Effect of the External Physical Vibration Lithecbole on the Discharge of Upper Urinary Stones: A Systematic Review and Meta-analysis

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Purpose: The external physical vibration lithecbole (EPVL) is a new device that accelerates the discharge of urinary stones by changing the patient's body position and providing multi-directional simple harmonic waves. It is clinically employed to improve the stone-free rate (SFR). However, it is not widely accepted in clinical practice due to the lack of high-level evidentiary support and a standard protocol. The present meta-analysis aims at the evaluation of the efficacy and safety of EPVL treatment in improving the SFR.

Methods: This study was a systematic review and meta-analysis. A systematic literature review was conducted using PubMed, Scopus, Embase, Medline, the Web of Science, and the Cochrane Library to find randomized controlled trials (RCTs) as recent as April 2020 that evaluated the efficacy and safety of EPVL treatment for patients with stones/residual stones in the upper urinary tract.

Results: In total, 7 prospective studies with 1414 patients were included. Compared with patients in the control group, patients treated with an EPVL (the intervention group) had higher SFRs (95% CI: 0.59-0.86, RR = 0.71, P = .0004) and lower complication rates (95% CI: 1.37-3.12, RR = 2.07, P = .0006). In a subgroup analysis based on previous surgery (ESWL, RIRS), the intervention group had an improved SFR as compared to the control group (95% CI: 0.59-0.95, RR = 0.75, P = .02; 95% CI: 0.56-0.73, RR = 0.64, $P <$ .00001, respectively). In a subgroup analysis based on stone location, the SFRs for stones in the upper/middle/lower calyx and renal pelvis were significantly higher in the intervention group than in the control group: for residual stones in the upper and middle calyx, 95% CI: 0.63-0.98, RR = 0.79, and P = .03; for residual stones in the lower calyx, 95% CI: 0.54-0.75, RR = 0.64, and $P <$ .00001; for residual stones in the renal pelvis, 95% CI: 0.47-0.79, RR = 0.61, and P = .0002. However, the SFRs for ureter stones were not significantly different between groups (95% CI: 0.82 -1.05, RR = 0.93, P = .23).

Conclusion: The external physical vibration lithecbole can effectively improve the SFR after ESWL and RIRS without significant side effects, especially for residual stones in the upper/middle/lower calyx and renal pelvis.

Keywords: external physical vibration lithecbole; upper urinary stones; residual stones, meta-analysis

INTRODUCTION

Urinary tract stones are a common urological disease, and create life and economic burdens for about 5-15% of the world's population.[1,2] With the development of technology, several surgical procedures can be used to treat stones, including extracorporeal shock wave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS), percutaneous nephrolithotomy (PCNL), and laparoscopic surgery. Because surgical equipment and treatment concepts are continuously updated, the phenomenon of residual stones has been greatly improved. However, the presence of residual stones after surgery remains a bothersome problem for urologists. Residual stones can potentially reaggregate and grow, thereby causing recurrent stone formation, infection, renal colic, obstruction, and eventually kidney failure.[3]

Many methods can promote the discharge of residual stones, including drinking more water, exercising more, medical expulsive therapy (MET), and percussion, diuresis, and inversion (PDI).[4-7] Some emerging technologies, such as the use of iron oxide microparticles and ultrasonic propulsion, can also improve the stone removal rate;[8,9] however, these two technologies have not been widely used in clinical practice. Recently, based on the principles of PDI treatment, the external physical vibration lithecbole (EPVL) device has been designed to discharge stone fragments. The device mainly provides harmonic vibration via stationary and mobile vibrators, thereby pushing the stones to discharge from the body. Several randomized controlled trials (RCTs) have compared the efficacy and safety of the EPVL in treating upper urinary tract residual stones. In 2015, a study conducted by Long et al. showed that, in the treatment of lower-pole renal stones, the stone removal rate of the EPVL plus ESWL group reached 76.5%, while that of the group that received ESWL treatment alone was only 43.8% (P = 0.008).(10) EPVL treatment can also accelerate the discharge of residual stones after RIRS. Zhang et al.[11] designed a prospective randomized controlled study to determine the length of time between

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Table 1. Baseline characteristics of individual studies included in the meta-analysis.

Study	Country	Study design	Mean age (T/C, years)	BMI (T/C)	Sample size (T/C)	LE	Quality
Long et al. 2016 (10)	China	RCT	44 ± 9.5/45 ± 9.9	25.2 ± 3.4/25.6 ± 2.9	34/37	1b	3
Wu et al.2017 (15)	China	RCT	47.1 ± 1.0/46.9 ± 1.2	24.5 ± 0.3/24.1 ± 0.3	87/86	1b	5
Liu et al. 2017 (12)	China	RCT	37.4 ± 15.3/38.3 ± 16.8	NA/NA	236/222	1b	3
Wu et al. 2018 (14)	China	RCT	42.9 ± 1.5/42.7 ± 1.3	23.6 ± 0.3/23.8 ± 0.3	76/77	1b	5
Tao et al.2018 (13)	China	RCT	49.3 ± 6.1/50.4 ± 5.7	23.6 ± 2.9/23.1 ± 3.3	127/144	1b	5
Jing et al.2018 (16)	China	RCT	38.7 ± 10.72/38.2 ± 10.6	24.1 ± 2.98/23.9 ± 2.6	56/56	1b	4
Zhang et al.2019 (11)	China	RCT	47.58 ± 10.26[a]	23.95 ± 2.91[a]	45[a]	1b	5
			49.72 ± 11.2[b]	24.78 ± 3.17[b]	44[b]		
			51.83 ± 9.31[c]	24.06 ± 3.56[c]	42[c]		
			/47.04 ± 9.1[d]	/24.55 ± 3.59[d]	/45[d]		

Abbreviations: T/C: treatment group vs. control group.
a, b, c, d: The study by Zhang et. al (2019) reports three treatment groups, a, b and c, and group d is the control group.

