

The efficacy and safety of tubeless percutaneous nephrolithotomy: a systematic review and meta-analysis

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Abstract The objective of this study was to conduct a systematic review and meta-analysis to evaluate the efficacy and safety of tubeless versus standard percutaneous nephrolithotomy (PCNL). Relevant randomized or quasi-randomized controlled trials studies were identified from electronic database (Cochrane CENTRAL, Medline and EMBASE et al.). The retrieval time ended in August 2010. The quality of the included trials was assessed and the data were extracted independently by two reviewers. We divided the participants who received standard PCNL into two subgroups: small tube (4–10 F) group and big tube (14–24 F) group to reduce heterogeneity and bias. Efficacy (hospital stay time, operative time, stone-free rate) and safety (postoperative pain and analgesia requirement, postoperative fever, blood transfusion, urine leakage) were explored by using review manager v5.0. Fourteen randomized controlled trials comprising 776 subjects met the inclusion criteria. Our meta-analysis showed that there were statistically significant differences in hospital stay, postoperative analgesic requirement and urine leakage between tubeless and standard PCNL. In operative time, significant difference was found between tubeless and big tube group. No statistically significant differences were found in stone-free rate, postoperative fever, and blood transfusion between tubeless and standard PCNL. In conclusion, Tubeless PCNL was an effective and safe procedure for treatment of renal stones in selected patients, with shorter hospital stay, less analgesic requirement, lower urine leakage and without increased complications. Patients can

receive great benefit from tubeless PCNL and it will become more palatable to patients as well as more cost-effective than standard PCNL in the future.

Keywords Percutaneous nephrolithotomy · Standard · Tubeless · Nephrostomy tube · Ureteral stent

Abbreviations

PCNL	Percutaneous nephrolithotomy
VAS	Visual analog scale
CI	Confidence interval
SD	Standard deviation
OR	Odds ratio
MD	Mean difference

Introduction

Since the first performance of percutaneous nephrolithotomy had been reported by Fernstrom et al. [1] in 1976, it was widely accepted and became an established technique for management of renal calculi. The placement of a nephrostomy tube after PCNL is considered as the standard procedure. The main purpose of the nephrostomy tube is to provide adequate renal drainage, tamponade access tract bleeding and offer access for a second-look procedure when necessary [2].

However, in recent years, with growing realization of significant postoperative discomfort and morbidity after standard PCNL because of nephrostomy tube and with recent developments in surgical techniques and equipments, many modifications had been attempted in PCNL operations, such as termed mini-PCNL [3], using smaller nephrostomy tube or using ureteral stent instead of nephrostomy tube after PCNL has been later known as tubeless PCNL and reduces

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postoperative complaints caused by the tube [4]. Since tubeless PCNL was first introduced by Bellman [4], there had been widespread interest and enthusiasm in tubeless PCNL. A large number of studies about this technique were performed and it was shown that this technique had several advantages including shorter hospital stay, and less postoperative pain and analgesic requirement without increased complications. So, tubeless PCNL has been advocated by more and more urologists all over the world. But these studies ignored the drawbacks of the technique such as stent-related symptoms [5], requirement of cystoscopy for its removal and impossibility of performing a second-look procedure for residual stone when necessary.

As a result, the controversy over which was the ideal drainage strategy after percutaneous nephrolithotomy had existed in recent years. Therefore, it is necessary to conduct a systematic review and meta-analysis of evidence from randomized controlled trials to evaluate the efficacy and safety of tubeless PCNL.

Materials and methods

Types of studies

Randomized or quasi-randomized controlled trials were eligible.

Types of participants

The inclusion criteria of the participants of all of the studies were age >18 years, absence of congenital abnormalities, single-tract access and preoperative normal kidney function. The exclusion criteria of the participants were serious bleeding at the end of surgery, perforation of the pelvicaliceal system, solitary kidney and significant residual stone.

Search strategy

The search strategy was conducted by two authors independently. Relevant trials were obtained from the following sources: Cochrane Central Register of Controlled Trials (CENTRAL), Medline, EMBASE et al. The following Mesh search heading terms were used to identify relevant studies: (percutaneous nephrolithotomy, percutaneous nephrostomy, PCNL or PNL); (tubeless, ureteral stent, double-J stent, ureteral catheter or pigtail catheter); and (standard, tube, nephrostomy tube or nephrostomy drainage). Randomized or quasi-randomized controlled trials that compared employing tubeless (ureteral stent or double-J stent) versus standard (nephrostomy tube) strategy for drainage of urine after PCNL for patients with renal stone were included if they met the criteria. The retrieval time

ended in August 2010. There was no language restriction. Furthermore, the reference list of the identified studies and the abstracts from the annual meetings of the American Urological Association and European Association of Urology were searched independently by HCY and SZ. The discrepancy was resolved in consultation with QW.

Assessment of quality

The quality of the included studies was assessed separately by HCY and SZ with blinding to authorship or journal using the Jadad [6] scale score, and reporting (6 items) for each study ranged from 0 to 8 points. A score of 2 points or less was defined as low quality, scores of 3–4 as moderate quality and scores of 5 points or more as high quality. The quality items to be evaluated were: being double blind, allocation concealment, completeness of follow-up and incomplete outcome data.

