#### REVIEW



# Complications and outcomes of tubeless versus nephrostomy tube in percutaneous nephrolithotomy: a systematic review and meta-analysis of randomized clinical trials

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#### Abstract

We aimed to perform a systematic review of randomized trials to summarize the evidence on the safety and stone-free rate after Tubeless percutaneous nephrolithotomy (PCNL) (ureteral stent/catheter, no nephrostomy) compared to Standard PCNL (nephrostomy, with/without ureteral stent/catheter) to evaluate if the tubeless approach is better. The inverse variance of the mean difference with a random effect, 95% Confidence Interval (CI), and *p* values was used for continuous variables. Categorical variables were assessed using Cochran–Mantel–Haenszel method with the random effect model, and reported as Risk Ratio (RR), 95% CI, and *p* values. Statistical significance was set at *p* < 0.05 and a 95% CI = 26 studies were included. Mean operative time was significantly shorter in the Tubeless group (MD—5.18 min, 95% CI – 6.56, – 3.80, *p* < 0.00001). Mean postoperative length of stay was also significantly shorter in the Tubeless group (MD—1.10 day, 95% CI – 1.48, – 0.71, *p* < 0.00001). Incidence of blood transfusion, angioembolization for bleeding control, pain score at the first postoperative day, the number of patients requiring postoperative pain medication, fever, urinary infections, sepsis, perirenal fluid collection, pleural breach, hospital readmission, and SFR did not differ between the two groups. Incidence of postoperative urinary fistula was significantly lower in the Tubeless group (RR 0.18, 95% CI 0.07, 0.47, *p* = 0.0005). This systematic review shows that tubeless PCNL can be safely performed and the standout benefits are shorter operative time and hospital stay, and a lower rate of postoperative urinary fistula.

Keywords Percutaneous nephrolithotomy · Kidney stone · Percutaneous nephrostomy · Ambulatory surgical procedures

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#### Introduction

The eternal debate for percutaneous nephrolithotomy (PCNL) exit strategy is whether a nephrostomy tube is necessary and its impact on the procedure and complications. Furthermore, the presence of a nephrostomy tube may hamper PCNL as a day surgery/ambulatory procedure. PCNL access and exit strategies have been well defined by CROES and large-volume randomized controlled trials [1]. Exit strategies in PCNL are typically tubeless (refers to the placement of a double J stent alone), totally tubeless (refers to no nephrostomy and no double J stent), and nephrostomy alone [2]. There is a lack of consensus on what measurable intraoperative and postoperative outcomes, including exit strategy, are best suited for a day surgery/ambulatory PCNL. Tubeless PCNL could be the ideal approach in selecting which patients might be suitable for same-day discharge.

Three past systematic reviews favored tubeless PCNL over PCNL with a nephrostomy tube as it significantly shortened hospital stay allowing for a faster return to normal activity facilitated by lower immediate postoperative pain scores, reduced analgesic requirement, and urine leakage [2–4]. However, questions persist if this approach could increase complications rates, such as bleeding, urinomas, or perinephric abscess as well as hospital readmissions. The present study aims to evaluate how recent technical and technological refinements in PCNL have influenced urologists toward a clearer understanding of which choices, surgical outcomes, and parameters can be considered for PCNL, especially when planning their exit strategy with the usage of a nephrostomy tube placement vis-a-vis a tubeless approach.

# Methods

#### Aim of the review

The present study aims to systematically review the safety and stone-free rate after tubeless PCNL (ureteral stent/ ureteral catheter and no nephrostomy tube) as compared to standard PCNL (with nephrostomy tube with or without ureteral stent/ureteral catheter) for kidney stones. The main outcome is to evaluate for differences in surgical time, length of stay, and postoperative complications between two procedures. The secondary outcome is to assess if there is any difference in the stone-free rate (SFR) between the two procedures. We also intend to observe if there were any specific trends in tract sizes over the years as well as the use of different exit strategies in the tubeless cohort. Finally, we aim to compare the results of our metaanalysis to those of previous years.