RIRS and EPVL treatment that can achieve the best therapeutic effect for patients with residual stones; the results showed that the earlier the treatment, the higher the stone removal rate, and the greater the reduction of corresponding complications.
However, to date, no systematic review or meta-analysis has evaluated the effectiveness of EPVL. Therefore, a systematic review and meta-analysis were conducted to assess the efficacy and safety of the EPVL in the treatment of upper urinary tract stones or stone fragments.

MATERIALS AND METHODS

Literature search

The systematic review was performed according to the Cochrane review guidelines and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. A systematic literature review using PubMed, Scopus, Embase, Medline, the Cochrane Library, and the Web of Science was performed to identify RCTs that had assessed the efficacy and safety of the EPVL in the treatment of upper urinary tract stones or stone fragments. The search strategy was [("inversion" OR "vibration" OR "EPVL") AND ("stone" OR "calculus" OR "urolithiasis")]. The reference lists of relevant publications were also checked to identify any additional potential studies, and the potentially eligible studies from the cited references in the enrolled papers were also assessed. In addition, abstract booklets and presentations from annual academic con-

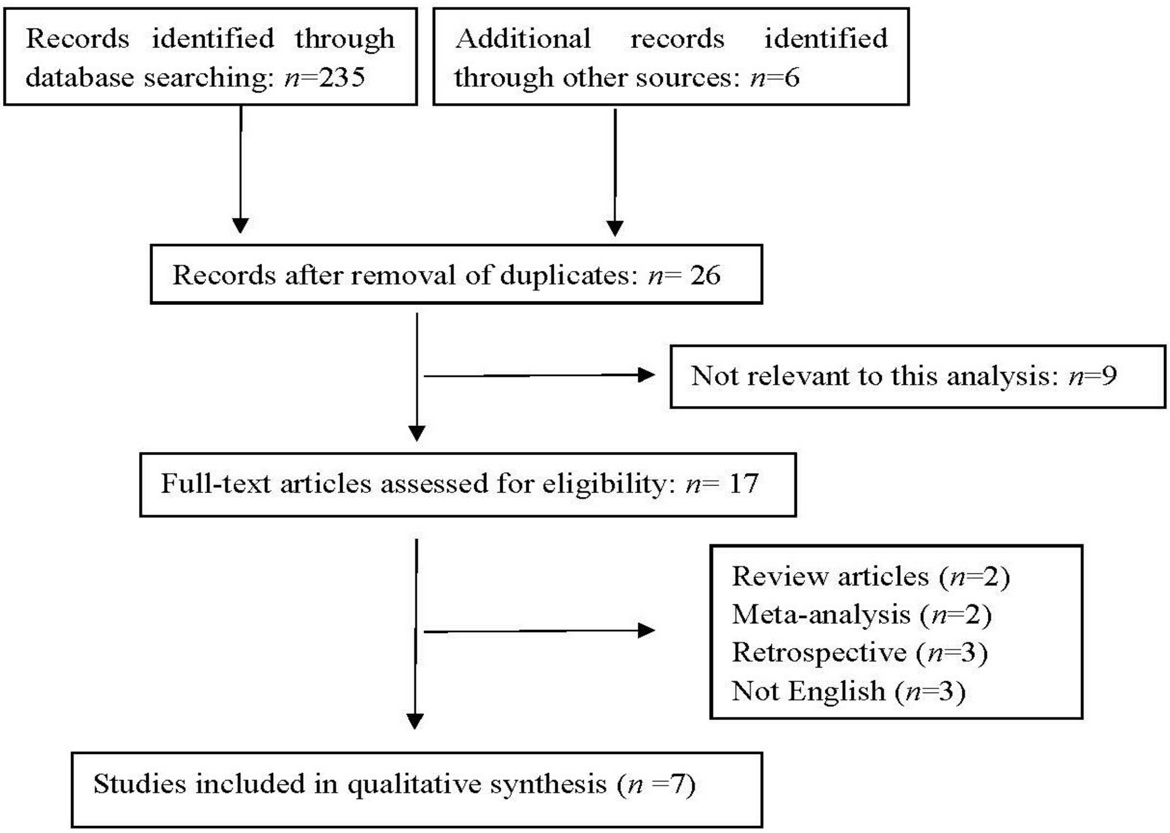

Figure 1. Flow chart of the study selection.

Table 2a. Detailed comparisons and results of eligible studies.