Data extraction and analysis

Data from the included studies were independently extracted onto a standardized form by two reviewers (HCY, LRL), and any discrepancy was resolved in consultation with QW. The primary measured outcomes were hospital stay, operative time, postoperative pain (VAS), analgesic requirement urine leakage and stone-free rate. The secondary outcomes were blood transfusion and postoperative fever. Several studies reported mean and *p* value of hospital stay, operative time and postoperative analgesia requirement, so we estimated the standard deviation (SD) using the statistical method [7]. We contacted the authors of included studies to find out if there were missing data or inaccurate information. For continuous data [hospital stay, operative time, postoperative pain (VAS) and analgesia requirement], mean difference (MD) with 95% confidence intervals (CI) was used. For dichotomous data (stone-free rate, urine leakage, postoperative fever, blood transfusion), odds ratio (OR) was used with 95% CI. Heterogeneity was analyzed using a chi-squared test on $N - 1$ degrees of freedom, with *p* value of 0.05 used for statistical significance and the I^2 statistic. In case of lack of heterogeneity, fixed-effects model was used for the meta-analysis, or else random-effects model was used. When $I^2 < 70\%$, the heterogeneity was acceptable. All meta-analysis were performed by the Review Manager Software version 5.0. When data were reliable and sufficient, subgroup analysis was introduced by grouping the trials to explore possible heterogeneity. In our study, we divided standard PCNL into two subgroups: small tube group (4–10 F) and big tube group (14–24 F) in terms of the size of the tube to reduce heterogeneity [8]. When significant heterogeneity existed, sensitivity analysis was used to explore the reliability of the results.

Results

According to the search strategy determined previously, after study assessment there were 14 randomized controlled trials [5, 8–20] including 776 cases, which were identified for analysis in this review. Eight of the included studies [9, 11, 12, 14–18], which received standard PCNL, used big nephrostomy tube (14–24 F), and three of the included studies [5, 13, 19] used small nephrostomy tube (4–10 F). Two studies [8, 10] compared the big tube group, the small tube group and the tubeless group simultaneously. One study [20] did not describe the size of the nephrostomy tube, so we included the study in the big tube group. Baseline information was comparable between the tubeless PCNL and standard PCNL groups. The literature screening process has been shown in Fig. 1. The baseline characteristics and quality assessment of the included studies are summarized in Table 1.

Hospital stay (hours)

Hospital stay was measured in 11 studies [5, 8, 9, 11–13, 15–19] including 621 patients; meta-analysis of these studies showed that tubeless PCNL had less hospital stay time than standard PCNL with a statistically significant difference (MD: -24.39 ; 95%CI: -32.58 to -16.21 ; $p < 0.00001$), but with statistical heterogeneity ($I^2 = 81\%$). Subgroup analysis indicated that there was a statistically significant difference in hospital stay between the tubeless group and small tube group (MD: -11.61 ; 95%CI: -19.98

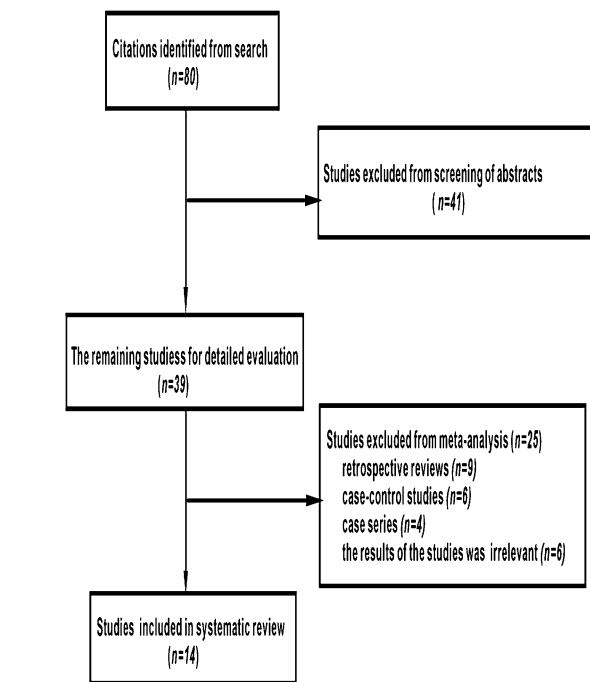


Fig. 1 The literature screening process

to -3.25 ; $p = 0.006$) with statistical heterogeneity ($I^2 = 22\%$), whereas the tubeless group also had more significant difference than the big tube group (MD: -29.83 ; 95%CI: -37.24 to -22.42 ; $p < 0.00001$) with statistical heterogeneity ($I^2 = 61\%$) (Fig. 2).

