement.

# Results

Three randomized controlled trials and two case-controlled trials that satisfied the inclusion criteria were enrolled in this meta-analysis. Overall, the stone-free rate (SFR) in patients who underwent vacuum-assisted sheath was significantly higher than those who underwent conventional sheath (RR = 1.18, 95% CI = 1.08,1.29; P = 0.0002), with insignificant heterogeneity among the studies (I2 = 44%, P = 0.13). In terms of the outcome of complications, vacuum-assisted sheath could bring a benefit to the postoperative infection rate (RR = 0.45, 95%CI = 0.33,0.61; P < 0.00001) with insignificant heterogeneity among the studies (I2 = 0%, P = 0.76). There was no significant difference in blood transfusion rate (RR = 0.54, 95%CI = 0.23,1.29; P = 0.17) with insignificant heterogeneity (I2 = 41%, P = 0.15,). Only two studies reported the perforation and the results were statistically insignificant (RR = 0.25, 95%CI = 0.05,1.17; P = 0.08) with insignificant heterogeneity (I2 = 0%, P = 0.43).

# Conclusions

Using vacuum-assisted sheath in MPCNL improves the safety and efficiency compared to the conventional sheath. Vacuum-assisted sheath significantly increases the SFR and reduces complications like postoperative infection, blood transfusion, and perforation

## Background

Urolithiasis is the third most common disease of the urinary tract and its prevalence has increased over the past decades [1]. The kidney stone prevalence rate worldwide is approximately 1.7–8.8% and it cost about $2.1 billion in 2020 alone [2]. Patients with nephrolithiasis often suffer from short-term complications such as acute renal colic, nausea, vomiting, and hematuria, and long-term complications such as chronic renal failure and hydronephrosis [3]. Therefore, treatment of calculi has always been the focus of surgeons. For renal stones of size > 2cm, the American Urological Association recommends percutaneous nephrolithotomy (PCNL) as the primary treatment [4]. Previous studies have shown that standard PCNL is a highly effective approach [5]. However, it is often associated with major complications like bleeding with the need for blood transfusion, post-operative fever, and pneumothorax [6].

In 2001, Minimally Invasive Percutaneous Nephrolithotomy (MPCNL) which involves the use of a small access sheath − 20F or less was introduced in clinical practice [7, 8]. Despite the popularity of MPCL due to the lower risk of trauma and morbidities, it suffers from certain drawbacks. The efficiency of extraction of stone fragments and dust is lower than standard PCNL. Furthermore, the size of the sheath and the force of irrigation can lead to a higher incidence of infections due to the rise in renal intra-luminal pressure and limitations in the lithotripsy equipment [9]. With the development of new technologies, the vacuum-assisted sheath has emerged. It can suck out the stone fragments and irrigation fluid continuously and contemporarily in the gap between the scope and sheath. Some studies on this issue had been conducted recently but the outcomes of the effect and efficiency of the MPCL with vacuum-assisted sheath are unsettled.

To date,there is still a lack of high-level evidence. The present write-up, therefore, aims to systematically review and perform a meta-analysis of the current studies to investigate the effectiveness and safety of vacuum-assisted sheath for the treatment of nephrolithiasis.

## Materials And Methods

The systematic review and meta-analysis were carried out following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement and the Cochrane Handbook for Systematic Reviews of Interventions [10]. Ethical approval and patient consent were not required as all the analyses were performed on previously published studies.

#### Literature search and selection criteria

We systematically searched relevant published articles in several databases including PubMed, Embase, Web of Science, EBSCO, and the Cochrane Library from inception to March 2021 with the following keywords: “percutaneous nephrolithotomy,” “minimally,” “sheath,” “evacuation,” and “suction.” The reference lists in the retrieved studies and relevant reviews were hand-searched, and the above process was repeated to ensure that all eligible studies were included.

The inclusion criteria were as follows: (1) study design retrospective comparative studies, prospective cohort studies, or randomized controls studies, (2) patient had a history of kidney stones and underwent the minimally invasive PCNL, (3) intervention approach is suctioning sheath versus normal sheath, and (4) availability of the entire text. Studies satisfying those inclusion criteria in all languages were included.