#### Literature search

This study was performed according to the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework. A broad literature search was performed on 5th October 2021, using EMBASE, MEDLINE, and Cochrane Central Controlled Register of Trials (CEN-TRAL). Medical Subject Heading (MeSH) terms and keywords such as "kidney calculi", "urolithiasis", "Percutaneous Nephrolithotomy", "PCNL", "percutaneous lithotripsy", "JJ or double J or pigtail or stent or catheter, "tubeless", or "no tube" were used. No date limits were imposed. The search was restricted to English papers only. Animal and pediatric studies were excluded. Appendix shows the search strategy. Additional articles were sought from the reference lists of the included articles. This review was registered in PROSPERO (CRD42021291272).

#### Selection criteria

The PICOS (Patient Intervention Comparison Outcome Study type) model was used to frame and answer the clinical question. P: adults undergoing PCNL for kidney stones; Intervention: standard PCNL (with nephrostomy tube with or without ureteral stents); Comparison: tubeless PCNL (no nephrostomy tube with ureteral stent); Outcome: surgical time, length of postoperative stay, infection complications (fever defined as body temperature >  $38 \,^{\circ}$ C, urinary tract infection, sepsis), bleeding complications (hemoglobin drop, blood transfusion, need for angioembolization rates), postoperative pain (visual analogue scale (VAS) score at fist postoperative day, patients requiring pain medication), urinary fistula (urinary leakage that may necessitate secondary drainage), perirenal fluid collection, pleural breach, hospital readmission for any reason and stone-free rate; Study type: prospective randomized studies. Patients were assigned to two groups according to the type of mode of exit strategy after PCNL (Tubeless PCNL vs Standard PCNL).

#### Study screening and selection

Two independent authors screened all retrieved records through Covidence Systematic Review Management<sup>®</sup> (Veritas Health Innovation, Melbourne, Australia). A third author solved discrepancies. Studies were included based on PICOS eligibility criteria. Prospective randomized studies were accepted. Retrospective and prospective nonrandomized studies, reviews, meeting abstracts, letters to the editor, case reports, and editorials were excluded. The full text of the screened papers was selected if found relevant to the purpose of this study. The search was further expanded by performing a manual search based on the references of the full-text relevant papers.

#### **Statistical analysis**

Surgical time, hemoglobin drop, postoperative length of stay, and VAS score were pooled using the inverse variance of the mean difference with a random effect, 95% confidence interval (CI), and p values. Incidence of blood transfusion, angioembolization for bleeding control, patients requiring postoperative pain medication, postoperative infection complications, urinary fistula, perirenal fluid collection, pleural breach, readmission, and stone-free rate were assessed using Cochran-Mantel-Haenszel Method with the random effect model and reported as risk ratio (RR), 95% CI, and p values. Analyses were two-tailed and the significance was set at p < 0.05 and a 95% CI. OR less than one indicates a lower risk in the tubeless group. Study heterogeneity was assessed utilizing the  $I^2$  value. Substantial heterogeneity was defined as an  $I^2$  value > 50%. Meta-analysis was performed using Review Manager (RevMan) 5.4 software by Cochrane Collaboration. The quality assessment of the included studies was performed using the RoB 2 Cochrane Risk of Bias tool.

# Results

Literature search retrieved 1424 papers. Three papers were found from other sources. Thirty-two duplicates were excluded, leaving 1395 studies for screening. Another 1266 papers unrelated to the study purpose were further excluded after the title and abstract screening. The full texts of the remaining 129 studies were screened and 103 papers were further excluded. Finally, 26 studies were accepted and included for meta-analysis. Supplementary Fig. 1 shows the 2020 PRISMA flow diagram.

#### Study characteristics and quality assessment

Twenty-six randomized studies compared Tubeless and Standard PCNL [5–30]. Study characteristics are summarized in Table 1. There were 1839 patients included in 26 studies: 907 patients underwent Tubeless PCNL and 932 underwent Standard PCNL.

Supplementary Fig. 2 demonstrates the details of the quality assessment of included studies. Fourteen studies showed a low overall risk of bias. Ten studies showed some concerns regarding the overall risk of bias and the remaining two studies a high overall risk of bias. The most frequent reason for bias was bias due to deviation of the intended intervention and measurement outcomes, followed by bias due to the randomization process.