Table 1 Baseline characteristics and quality assessment of the included studies

Study	Mean age (T/S)	Gender (M/F*)	Mean stone size (cm ²)	Size of work sheath (F)	Size of US/NT (F)	Jadad scale score (6 items)	Number of dropouts
Shah	44.18/46.69	20:13/21:11	5.35/4.95	30	6/8	3	ND
Choi	52.9/47	ND	2.85/2.68	30	6/8.2	3	ND
Weiland	54/65	5:3/6:3	3.2/6.7	30	8.2/8.3	5	1
Desai ^a	43.4/44.8/41.1	8:2/8:2/6:4	2.63/2.43/2.49	30	6/20, 9	4	ND
Marcovich ^a	58/67/67	8:12/9:11/9:11	3.4/3/3.6	30	7/24, 8	3	ND
Sofikerim	47.8/54.1	10:14/14:10	4.25/4.28	30	6/18	3	ND
Singh	31/34	1:14:1/1:1	7.5/8	ND	ND/24	4	ND
Tefekli	38.4/41.3	8:9/11:7	2.95/3.25	30	ND/14	3	ND
Feng	62/56	ND	4.38/8.36	34	ND/22	4	2
Agrawal	33/31	3:1/3:1	3.8/3.6	28	6/16	5	ND
Istanbuluoglu	47.48/43.91	25:20/24:21	4.48/4.53	30	ND/14	4	ND
Kara	67.7/66.5	18:12/20:10	2.56/2.53	30	ND/18	4	ND
Mishra	42.3/42.5	ND	2.73/2.93	26.5	ND/20	4	ND
Falahatkar	46.6/46.6	28/17	ND	30	ND	3	ND

T tubeless, S standard, F* female, M male, US ureteral stent, NT nephrostomy tube, ND not depicted

^a Tubeless versus big tube and small tube simultaneously

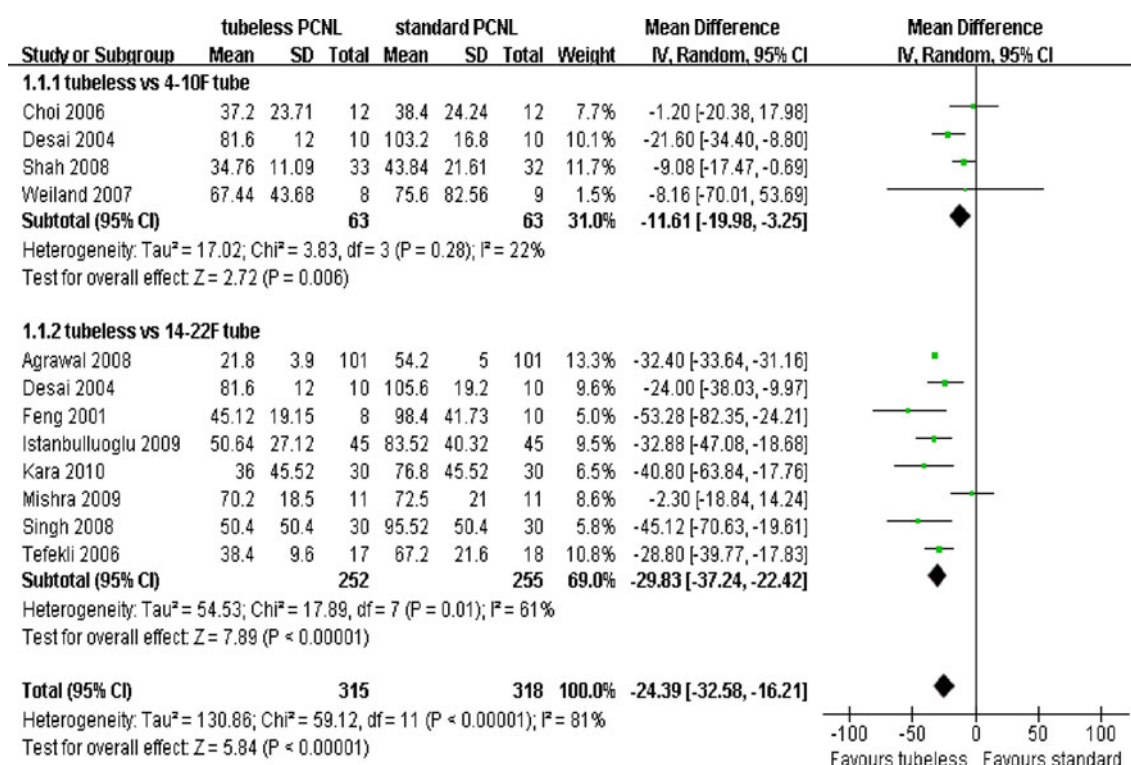


Fig. 2 Pooled estimate of hospital stay (hours) utilizing random-effect model

Operative time (hours)

Seven studies [5, 8, 9, 11, 13, 15, 18] including 322 patients reported operative time. Meta-analysis of these studies showed that no difference was found in operative time between tubeless and standard PCNL (MD: -4.75; 95%CI: -10.92 to 1.43; $p = 0.13$). But subgroup analysis indicated that tubeless PCNL took less operative time than the big tube group with a statistically significant difference (MD: -9.26; 95%CI: -16.76 to -1.77; $p = 0.02$) and acceptable statistical heterogeneity ($I^2 = 58\%$). No statistically significant difference was found between the tubeless and small tube group (MD: 2.57; 95%CI: -2.66 to 7.8; $p = 0.34$) (Fig. 3).

Postoperative analgesic requirement

Twelve studies reported on postoperative use of analgesic, which has been summarized in Table 2. Five studies used the same drug (diclofenac) as analgesic, but one study [14] did not provide complete data; so, only four studies could be analyzed. Meta-analysis of the four studies [5, 8, 11, 15] indicated that tubeless PCNL showed statistically significant advantage over the standard PCNL in analgesic requirement (MD: -105.99; 95%CI: -136.87 to -75; $p < 0.00001$) with heterogeneity ($I^2 = 36\%$). Subgroup analysis showed that significant difference was found in the tubeless group versus the small tube group (MD: -75.37;

95%CI: -123.84 to -26.9; $p = 0.002$; $I^2 = 0\%$) and big tube group (MD: -119.26; 95%CI: -156.84 to -81; $p < 0.00001$; $I^2 = 43\%$), respectively (Fig. 4).