### Data extraction and outcome measures

Baseline information extracted from the original studies included the first author, year of publication, number of patients, patient age and gender distributions, type of calcium stone, detailed methods for the two groups, and the evaluation of the evidence level. Data were independently extracted by two investigators and the discrepancies were resolved by consensus.

The primary outcomes were stone-free rate (SFR) and perioperative complications (including postoperative infection rate, blood transfusion rate, and perforation rate). Secondary outcomes were operative time and hospitalization.

### Quality assessment of individual studies

All assessments were performed independently by two researchers with differences resolved by discussion. The methodological quality of each RCT was assessed according to the Jadad Score, which comprises the following three evaluation elements: randomization (0–2 points), blinding (0–2 points), and dropouts and withdrawals (0–1 points)[11]**.** One point was awarded for each element that was conducted and appropriately described in the original article. The total score varies from 0 to 5 points. An article with a Jadad score of ≤2 is considered to be of low quality, while a Jadad score of ≥3 indicates the high quality of a study[12]**.** The Methodological Index for Nonrandomized Studies (MINORS) score was used to evaluate the risk bias of the nonrandomized designed studies. The MINORS score is based on 12 criteria that are scored on a scale of 0 to 2; a score of 2 indicates that the criteria were reported adequately; 1 indicates that it was reported but inadequately; and a score of 0 indicates that it was not reported. An overall score of 24 is considered a perfect score and indicates a low risk of bias. As the MINORS score decreases, the risk of bias increases accordingly[13].

### Statistical analysis

Risk ratios (RR) with 95% confidence intervals (CIs) were calculated for dichotomous outcomes. Heterogeneity was evaluated using the $I^2$ statistic, with $I^2 >$ 50% taken to indicate significant heterogeneity[14]. Sensitivity analysis was performed for evaluating the influence of a single study on the overall estimate by omitting one study in turn or performing subgroup analysis. The random-effects model was used for meta-analysis. Owing to the limited number of included studies (<10), publication bias was not assessed. Statistical significance was accepted at $P < 0.05$. All statistical analyses were performed using Review Manager Software Version 5.3 (The Cochrane Collaboration, Software Update, Oxford, UK).

## Result

### Literature search, study characteristics, and quality assessment

A total of 126 articles were initially identified from the databases. After removing the duplicates, 91 articles were retained. Then, 83 studies were excluded from the study due to unrelated abstracts and titles. We also excluded from our analysis: one article with insufficient data, one article without full text, and one review article. Finally, three randomized controlled trials (RCTs) and two case-controlled trials (CCTs) with 1163 patients that satisfied all the inclusion criteria were subjected to the meta-analysis [15-19]. The article selection process was followed by the PRISMA statement (Fig 1). The baseline characteristics of the five included studies are shown in Table 1. Studies included in this meta-analysis were published between 2016 and 2020, and the total sample size was 1163. The JADAD score for three studies was 2, 3, and 4. One study is of low quality as no blinding was used and the report of explanation of the specific method of randomization [15, 16, 19]. The MINORS score for the two studies were 20 and 22, respectively [17, 18].

### Primary outcomes

### Stone-free rate

All studies included for the analysis reported the SFR, where stone-free is defined as stone fragments≤4 mm. Our results indicated that the SFR in vacuum-assisted sheath was significantly higher as compared to the conventional sheath group (RR=1.18, 95%CI=1.08,1.29; P=0.0002) with insignificant heterogeneity among the studies ($I^2$=44%, P =0.13, Fig 2).

### Perioperative complications：postoperative infection rate, blood transfusion rate, and perforation rate.

All the studies reported infection-related complications and blood transfusion rate. Three studies reported postoperative fever [15, 16, 19], while one study reported infections [18], and the other reported postoperative fever, infection needing antibiotics, and sepsis [17]. These results indicated that vacuum-assisted sheath provided a benefit to the postoperative infection rate (RR=0.45, 95% CI=0.33,0.61; P<0.00001) with insignificant heterogeneity among the studies ($I^2$=0%, P =0.76) (Fig 3). There was no significant difference in blood transfusion rate (RR=0.54, 95%CI=0.23,1.29; P=0.17) with insignificant heterogeneity ($I^2$=41%, P =0.15) (Fig 4) reported in the four studies [15-17, 19]. Only two of the studies reported perforation and the result was statistically insignificant (RR=0.25, 95%CI=0.05,1.17; P=0.08) with insignificant heterogeneity ($I^2$=0%, P =0.43) (Fig 5) [17, 19].