Study	Previous surgery	Stone location	Stone size	Intervention strategy (T/C)	Follow-up time	No. of stone-free patients (T/C)	No. of complications (T/C)
Long et al. 2016	ESWL	Lower calyx	6-20 mm before ESWL	EPVL/ Observation	3 weeks	26 (76.5%) /18 (48.6%)	5 (14.7%) /6 (16.2%)
Wu et al. 2017	RIRS	Upper urinary	≤4 mm after RIRS	EPVL/ Observation	4 weeks	78 (89.7%) /52 (60.5%)	6 (6.9%) /28 (32.2%)
Liu et al. 2017	NA	Distal ureter	3.2-10 mm	EPVL + tamsulosin/tamsulosin	2 weeks	223 (94.5%) /208 (93.7%)	NA/NA
Wu et al. 2018	ESWL	Upper urinary	≤15 mm before ESWL	EPVL/ Observation	4 weeks	69 (90.8%) /58 (75.3%)	2 (2.6%) /5 (6.5%)
Tao et al. 2018	ESWL	Upper urinary	10-20 mm before ESWL	EPVL/ Observation	4 weeks	117 (92.1%) /121 (84%)	11 (8.7%) /10 (6.9%)
Jing et al. 2018	ESWL	Upper urinary	Largest stone diameter 8-15 mm before ESWL	EPVL/ Observation	4 weeks	31 (55.4%) /13 (23.2%)	24 (42.9%) /38 (67.9%)
Zhang et al. 2019	RIRS	Unilateral renal	≤4 mm after RIRS	EPVLa, b, c /Observationd	4 weeks	41a (91.1%) 37b (84.1%) 32c (76.2%) /23d (51.1%)	4a (8.9%) 8b (18.2%) 10 c (23.8%) /21d (46.7%)

ferences were also consulted, and the corresponding authors of unpublished studies were contacted via email. The literature retrieval was halted in April 2020. Two of the authors (Zi-hao Xu and Hao Wang) independently and thoroughly carried out the literature search, article selection, quality assessment, and data extraction, and disagreements were resolved by an open discussion with a third reviewer.

Inclusion and exclusion criteria

The inclusion criteria for eligible studies were as follows: (1) the report of RCTs; (2) the comparison of EPVL treatment with conservative non-intervention; (3) the report of sufficient data, including the stone size and stone location; (4) published in English. The exclusion criteria were as follows: (1) reviews, editorials, or conference abstracts; (2) repeated publications; (3) retrospective studies; (4) published in languages other than English.

Assessment of the quality of studies and data extraction

The GRADE system was used to assess the level of evidence (LE), and the Jadad scale was used to assess the methodological quality of all included studies. Furthermore, the Cochrane risk-of-bias tool was utilized to evaluate the potential kinds of bias. The extracted data included the study design, methodological quality, stone size, previous surgery, stone location, treatment method, follow-up time, stone-free rate (SFR), and stone-related complications. In the control group, patients were recommended to increase their physical activity and fluid intake. In the intervention group,

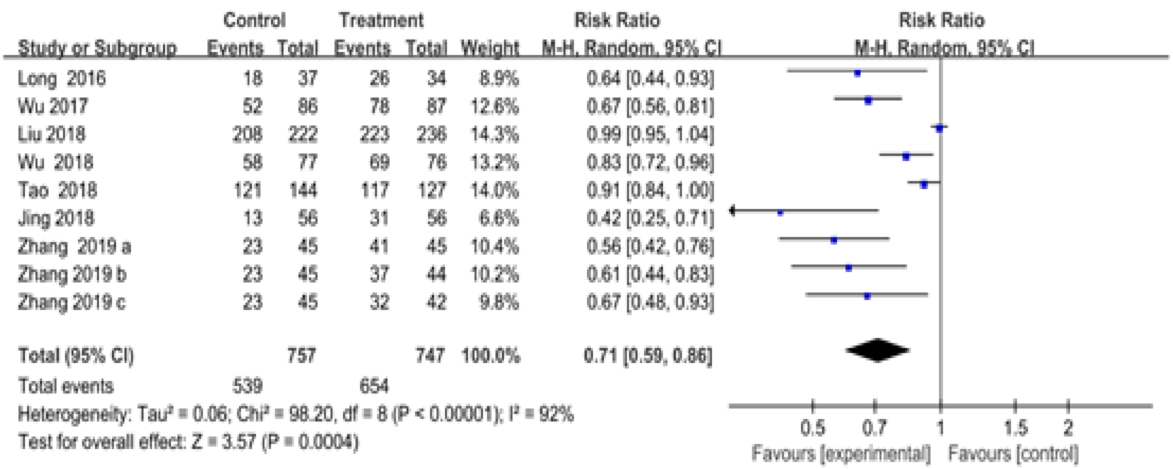

Figure 2. Comparison between total SFRs for patients in the treatment (EPVL) and control groups.

Table 2b. Types of complications.