Postoperative pain (VAS)

Postoperative pain was measured using visual analog scale (VAS) in five studies [5, 12, 13, 15, 19]. Meta-analysis of these studies showed that tubeless PCNL could decrease postoperative pain compared with standard PCNL with statistically significant difference (MD: -1.07; 95%CI: -2.01 to -0.13; $p = 0.03$), but with significant heterogeneity ($I^2 = 96\%$). Subgroup analysis indicated that there was a statistically significant difference between the tubeless group and big tube group (MD: -2.43; 95%CI: -3.17 to -1.68; $p < 0.00001$) with significant heterogeneity ($I^2 = 96\%$). No statistically significant difference was found between tubeless and small tube groups (Fig. 5).

Stone-free rate

The eight included studies [5, 9–11, 14–16, 20] reported postoperative stone-free rate, and the pooled result of meta-analysis indicated that there was no statistically significant difference between the tubeless and big tube (14–24 F) group (OR: 1.55; 95%CI: 0.85–2.82; $p = 0.15$) with statistical heterogeneity ($I^2 = 0\%$). But, these studies showed that

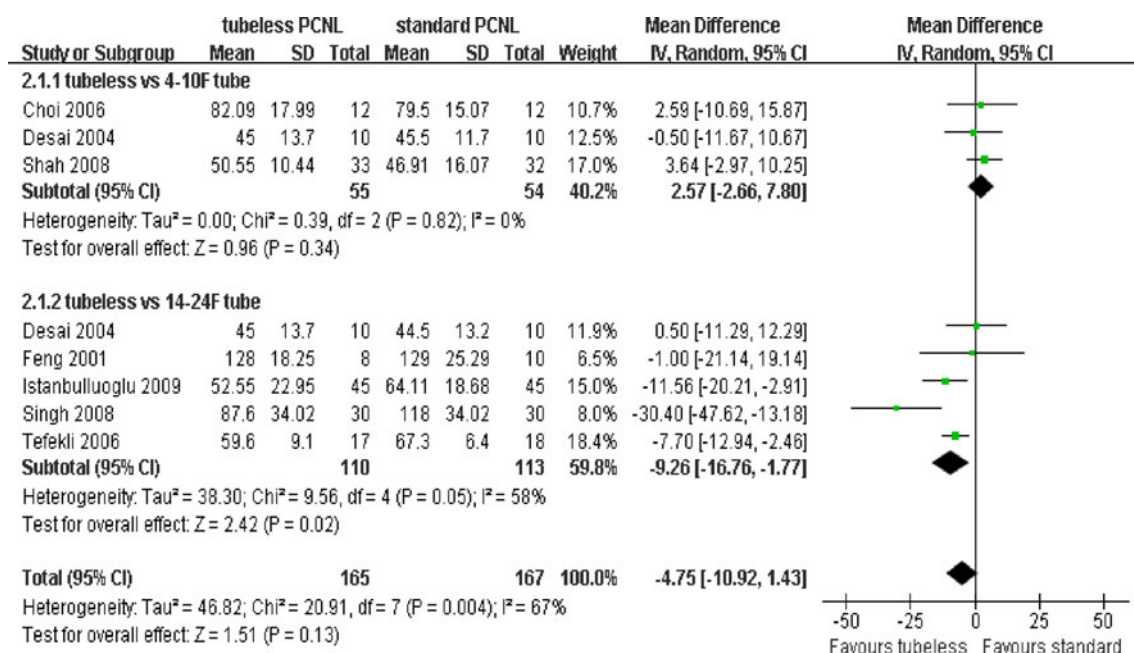


Fig. 3 Pooled estimate of operative time utilizing random-effect model

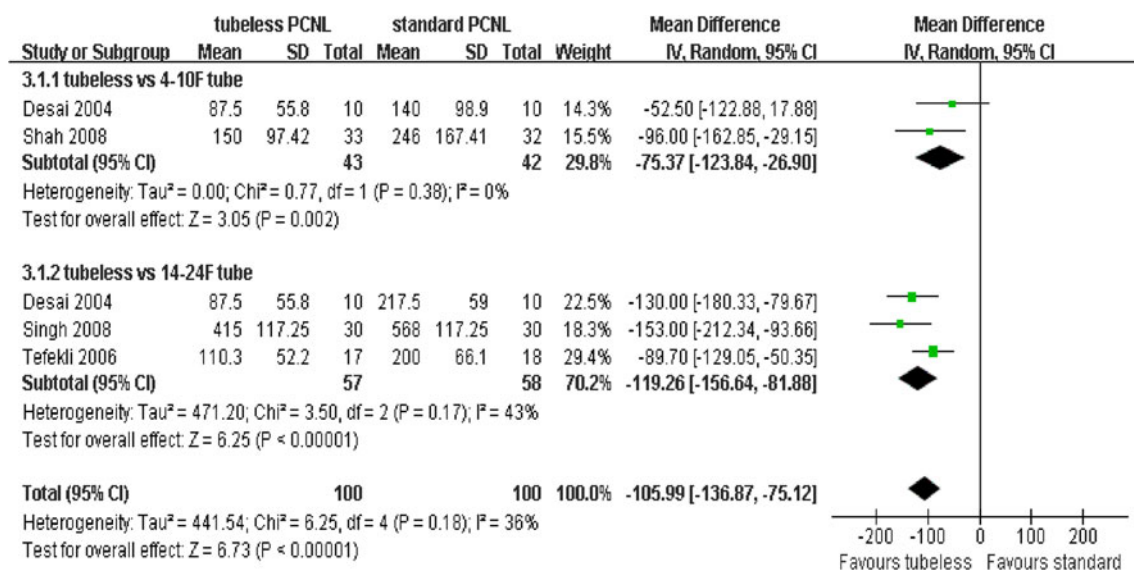


Fig. 4 Pooled estimate of postoperative analgesic requirement (diclofenac) utilizing random-effect model

tubeless PCNL was slightly superior to standard PCNL considering stone-free rate (Fig. 6).

Urine leakage

Urine leakage was measured in four studies [5, 10, 12, 18] including 393 patients. Statistically significant difference was found between tubeless PCNL and standard PCNL (OR: 0.19; 95%CI: 0.07–0.58; $p = 0.004$; $I^2 = 0\%$). Sub-group analysis showed that statistically significant differ-