#### Meta-analyses of surgical time and length of stay

Meta-analysis from 16 studies (550 cases in Tubeless and 570 cases in Standard PCNL) showed that the mean operative time was significantly shorter in Tubeless compared to Standard PCNL (MD—5.18 min, 95% CI – 6.56 to – 3.80, p < 0.00001). There was no significant heterogeneity among the studies ( $I^2$  5%) (Fig. 1A).

Meta-analysis of 20 studies (742 cases in Tubeless and 756 cases in Standard PCNL) showed that the mean postoperative length of stay was also significantly shorter in Tubeless compared to Standard PCNL (MD—1.10 days, 95% CI – 1.48 to – 0.71, p < 0.00001). Study heterogeneity was considerable ( $I^2$  97%) (Fig. 1B).

#### Meta-analyses of bleeding

Meta-analysis from 19 studies (608 cases in Tubeless PCNL and 635 cases in Standard PCNL) showed that blood transfusion did not differ between the two groups (RR 0.76 95% CI 0. 14–1.41, p=0.38). There was no significant heterogeneity among the studies ( $I^2$  0%) (Fig. 2A).

Meta-analysis from 6 studies (246 cases in Tubeless PCNL and 244 cases in Standard PCNL) showed that angioembolization for bleeding control did not differ between the two groups (RR 1.91 95% CI 0.34–10.74, p = 0.46). There was no significant heterogeneity among the studies ( $I^2$  0%) (Fig. 2B).

#### Meta-analyses of postoperative pain

Meta-analysis from 12 studies (428 cases in Tubeless PCNL and 443 cases in Standard PCNL) showed that the mean VAS score at the first postoperative day did not differ between the two groups (MD—3.14 points 95% CI – 8.75 to 2.47, p = 0.27) (Fig. 3A). Study heterogeneity was considerable ( $l^2$  100%).

Meta-analysis from 7 studies (140 cases in Tubeless PCNL and 140 cases in Standard PCNL) showed that patients requiring postoperative pain medication did not differ between the two groups (RR 0.96 95% CI 0.61–1.51, p = 0.86) (Fig. 3B). Heterogeneity among the studies was significant ( $l^2$  93%).

#### Meta-analyses of infection complications

Meta-analysis from 13 studies (435 cases in Tubeless PCNL and 431 cases in Standard PCNL) showed that the incidence of postoperative fever did not differ between the two groups (RR 0.67 95% CI 0.40–1.13, p=0.13) (Fig. 4A). There was no significant heterogeneity among the studies ( $I^2$  0%).

Table 1 Chara	ncteristics of stu	dies comparii	ng Tubeless PC	CNL vs Standard	PCNL include	d in the review						
Author year of publica- tion	Tract dilata- tion	Amplatz sheath size, Fr	Nephros- tomy tube size, Fr	Stent size, Fr	Tract closure	Stent dwell- ing time	Nephrostomy dwelling time	Definition of stone-free	Mean age Tubeless PCNL, years	Mean age Standard PCNL, years	Mean stone burden Tubeless PCNL	Mean stone burden Stand- ard PCNL
Agrawal 2008 [ <b>5</b> ]	NA	26	16	9	Suture	2 weeks	2–3 days	NA	33	31	$3.8~\mathrm{cm}^2$	$3.6~\mathrm{cm}^2$
Ali 2019 [6]	Alken coaxial metallic dilators	26	ΝA	AN	оп	NA	NA	NA	44.04	44.24	NA	NA
Bhat 2017 [7]	One-shot 30 Ch Amplatz dilator	30	22	AN	оп	NA	NA	NA	NA	NA	NA	NA
Chalise, 2017 [ <b>8</b> ]	NA	NA	20–24	NA	Suture	NA	36-48 h	NA	37.1	37.9	23 mm	23.7 mm
Choi 2006 [9]	Serial metal dilators	34	8.2	9	Gel matrix thrombin	3–5 Days if no significant residual fragments	3-5 Days if no significant residual fragments	No frag- ments	52.9	47	28.5 mm	26.8 mm
Cormio 2012 [10]	Balloon/plas- tic dilators	30	16	٢	Tachoseal	1 day	3 days	4 mm or less	51.38	49.24	32.17 mm	30.22 mm
Desai 2004 [11]	Alken metal dilators	26–30	20	9	No	4 weeks	2 days	NA	43.4	41.1	25 mm <sup>3</sup>	264 mm <sup>3</sup>
Etemadian 2011 [12]	One-shot Amplatz dilator	30	24	NA	No	24-48 h	24-48 h	NA	44.58	46.55	36.26 mm	35.35 mm
Feng 2001 [13]	Amplatz dilators	34	22	NA	NA	1 week	2 days	No stones	62	53	4.38 cm2	$8.36~\mathrm{cm}^2$
Garg 2019 [14]	NA	NA	NA	NA	NA			NA	36.78	36.78	NA	NA
Goldberg 2020 [15]	Balloon	30	12	6	NA	2 weeks	2 days	≤3 mm	55.37	55.38	23 mm	24.2 mm
Gonen 2019 [16]	Amplatz dilator	30	14	9	NA	24 h	2 days	NA	47.5	45	35.73 mm <sup>3</sup>	386.2 mm <sup>3</sup>
Jiang 2017 [17]	NA	NA	18	5	NA	2 weeks	2 days	NA	45.9	48.1	166 mm <sup>3</sup>	189.7 mm <sup>3</sup>
Kara 2020 [18]	NA	28	18	NA	NA	24 h	3–5 days	NA	67.7	66.5	25.6 mm	22.3 mm
Kirac 2013 [19]	NA	30	14	NA	NA	14–21 days	1–3 days	No frag- ments	43.5	42.5	25.4 mm	30.5 mm
Kumar 2020 [20]	NA	26	20	NA	no	NA	NA	NA	NA	NA	NA	NA