### Secondary outcomes

### Operative time

Four studies containing operative time data [15-17, 19] were analyzed and the results indicated that vacuum-assisted sheath had a significantly shorter time than the conventional sheath group (MD =-16.28; 95% CI=-20.63, -11.92; P<0.00001) with insignificant heterogeneity ($I^2$=50%, P=0.11, Fig 6).

### Hospitalization

Three studies reported hospitalization data and the results showed no significant difference between the two groups (MD =-1.66, 95%CI=-4.10, 0.77, p=0.18) with significant heterogeneity ($I^2$=96%, P =0.18) [17-19].

## Discussion

PCNL has been accepted as the gold standard for treatment of large sized renal stones and is widely used in clinical practice [3, 20]. Although technological advances have ensured a lot of progress in this field, many complications still exist [21]. To improve the safety and efficacy of this procedure, a small-size sheath was invented with the advent of mini-perc technology [22]. Due to the smaller size of the sheaths, MPCNL is associated with flaws like longer operative time and infectious complications [23]. Recently, a sheath with irrigation and suctioning system has been developed which can let continuous infusion with saline intraoperatively[24]. The vacuum aspiration can be regulated manually or mechanically to keep the collecting system under negative pressure. Also, the nephroscope moves in and out conveniently through the movable sealing lid, while preventing extremely high or low pressure[18]. To evaluate effect and efficacy of the vacuum-assisted sheath, this meta-analysis was done.

SFR is the main parameter for judging the efficacy of minimally invasive stone removal surgery [25]. Despite the difference in imaging modalities and follow-up time in the definition of SFR, our results show that vacuum-assisted sheath has an improved stone clearance compared to the normal sheath. One possible explanation may be the low positive or low negative state of intrapelvic pressure controlled by the sheath while flushing and irrigation. In this situation, the kidney parenchyma gets shrunk, the tension in the renal pelvis decreases and the renal parenchymal compliance is improved. Thus, the nephroscope can reach more renal calyces. Furthermore, when the calyceal neck is narrow or the angle is hard to reach, this sheath can perform lithotripsy and simultaneously suction out the fragments, making it a one-step procedure. Also, continuous negative pressure suction ensures a clear surgical field to avoid missing stone fragments and therefore, a higher SFR is reached [15].

In previous studies, Li *et al.* and Xu *et al.* reported a higher incidence of postoperative fever [26, 27]. Due to the small size of the sheath, the higher-pressure perfusion is easy to be performed. It is known that the limit of renal intrapelvic pressure is 30 mmHg [28]. Higher pressure can injure the integrity of the pelvic wall epithelium leading to pyelocalyceal perforation and the exposure of the lymphatic and venous system [29]. Besides, tissue edema and congestion caused by urinary tract infection and stone, are more likely to cause pelvic fluid absorption. When the bacteria along with the associated toxin reflux are absorbed, it may lead to infectious complications like postoperative fever or sepsis [30]. By using the suction sheath, the renal pelvis is kept in a negative pressure state. Therefore, the infectious fluid flows smoothly and the absorption of irrigation, bacteria, and toxin reflux is reduced. Du *et al.* found that MPCNL with vacuum-sheath has a low intrapelvic pressure compared to standard PCNL and MPCNL [15]. Xu *et al.* found that the intrapelvic pressure ≥ 30 mmHg is achieved in the non-vacuum-sheath group [16].

Prolonged operative time is another independent risk factor for infectious complications [31]. The smaller size of access causing a limitation for more options for lithotripsy is a major inherent limitation of MPCNL. Another limitation is the small visual field in the miniature endoscopes, which leads to a longer time to break the stones into smaller fragments [32]. Despite the different definitions of the operation time, present evidence indicates that vacuum-assisted sheath can significantly shorten the operation time. The usage of vacuum-assisted sheath could simultaneously suck out the small clots and fragments of stone in the gap. Furthermore, a clearer vision was achieved during the procedure to shorten the surgery time [17]. Though shorter operation time may decrease blood loss, it is not proven to be the case in our study as it depends on many factors like puncture site, number, and size of the sheath [33].