ence was found between the tubeless group and the big tube group (OR: 0.14; 95%CI: 0.03–0.63; $p = 0.01$; $I^2 = 0\%$); no statistical difference was found between the tubeless group and the small tube group (OR: 0.32; 95%CI: 0.06–1.62; $p = 0.49$) (Fig. 7).

Blood transfusion

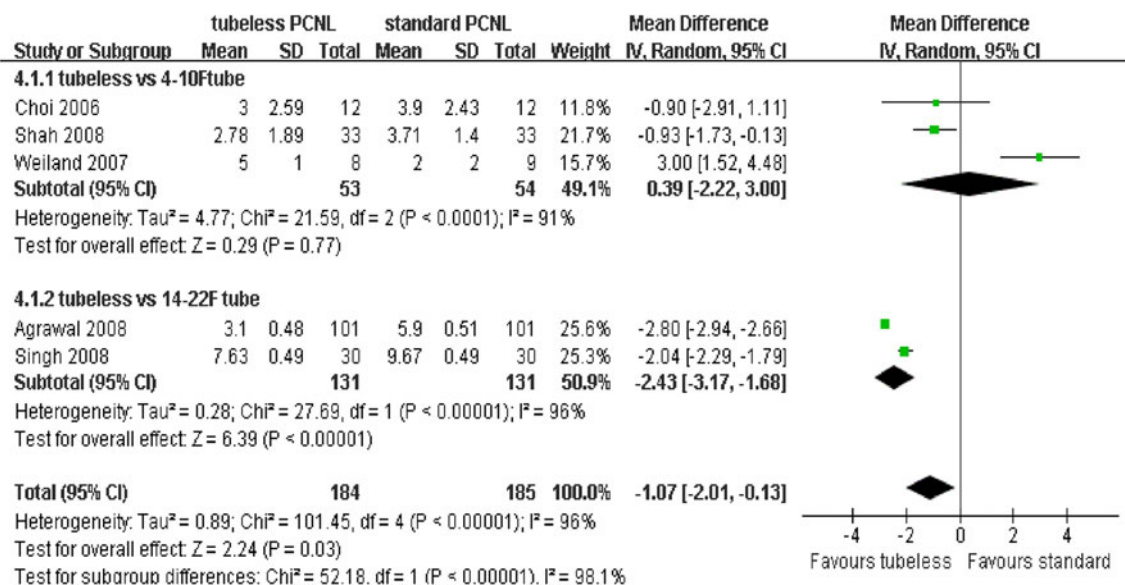
Nine studies [5, 9, 10, 12–15, 18, 20] compared the outcomes of postoperative need for blood transfusion. There

Table 2 Postoperative analgesic requirement

Studies	Analgesic	Tubeless	Standard	<i>p</i> value
Mishra	Tramadol	68.2 ± 46.2	72.7 ± 51.8	0.25
Marcovich ^a	Morphine	8.6 ± NR	BT:7.7 ± NR/ST:7.5 ± NR	0.89
Feng	Morphine	5.25 ± 5.02	52.0 ± 71.15	NR
Choi	Morphine	1.91 ± 2.5	3.60 ± 4.63	0.2802
Kara	Meperidine	0.5 ± NR (mg/kg)	1.4 ± NR (mg/kg)	<0.01
Agrawal	Meperidine	81.7 ± 24.5	126.5 ± 33.3	<0.01
Falahatkar	Meperidine	99.07 ± NR	101.56 ± NR	NR
Tefekli	Diclofenac	110.3 ± 52.2	200.0 ± 66.1	<0.05
Desai ^a	Diclofenac	87.5 ± 55.8	BT:217 ± 59/ST:140 ± 98.9	<0.05/0.08
Singh	Diclofenac	415 ± 117.25	568 ± 117.25	<0.001
Sofikerim	Diclofenac	120 ± NR	263 ± NR	0.02
Shah	Diclofenac	150 ± 97.42	246.09 ± 167.41	0.006

SD standard deviation, *NR* no record, *BT* big tube, *ST* small tube

^a Tubeless versus big tube and small tube simultaneously

**Fig. 5** Pooled estimate of postoperative pain (VAS) utilizing random-effect model

was no statistically significant difference between tubeless PCNL and standard PCNL (OR: 0.73; 95%CI: 0.36–1.47; *p* = 0.37). Subgroup analysis indicated that no statistically significant difference was found in the tubeless group versus small tube group and big tube group (Fig. 8).