Study	Treatment group				Observation group			
	Hematuria	Lumbago	Leukocyturia	Dizziness	Hematuria	Lumbago	Leukocyturia	Dizziness
Long et al. 2016	2	2	NA	1	4	2	NA	NA
Wu et al. 2017	3	NA	3	NA	18	NA	10	NA
Liu et al. 2017	NA	NA	NA	NA	NA	NA	NA	NA
Wu et al. 2018	1	NA	1	NA	3	NA	2	NA
Tao et al. 2018	NA	NA	NA	7	NA	NA	3	NA
Jing et al. 2018	14	9	1	NA	19	14	3	NA
Zhang et al. 2019	2a/5b/5c	NA	2a/3b/5c	NA	11	NA	10	NA

Abbreviations: T/C: treatment group vs. control group; NA: not available.
a, b, c, d: The study by Zhang et al. (2019) reports three treatment groups, a (3 days after RIRS), b (7 days after RIRS), and c (14 days after RIRS), and group d is the observation group.

patients were treated with an EPVL device beside the above recommendations. The recording of complications included the reported effects of the treatment, such as hematuria, leukocyturia, and lumbago.

Statistical analysis

The methodological assessment was accomplished using RevMan 5.3 software. Because the SFR and complications in all included studies were dichotomous variables, the pooled risk ratios (RRs) with 95% confidence intervals (CIs) were implemented for statistical analysis. Subgroup analyses were conducted according to the stone location and complication type. The statistical heterogeneity among the included studies was assessed by chi-square tests based on Q and I^2 statistics (minimal heterogeneity: 0-25%, moderate heterogeneity: 25-50%, significant heterogeneity: >50%.) Fixed-effect models were used to analyze the heterogeneous data ($I^2 < 50\%$), and random-effects models were used to analyze the heterogeneous data ($I^2 > 50\%$). A two-sided P-value < 0.05 was considered to be statistically significant. Furthermore, the potential heterogeneity and publication bias were tested by performing subgroup pooled analysis and sensitivity analysis, and by creating funnel plots.

RESULTS

In total, 235 references were obtained from the initial examination. After screening layer-by-layer, 7 RCT studies[10-16] comprising 1414 patients were ultimately included.

The basic features of the included studies are reported in **Tables 1 and 2**. As reported in these studies, 747 patients received EPVL treatment for upper urinary tract stones or stone fragments, while 667 patients were allocated to the control group. All included studies had a low risk of bias, but the performance bias was high. The risk of bias for each included study is summarized in Table 3. Regardless, the evaluation of the results was blinded and relatively objective.

SFR

All the included studies[10-16] reported SFRs after intervention, and the SFR was concluded based on imaging (ultrasound, KUB, non-contrast CT scan when necessary) reflecting the discharge of residuals stones. The EPVL (intervention) group presented obviously higher SFRs than the control group (95% CI: 0.59-0.86, RR = 0.71, *P* = .0004) with random effects, but there was a significant heterogeneity among these studies (I^2 = 92%), as presented in Figure 2. Therefore, a subgroup analysis based on previous surgery (ESWL, RIRS) in the intervention group was performed, and an improved SFR was found as compared to the control group (95% CI: 0.59-0.95, RR = 0.75, *P* = .02 and 95% CI: 0.56-0.73, RR = 0.64, $P < .00001$, respectively) (Figure 3). In a subgroup analysis based on stone location, the SFRs for stones in the upper/middle/lower calyx and the renal pelvis were significantly higher in the intervention group than in the control group: for residual stones in the upper and middle calyx, 95% CI: 0.63-0.98, RR = 0.79, and P = .03; for residual stones in the lower calyx, 95% CI: 0.54-0.75, RR = 0.64, and $P < .00001$; for residual stones in the renal pelvis, 95% CI: 0.47-0.79, RR = 0.61, and P = .0002. However, the SFRs for ureter stones were not significantly different between groups (95% CI: 0.82 -1.05, RR = 0.93, *P* = .23) (**Figure 4**).

Complications

The overall complication rates between the intervention group and the control group are presented in **Figure 4**. Data on complications in the EPVL and control groups were provided for a total of 220 events in six studies.[10,11,13-16] In the meta-analysis, the complication

Table 3. Risk of bias of included studies.

Study	Random-sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective outcome reporting (reporting bias)	Other bias
Long et al. 2016	LOW	UNCLEAR	HIGH	LOW	LOW	UNCLEAR	LOW
Wu et al. 2017	LOW	LOW	HIGH	LOW	LOW	LOW	LOW
Liu et al. 2017	UNCLEAR	UNCLEAR	HIGH	LOW	LOW	UNCLEAR	UNCLEAR
Wu et al. 2018	LOW	LOW	HIGH	LOW	LOW	LOW	LOW
Tao et al. 2018	LOW	LOW	HIGH	LOW	LOW	LOW	LOW
Jing et al. 2018	LOW	UNCLEAR	HIGH	LOW	LOW	UNCLEAR	LOW
Zhang et al. 2019	LOW	UNCLEAR	HIGH	LOW	LOW	LOW	LOW