Admittedly, there are a few limitations to this study. First, only three randomized controlled trials were included in our study. Second, the impact of differences in puncture kidney calices and depth in sheath placement was not accessed in the included studies. Finally, there are some unpublished data and missing negative data in the original reports, and because of this publication bias, our conclusion may be skewed.

In conclusion, the present meta-analysis demonstrated that Using vacuum-assisted sheath in MPCNL improves the safety and efficiency compared to the conventional sheath. Vacuum-assisted sheath significantly increases the SFR and reduce postoperative infection. Due to the inherent limitations of included studies, the multicenter, large scale prospective RCTs should be performed in the future to validate our results.

## List Of Abbreviations

MPCNL minimally invasive percutaneous nephrolithotomy

SFR stone-free rate

PCNL percutaneous nephrolithotomy

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-analysis

MINORS The Methodological Index for Nonrandomized Studies

CIs Confidence intervals

RCTs Randomized controlled trials

CCTs Case-controlled trials

## Declarations

**Acknowledgements**

Not applicable

**Competing interests**

The authors declare that there is no competing interests

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**Contribution**

WZH, ZL, and ZXF participated in the design of this study. ZL drafted the manuscript. GLP, ZY collected and analysis the data, HY and ZXF critically revised the manuscript. All authors have read and approved the final manuscript.

**Consent for publication**

Not applicable.

**Availability of data and materials**

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

**Ethics approval and consent to participate**

Not applicable

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## Tables

Table 1
Characteristics of included studies

| No. | Author | year | Experimental group | | | | | Control group | | | | | Study Design | Qual asse |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Number (n) | Age (Mean ± SD) | Male (n) | Stone | Access sheath and lithotripsy energy | Number (n) | Age (Mean ± SD) | Male (n) | Stone size | Access sheath and lithotripsy energy | | |
| 1 | Huang | 2016 | 91 | 43.5 ± 2.9 | 53 | Stone dimension 16.7 ± 5.8mm | 16F vacuum sheath/ holmium laser | 91 | 44.1 ± 3.2 | 51 | 15.1 ± 6.3mm | 16F peel-away sheath/ holmium laser | RCT | 3[a] |
| 2 | Du | 2018 | 311 | 43.6 ± 17.4 | 187 | Stone size 13.6 ± 5.2cm$^2$ | 16-18F vacuum sheath/ ultrasound | 304 | 41.2 ± 16.9 | 181 | 13.9 ± 4.7cm$^2$ | 16-18F peel-away sheath/ ultrasound | RCT | 2[a] |
| 3 | Xu | 2020 | 30 | 52.1 ± 11.5 | 18 | Stone diameter 4.2 ± 1.0cm | 20F vacuum sheath/ pneumatic and holmium laser | 30 | 51.8 ± 9.6 | 14 | 3.8 ± 1.4 cm | 20F conventional sheath/ pneumatic and holmium laser | RCT | 4[a] |
| 4 | Lievore | 2020 | 104 | 57.0 ± 20.0 | 70 | Stone area 1.5 ± 1.3cm$^2$ | 16F vacuum sheath/ holmium laser | 52 | 56.0 ± 20.7 | 43 | 2.2 ± 1.0cm$^2$ | 16F metallic sheath/ holmium laser | CCT | 20[b] |
| 5 | Lai | 2020 | 75 | 37.5 ± 11.4 | 47 | Stone burden 676.1 ± 22.2 mm$^2$ | 18F vacuum sheath/ holmium laser | 75 | 43.2 ± 15.2 | 36 | 629 ± 33.7 mm$^2$ | 18F peel-away sheath/ holmium laser | CCT | 22[b] |