Postoperative fever

Postoperative fever rate was reported in eight studies [5, 10, 12, 14, 16–18, 20]. The meta-analysis of these studies showed that no statistically significant difference was found between tubeless PCNL and standard PCNL (OR: 0.71; 95%CI: 0.38–1.33; *p* = 0.29). Subgroup analysis indicated that there was also no statistically significant difference in the tubeless group versus small tube and big tube groups (Fig. 9).

Discussion

The main findings of this meta-analysis were that tubeless PCNL had shorter hospital stay and less analgesia requirement than standard PCNL, regardless of small tube or big tube group. Moreover, tubeless PCNL could significantly reduce operative time, decrease postoperative pain and diminish urine leakage in comparison to big tube group. There was no significant difference in operative time, postoperative pain and urine leakage between the tubeless group and small tube group; we considered that the reason for this was the insufficient sample size of the small tube group that included only four studies with reported outcomes. Shorter hospital stay and less analgesia requirements could cut back the cost of treatment and improve health-care quality. Shortening of operative time signified

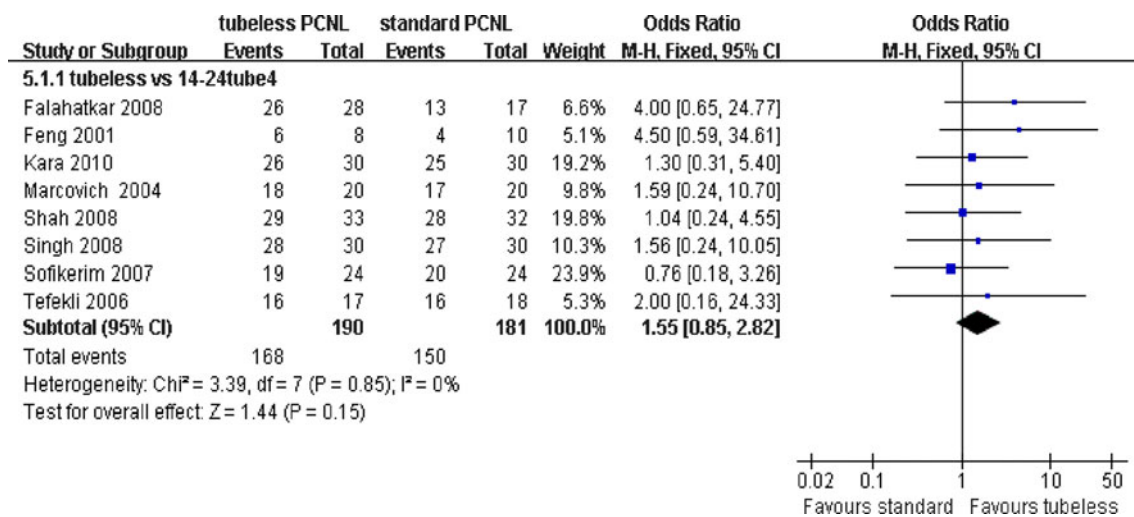


Fig. 6 Pooled estimate of stone-free rate utilizing fixed-effect model

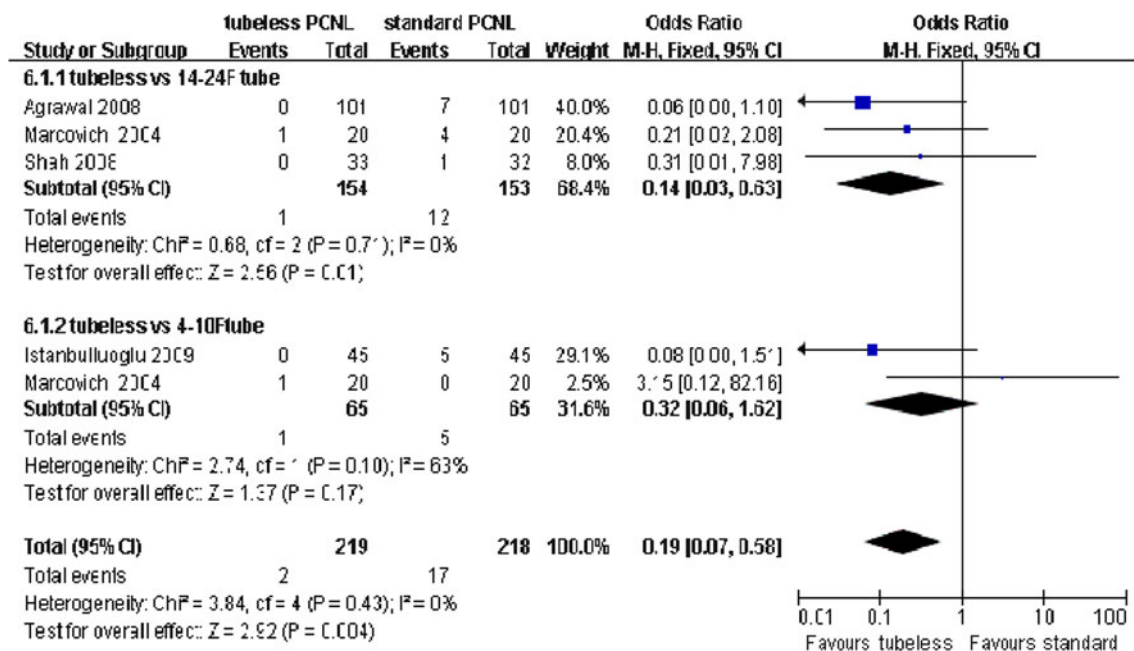


Fig. 7 Pooled estimate of urine leakage utilizing fixed-effect model

the reduction of many potential complications such as anesthetic accident and postoperative morbidity. However, we found that tubeless PCNL did not increase relevant complications such as postoperative fever and blood transfusions. Though many studies confirmed that one of the advantages of the nephrostomy tube was to tamponade the access tract in order to prevent bleeding, standard PCNL did not demonstrate the superiority in our study. So, we questioned the advantages and necessity of placing nephrostomy tube after PCNL.

However, it was noted that these advantages of tubeless PCNL were mainly attributed to the careful selection of uncomplicated routine patients, such as those without con-

genital abnormalities, with one percutaneous tract, no serious bleeding at the end of surgery, no perforation of the pelvicaliceal system and with insignificant residual stone. In addition, insertion of double-J stent had certain disadvantages, such as bothersome irritative urinary symptoms [5] and requirement of cystoscopy for its removal. These factors limited this technique to selected cases with strict selection criteria. However, with the development and improvement of technique and equipment and experience with tubeless PCNL, these limitations will be gradually overcome. Jou et al. [21] reported that perforation of the collecting system was not a contraindication; double-J stent could provide enough drainage for the kidney as long as it