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Table 1 (cont	inued)											
Author year of publica- tion	Tract dilata- tion	Amplatz sheath size, Fr	Nephros- tomy tube size, Fr	Stent size, Fr	Tract closure	Stent dwell- ing time	Nephrostomy dwelling time	Definition of stone-free	Mean age Tubeless PCNL, years	Mean age Standard PCNL, years	Mean stone burden Tubeless PCNL	Mean stone burden Stand- ard PCNL
Liu 2017 [21]	NA	16–18	16	9	NA	4 weeks	4–5 days	<4 mm	46.08	48.6	1.98 cm	1.82 cm
Marchant 2011 [22]	Fascial dila- tors	28	18	L	Oxidized cellulose gauze	10–14 days	3 days	NA	52.8		$6.4 \text{ cm}^2$	$7.8~\mathrm{cm}^2$
Mishra 2010 [23]	Metallic telescopic coaxial dilators	28	20	Ч Ч	manual com- pression for 5 min	24 h If no re-treat- ment was planned	24 h If no re-treat- ment was planned	No evidence of clini- cally insig- nificant residual fragments on CT	55	50	AA	NA
Sebaey 2016 [24]	14-F Teflon	14	14	NA	Suture	2–3 days	NA	NA	48.4	50.1	182 mm <sup>3</sup>	191mm <sup>3</sup>
Shah 2008 [25]	Telescopic dilators	30	×	Q	Strapped with a pressure dressing	Until clear- ing urine	24 h	<4 mm	48.66	42.08	535.3 mm <sup>2</sup>	495.91 mm <sup>2</sup>
Shoma 2011 [26]	NA	NA	22	NA	Suture	Until clear- ing urine	Until clear- ing urine	Residual stones of 4 mm	31	34	1226 mm <sup>2</sup>	1004 mm <sup>2</sup>
Singh 2008 [27]	NA	NA	22	NA	NA	NA	NA	NA	52.6	55.2	750 mm <sup>2</sup>	800 mm <sup>2</sup>
Sofikerim 2007 [28]	NA	30	18	9	Suture	14 days	2 days	No stones	38.4	41.3	425 mm <sup>2</sup>	428 mm <sup>2</sup>
Tefekli 2007 [29]	NA	30	14	NA	Suture	24 h	48 h	No stones	58	57.4	300 mm <sup>2</sup>	$310 \text{ mm}^2$
Zhao 2016 [30]	NA	30	12	NA	Suture or fibrine sealant	2 weeks	48 h	No stones	48.88	53.05	259 mm <sup>2</sup>	276.6 mm <sup>2</sup>
Fr French, PC	JNL percutaneo	us nephrolithot	tomy, NA not 8	available								