[a]: Jadad score; [b]: MINORS score

## Figures

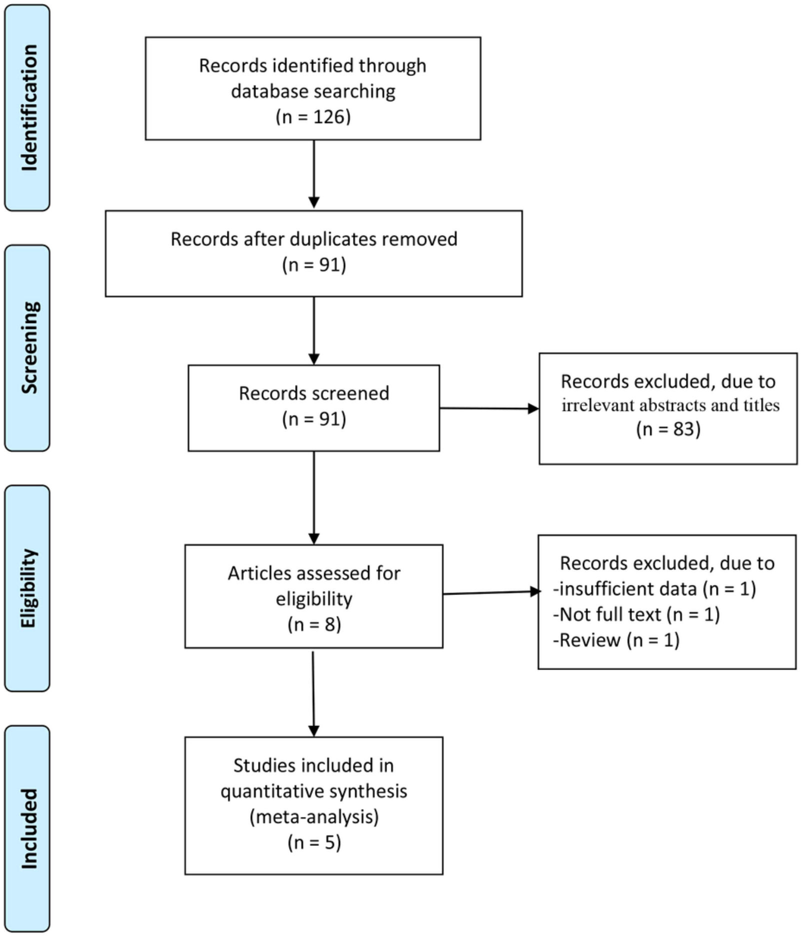



Figure 1

Flow diagram of study searching and selection process.