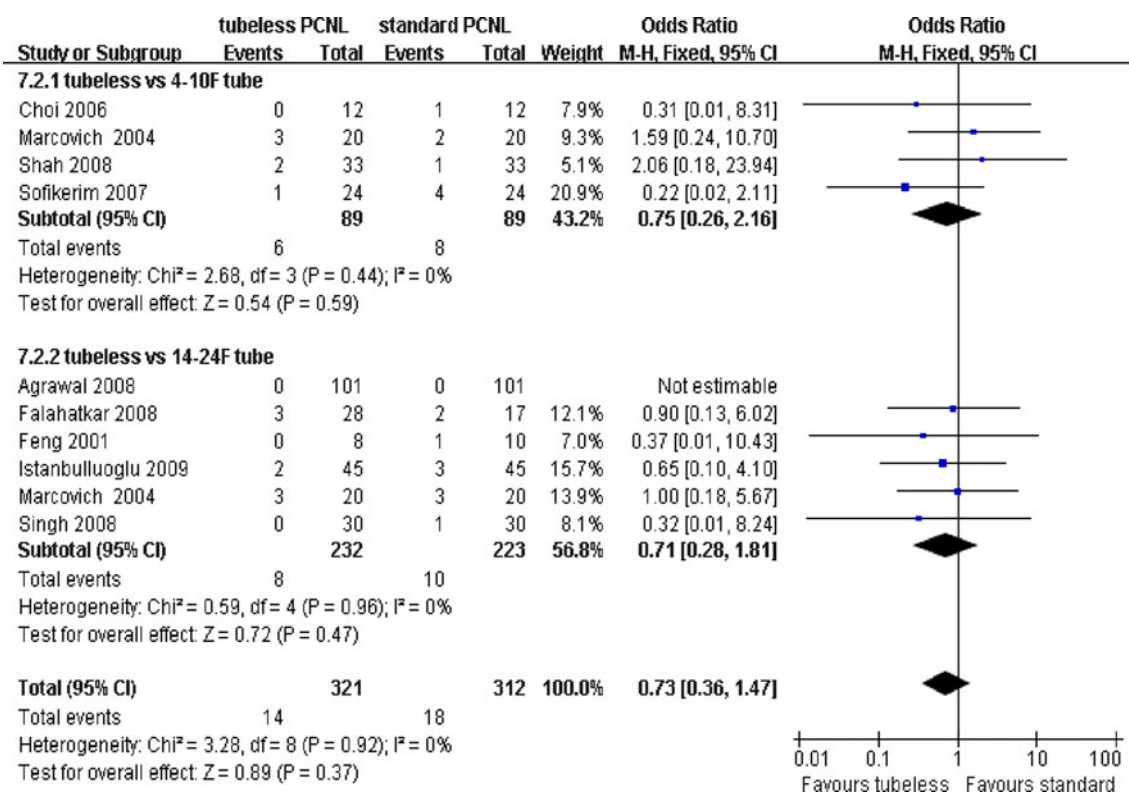


Fig. 8 Pooled estimate of blood transfusion utilizing fixed-effect model

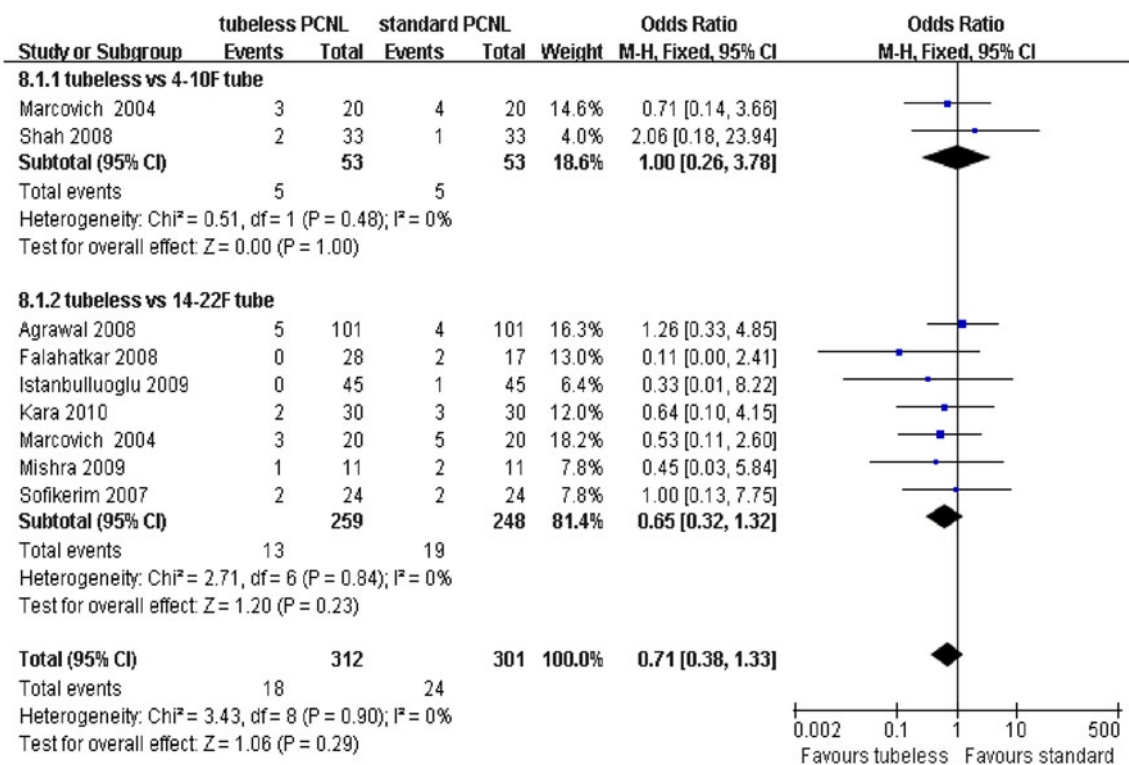


Fig. 9 Pooled estimate of postoperative fever utilizing fixed-effect model

was fixed. The site and numbers of puncture were also not regarded as a limiting factor [22]. The stone burden was no longer regarded as a limiting factor, as Al-Baadani T operated on stones up to 70 mm size, and even staghorn or multiple stones [22]. Besides, to prevent bleeding after tubeless PCNL, different modified techniques had been employed, including use of different hemostatic sealants to seal the percutaneous tract [23], cauterization of the bleeders inside the kidney or in the tract [21] and the use of balloon dilator instead of Amplatz dilators [24]. These modifications would tilt the balance in its favor and extend the range of application of tubeless PCNL. In recent years, some studies have also demonstrated the feasibility of tubeless PCNL in children [25] and obese patients [26] with supracostal access [14], and also in those with previous open renal surgery [27] and as outpatient [28]. We believe that tubeless PCNL would play a more important role in the treatment of renal stones and even become the new gold standard in the future [22].

The 14 trials that we included for analysis were all randomized controlled trials; it helped us to reduce confounding data, limit bias and draw scientific and reliable conclusions. Furthermore, we used methods recommended to improve the quality of systematic reviews and meta-analysis. However, like all systematic reviews, this report had some limitations.

In our review, evaluation of study quality was hampered by the lack of adequate description in publications or the existence of methodological deficiencies. Only seven studies [5, 8, 12, 15, 17–19] described appropriate randomization procedures, but did not report adequate allocation concealment. Two studies [9, 19] listed