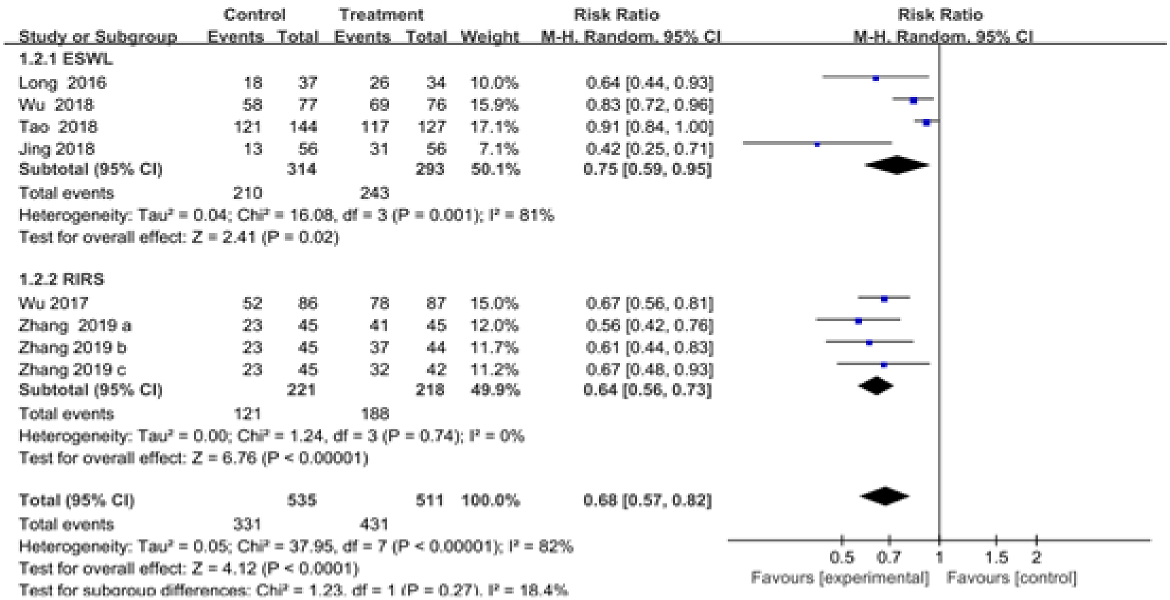

Figure 3. Comparison of SFRs for different previous surgeries in patients in the EPVL and control groups.

rate was found to be significantly lower in the intervention group than in the control group (95% CI: 1.37-3.12, RR = 2.07, P = .0006) (**Figure 5**) with random effects, and also exhibited significant heterogeneity (I^2 = 57%). Subgroup meta-analysis was then carried out as subsequently described, and the results are exhibited in **Figure 6**.

1. Hematuria

Five studies including 775 participants (384 in the intervention group and 391 in the control group) report-

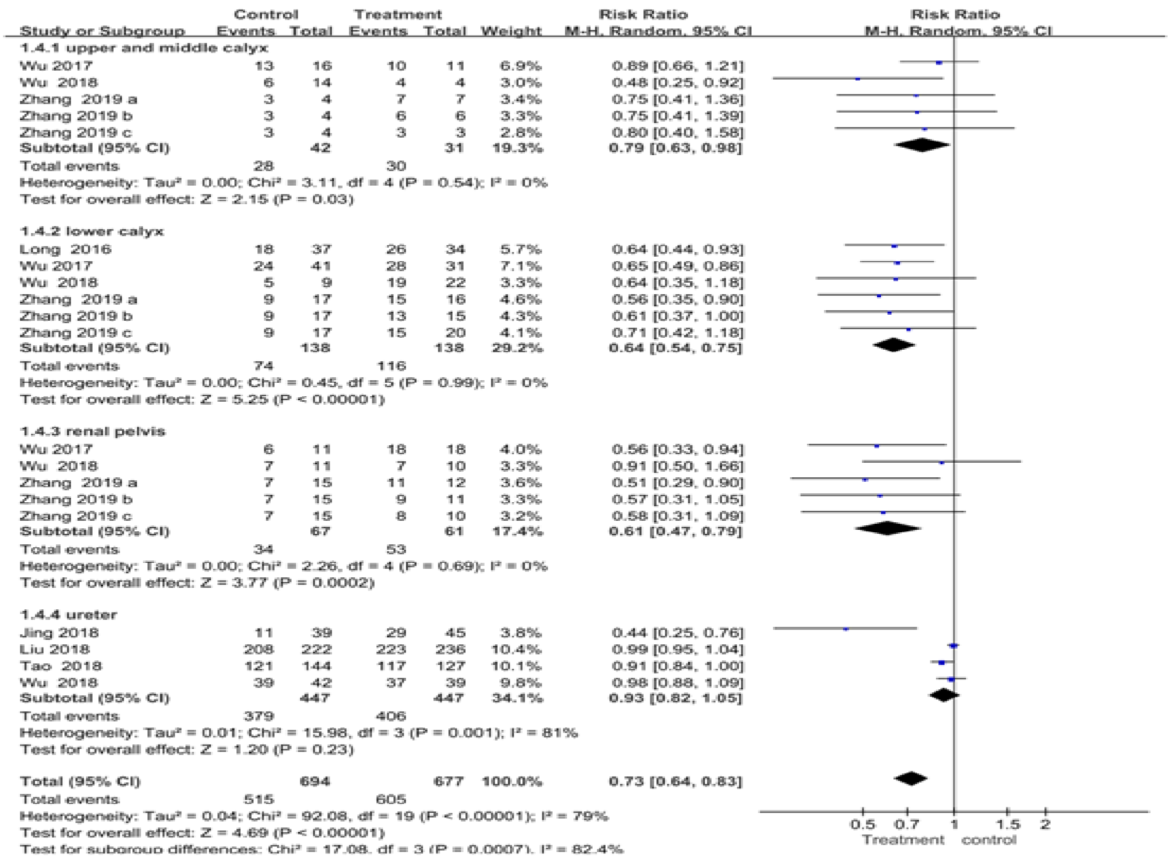

Figure 4. Comparison between SFRs for different stone locations in patients in the EPVL and control groups.