		Tube	less PC	NL	Stan	dard PC	NL		Mean Difference	Mean Difference
A) Granding 1 diments (mainstead)	Study or Subaroup	Mean	SD	Total	Mean	SD	Total	Weight	IV. Random. 95% CI	IV. Random, 95% CI
A) Surgical time (minutes)	AII 2009	79.24	21.5	25	84 64	20.09	25	1.4%	-5 40 (-16 93 6 13)	
	Chalise	73.3	23.9	49	79.9	22.5	47	2.2%	-6.60 [-15.88, 2.68]	
	Chol 2006	82.09	17.99	12	79.5	15.07	12	1.1%	2.59 [-10.69, 15,87]	
	Cormio 2012	83.67	42.95	49	88.4	43.41	47	0.6%	-4.73 [-22.01, 12.55]	
	Desal 2004	44.5	13.2	10	45	13.7	10	1.4%	-0.50 [-12.29, 11.29]	
	Etemadian 2011	68	4.3	100	74	5.6	100	49.9%	-6.00 [-7.38, -4.62]	<b>•</b>
	Feng 2001	128	8	8	129	8	10	3.3%	-1.00 [-8.44, 6.44]	
	Garg 2019	59,97	26.4	40	67.55	28	40	1.3×	-7.58 [-19.51, 4.35]	
	Goldberg 2020	105,1	28,4	38	116	38.8	37	0.8%	-10,90 [-26,32, 4,52]	·
	Jiang 2017	40,9	16,1	30	47,2	18,1	30	2,5%	-6,30 [-14,97, 2,37]	
	Kara 2010	38,5	6,86	30	42,5	7,35	30	12,8%	-4,00 [-7,60, -0,40]	_ <b>_</b>
	Kirac 2013	61,7	13,4	25	63,2	18,1	36	3,0%	-1,50 [-9,41, 6,41]	
	Kumar 2020	66,54	20,34	44	76,89	24,29	56	2,4%	-10,35 [-19,10, -1,60]	
	Sebaey 2016	40,6	11,9	40	46,1	18,4	40	4,0%	-5,50 [-12,29, 1,29]	
	Shah 2008	50,55	10,44	33	46,91	16,07	32	4,2%	3,64 [-2,97, 10,25]	
	Tefekli 2007	59,6	9,1	17	67,3	0,4	18	9,2%	-7,70 [-12,03, -3,37]	
	Total (95% CI)			550			570	100,0%	-5,18 [-6,56, -3,80]	•
	Heterogeneity: Tau <sup>2</sup> =	0,50; C	hť = 15	,86, df	i = 15 (i	P = 0,39	));	5%		
	Test for overall effect:	Z = 7,3	6 (P < 0	.00001	1)					Tubeless PCNL Standard PCNL
		Tub	eless P	CNL	Stan	dard PC	INL		Mean Difference	Mean Difference
<b>B)</b> Postoperative stay (days)	Study or Subgroup	Mean	SD	Tota	l Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
_) = coroporant c only (unjo)	Agrawal 2008	0.9	0.8	101	2.25	0.25	101	5.4%	-1.35 [-1.51, -1.19]	+
	All 2009	1.92	0.49	25	2.84	0.68	25	5.3%	-0.92 [-1.250.59]	-
	Bhat 2017	3.2	1.6	25	4.16	0.41	25	4.6%	-0.96 [-1.610.31]	_ <b>—</b>
	Chalise	3.1	0.88	49	4.9	2.1	47	4.6%	-1.80 [-2.45, -1.15]	
	Chol 2006	1.55	0.988	12	1.6	1.01	12	4.5%	-0.05 [-0.85, 0.75]	
	Cormio 2012	2.75	1.68	49	5.15	1.74	47	4.7%	-2.40 [-3.08, -1.72]	<u> </u>
	Desal 2004	4,3	0,7	10	4,4	0,8	10	4.7%	-0,10 [-0,76, 0,56]	
	Etemadian 2011	2,42	0,84	100	3,7	0,8	100	5.4%	-1,28 [-1,51, -1,05]	+
	Feng 2001	1,88	0,35	6	4,1	0,55	10	5.2%	-2,22 [-2,64, -1,80]	
	Goldberg 2020	3,3	1,73	38	3,7	2,1	37	4.3%	-0,40 [-1,27, 0,47]	
	Gonen 2019	2,26	0,41	30	2,86	0,5	30	5.4%	-0,60 [-0,83, -0,37]	+
	Kara 2010	1,5	0,24	30	3,6	0,49	30	5.4%	-2,10 [-2,30, -1,90]	+
	Kumar 2020	2,52	1,05	44	4,42	1,61	56	5,0%	-1,90 [-2,42, -1,38]	
	Marchant 2011	3,2	0,7	40	) 5	2,8	45	4,4%	-1,80 [-2,65, -0,95]	
	Mishra 2010	2,92	0,77	11	3,03	0,09	11	5,1%	-0,11 [-0,57, 0,35]	-+-
	Sebaey 2016	1,1	0,3	40	1,07	0,27	40	5,5%	0,03 [-0,10, 0,16]	+
	Shah 2008	1,44	0,46	33	1,83	0,9	32	5,3%	-0,39 [-0,74, -0,04]	
	Shoma 2011	2,7	2,04	50	3,25	1,92	50	4,5%	-0,55 [-1,33, 0,23]	
	Singh 2008	2,3	0,25	30	4,11	0,37	30	5,4%	-1,81 [-1,97, -1,65]	+
	Tefekii 2007	1,6	0,4	17	2,8	0,9	18	5,1%	-1,20 [-1,66, -0,74]	
	Total (95% CI)			742	2		756	100,0%	-1,10 [-1,49, -0,71]	◆
	Heterogeneity: Tau <sup>2</sup>	= 0,71:	Chi <sup>2</sup> = é	27,41	, df = 1	9 (P < 0	0.0000	1); <sup>2</sup> = 9	7% -	
	Test for overall effect	t: Z = 5.	57 (P <	0.000	01)					-4 -2 0 2 4
										Tubeless PCNL Standard PCNL