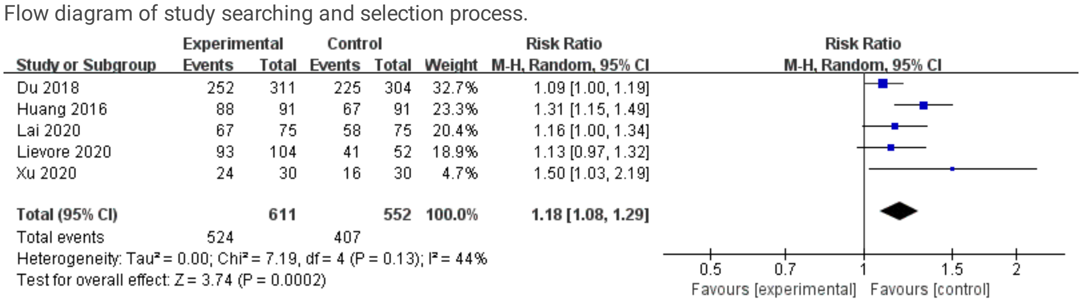



Figure 2

Forest plot for the meta-analysis of stone free rate

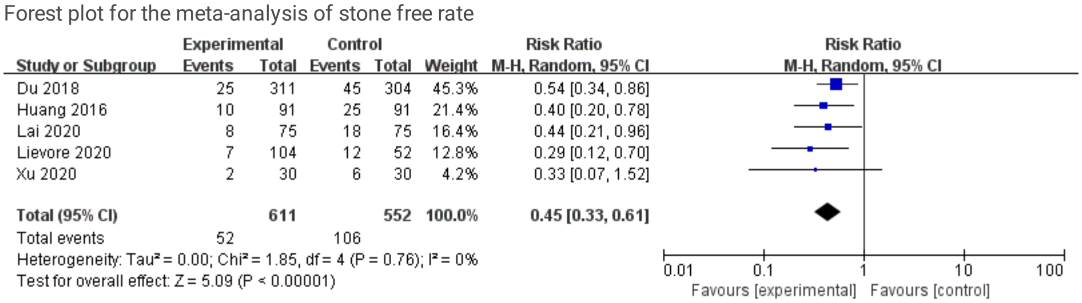
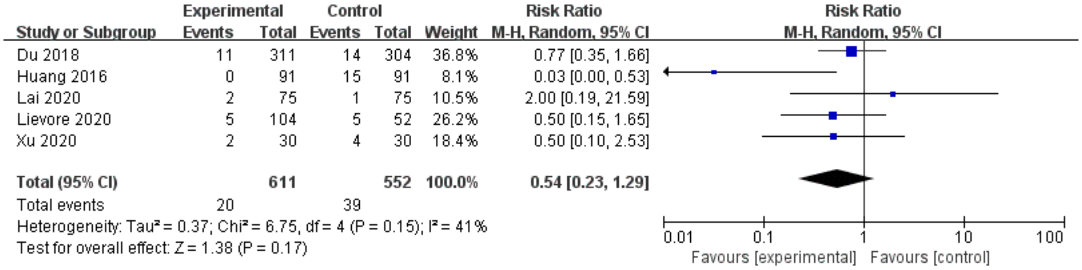


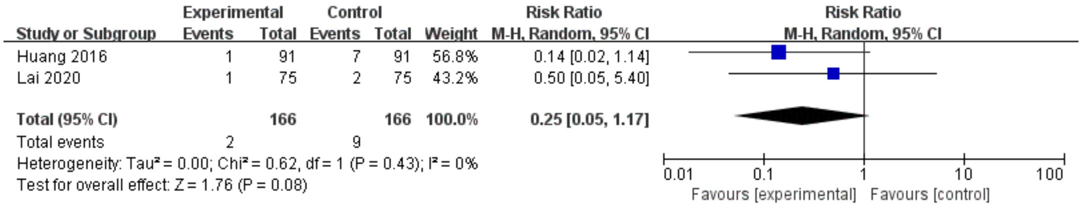

Figure 3

Forest plot for the meta-analysis of postoperative infection



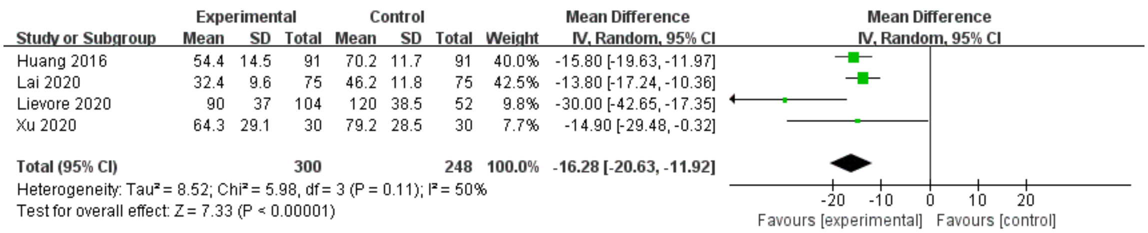

## Figure 4

Forest plot for the meta-analysis of blood transfusion



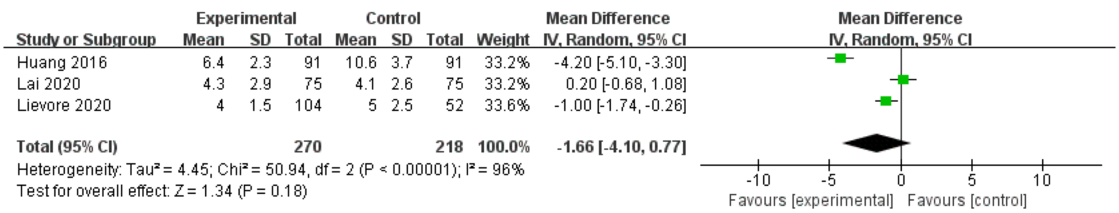

## Figure 5

Forest plot for the meta-analysis of perforation




## Figure 6

Forest plot for the meta-analysis of operative time




## Figure 7

Forest plot for the meta-analysis of hospitalization