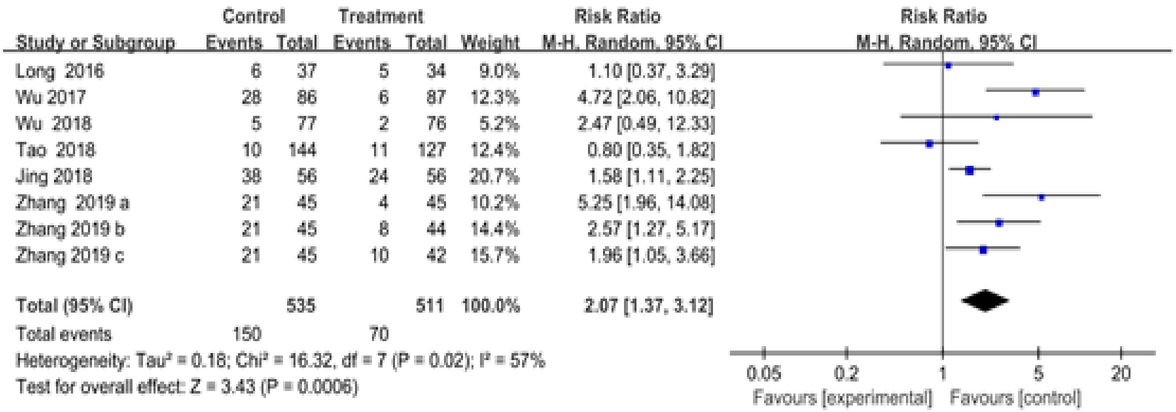

Figure 5. Comparison between complication rates of patients in the EPVL and control groups.

ed the incidence of hematuria after treatment. The rate was significantly lower in the intervention group than in the control group (95% CI: 1.62-3.45, RR = 2.37, P < .00001), and low heterogeneity was detected among these studies (I^2 = 20%).

2. Lumbago

Only two studies reported the incidence of lumbago after treatment. There was no significant difference between the intervention and control groups (95% CI: 0.72-2.88, RR = 1.44, *P* = .31).

3. Leukocyturia

Four studies including 704 participants (350 in the intervention group and 354 in the control group) reported the incidence of leukocyturia after treatment. The rate was significantly lower in the intervention group than in the control group (95% CI: 1.68-5.12, RR = 2.93, *P* = .0001), and no heterogeneity was detected among these studies (I^2 = 0.0%).

4. Dizziness

Only two studies reported the incidence of dizziness after treatment. There was no significant difference between the intervention and control groups (95% CI: 0.11-1.25, RR = 0.37, *P* = .11).