the number and the reason of withdrawals and dropouts. Moreover, all the studies did not use a blind method owing to the surgical characteristic of standard PCNL. Several studies reported the mean and *p* value of hospital stay [15, 16], operative time [15] and postoperative analgesia requirement [15], so we estimated the SD using the statistical method [6]. Therefore, our study probably had selection and measurement bias. Besides, some studies did not provide adequate statistical data and we could not acquire relevant data by contacting the authors, so that these data were lost, which also led to risk of bias. However, we hope that uniform statistical unit and methodology will be introduced into future studies, so that we can obtain complete data and stronger evidence.

The other limitations were the heterogeneity and the publication bias. These included studies had certain clinical and methodological heterogeneity. Therefore, subgroup analysis and sensitivity analysis were introduced to reduce heterogeneity. We used sensitivity analyses to explore the reliability of the results, which did not significantly change the results. However, the risk of bias and statistical heterogeneity still existed and further influenced the conclusions.

However, larger multi-center long-term RCTs of high quality will be still required to explore the difference between tubeless and standard PCNL, especially tubeless versus the small tube group in postoperative pain, stone-free rate, postoperative fever and blood transfusion.

Conclusion

Tubeless PCNL is an effective and safe procedure for treatment of renal stones in selected patients, with decreased hospital stay, less analgesia requirement, lower urine leakage and decreased complications. Patients can receive great benefit from tubeless PCNL. We consider that it will become more palatable to patients, as well as more cost-effective, than standard PCNL in the future.

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