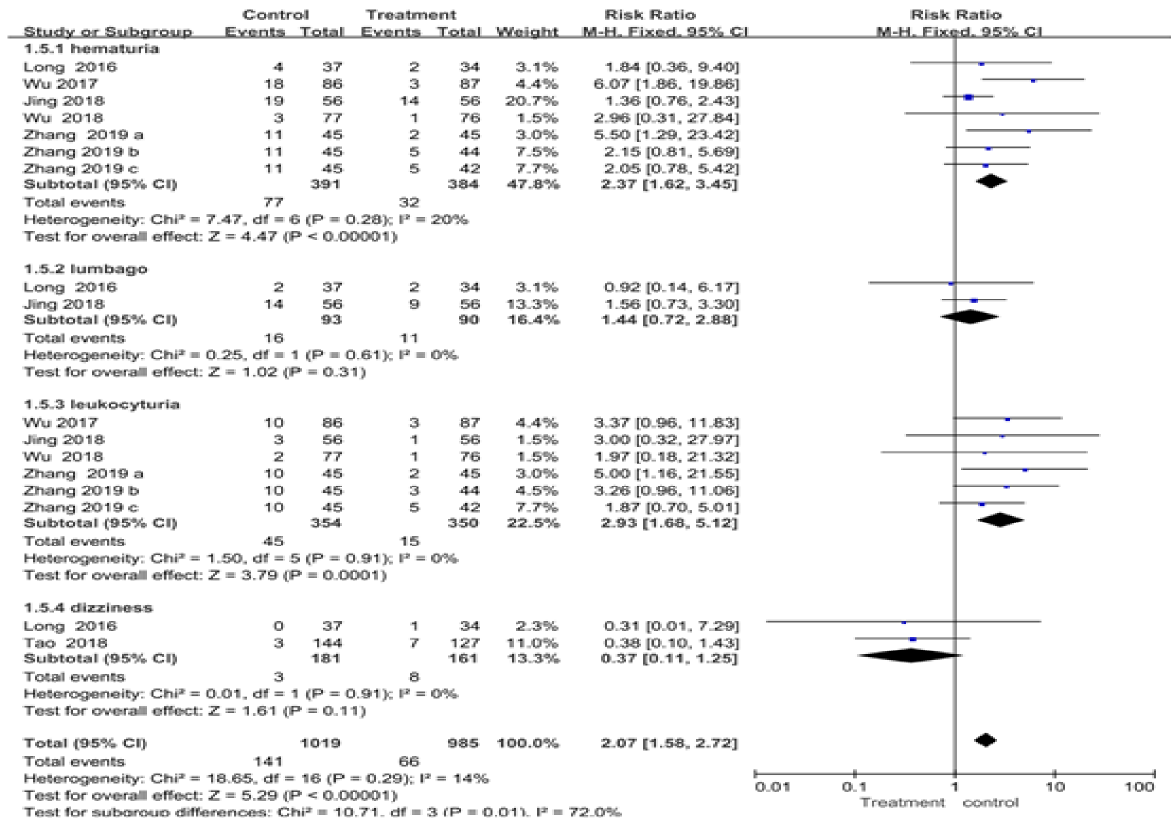

Figure 6. Comparison of complication rates for different types of complications in patients in the EPVL and control groups.

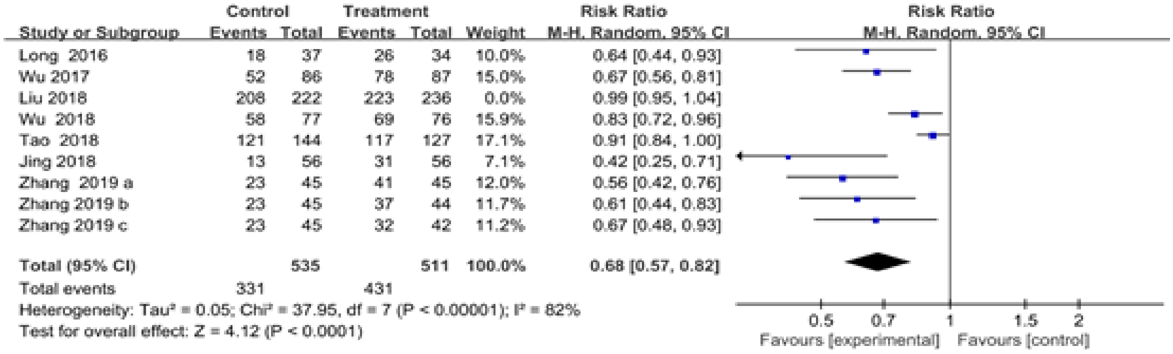

Figure 7. Sensitivity analysis forest plots.

Sensitivity analysis and publication bias

To examine the stability of the outcome, a sensitivity analysis was conducted. After the research by Liu et al.(12) was excluded, the I2 value changed from 92% to 82%, indicating that this research was the main cause of the heterogeneity. The forest plot without the inclusion of Liu et al.'s article is presented in Figure 7. All included studies reported SFRs, and a funnel plot for the SFR was created. The results demonstrate that there existed some publication bias, as the funnel plot was not symmetric (**Figure 8**).

DISCUSSION

The problem of residual stones has plagued urologists for decades. Although surgery can be performed to remove most stones, and while complete stone removal can be achieved in some patients, residual stones remain an unavoidable problem. Additionally, 43-77% of asymptomatic residual stones will progress accordingly, causing corresponding symptoms.[17,18] In 2000, Honey et al.[4] reported for the first time that PDI therapy can effectively promote the excretion of calculus in the kidney. A meta-analysis showed that PDI therapy can improve the discharge of calculus after ESWL (OR: 0.62; 95% CI: 0.47-0.82). Although it has been concluded that PDI therapy is effective, only two related studies were included, and evidence of its effectiveness is lacking. Moreover, because the percussion in PDI therapy is not widely promoted in clinical practice, there have been few relevant studies.

However, the EPVL device has gradually been used clinically since its invention in China, and many researchers have conducted related clinical studies. This equipment includes a rotating bed and a physical vibration device, which accelerates the discharge of stones by changing the patient's body position and providing multi-directional simple harmonic waves. The EPVL

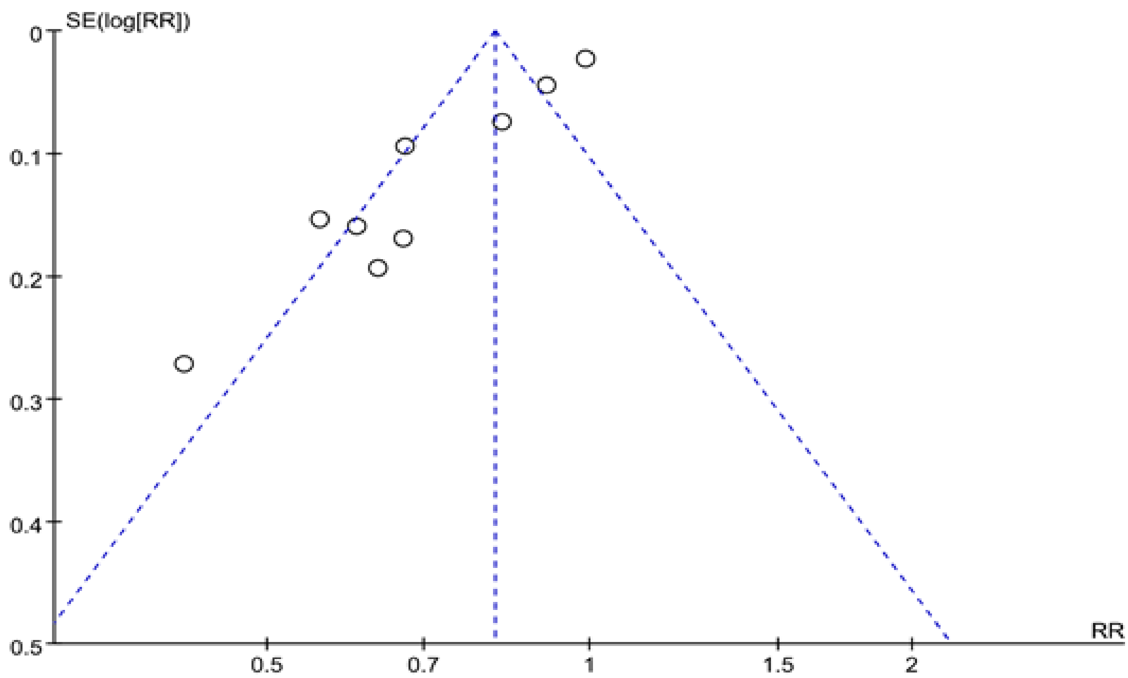

Figure 8. Funnel plot of publication bias.

is primarily used as an adjuvant treatment of residual stones after ESWL and RIRS. In 2019, a meta-analysis conducted by Chung et al. revealed that residual stones are more common after ESWL and RIRS than after PCNL, with likelihoods reaching 23.1-91.5% and 45.6-96.7%, respectively.[19] However, in the present subgroup analysis, EPVL treatment was found to better prevent residual stones after these two treatments.

The location of residual stones is a significant factor that affects their removal rate.[20] Due to the effect of gravity, stones remaining in the lower half of the kidney account for a large proportion, and are more difficult to remove than residual stones in the upper and middle areas.[21,22] However, the present subgroup analysis revealed that EPVL treatment can solve this problem very well; it can significantly improve the SFR in the lower kidney, and also in other parts of the kidney. The ureter is also a common site of urinary tract stones, but the subgroup analysis demonstrated that EPVL treatment has no significant effect on the SFR of ureteral stones. A prospective study conducted by Liu et al.[12] showed that EPVL treatment can achieve the same stone removal rate as medical expulsive therapy (MET) for lower ureteral stones of less than 10 mm in size, and there was no significant difference between the rate of stone discharge in the EPVL group and the MET group; researchers performed surgery on patients whose stones had not passed after two weeks, and found that their ureters had strictures. The safety of EPVL treatment is also an important issue that must be considered in clinical practice. There have been no reports of serious complications in many known studies; while there have been reports that patients experienced dizziness, nausea, and skin redness after receiving EPVL treatment, these side-effects all relieved themselves. The EPVL is a physical therapy device, and is a safe and non-invasive treatment method. The subgroup analysis of the probability of complications revealed that patients who received EPVL treatment had a lower probability of complications, including hematuria, lumbago, leukocyturia, and dizziness. EPVL treatment was found to reduce the phenomena of hematuria and leukocyturia, which are usually caused by the movement of stones in the ureter to the mucosa. It is believed that the following two factors led to this result: First, the vibration waves generated by the two EPVL vibrators can separate the stones from the ureter, and can also push the stones forward, thereby reducing the likelihoods of stones incarcerated in the ureter and inflammation; Second, the vibration waves drive the movement of the stones, thereby improving the rate of stone discharge and reducing the occurrence of related complications. In the present analysis, lumbago and dizziness were not found to be necessarily related to whether patients received EPVL treatment; however, the occurrence of these two complications in all experiments was relatively small.

It was also found that the current efficacy of EPVL treatment has certain defects; as an emerging technology, the EPVL device has not been widely used in clinical practice, and a specific treatment process and specifications have not yet been formed. All patients must drink water before receiving EPVL treatment, but there is no obvious conclusion regarding the specific amount. Additionally, scholars have not yet proposed the best position of the EPVL device during the main treatment period or the method of vibration wave transmission. Moreover, the rotation of the rotating bed allows the patient to assume a high dorsal position to facilitate the discharge of stones, but there is no clear conclusion about which angles of rotation can achieve the best effect. Standardized treatment programs and prospective RCTs involving more centers may be more objective in evaluating this technique.

This meta-analysis had several limitations. First, only 7 RCTs were included in this study, and the sample sizes used for subgroup analysis were small and differed greatly. Second, there were also certain differences between the experimental plans of each group for the exploration of the therapeutic effect of EPVL treatment, thereby leading to the risk of bias. In future related studies, more rigorous prospective RCTs are needed.

CONCLUSIONS

In summary, the results of the current meta-analysis provided evidence that, as compared with the control group, patients who received EPVL treatment had higher stone clearance and fewer related complications. The removal rates of stones in the upper/middle/lower calyx and renal pelvis were significantly higher in the intervention group, and significant side effects were not reported. Therefore, EPVL treatment is an effective and repeatable method for the discharge of residual stones.

CONFLICT OF INTERESTS

The authors declare that they have no conflicts of interest.

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