Fig. 1 Meta-analysis of surgical time and length of stay in studies comparing Tubeless PCNL vs Standard PCNL

		Tubeless	PCNL	Standard	PCNL		Risk Ratio	Risk Ratio
	Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
A) Blood transfusion	Agrawal 2008	0	101	0	101		Not estimable	
,	Bhat 2017	2	25	1	25	7,1%	2,00 [0,19, 20,67]	
	Chalise	1	49	7	47	9,1%	0,14 [0,02, 1,07]	
	Chol 2006	1	12	1	12	5,5%	1,00 [0,07, 14,21]	
	Desal 2004	0	10	0	10		Not estimable	
	Feng 2001	1	8	1	10	5,7%	1,25 [0,09, 17,02]	
	Gonen 2019	0	30	0	30		Not estimable	
	Jiang 2017	1	30	0	30	3,9%	3,00 [0,13, 70,83]	
	Kirac 2013	1	25	2	36	7,0%	0,72 [0,07, 7,52]	
	Kumar 2020	0	44	2	56	4,3%	0,25 [0,01, 5,15]	
	Llu 2017	0	31	0	31		Not estimable	
	Marchant 2011	0	40	0	45		Not estimable	
	Mishra 2010	0	11	0	11		Not estimable	
	Sebaey 2016	0	40	0	40		Not estimable	
	Shah 2008	2	33	1	32	7,0%	1,94 [0,18, 20,35]	
	Shoma 2011	5	50	6	50	30,7%	0,83 [0,27, 2,55]	
	Singh 2008	0	30	1	30	3,9X	0,33 [0,01, 7,87]	
	Sofikerim 2007	1	24	4	24	8,6X	0,25 [0,03, 2,08]	
	Zhao 2016	2	15	1	15	7,3%	2,00 [0,20, 19,78]	
	Total (95% CI)		608		635	100,0%	0,76 [0,41, 1,41]	•
	Total events	17		27				-
	Heterogeneity: Tau2 =	<ul> <li>0,00; Chl<sup>2</sup></li> </ul>	= 7,52,	df = 11 (	P = 0,76	);		
	Test for overall effect	: Z = 0,88 (	P = 0,36	3)				Tubeless PCNL Standard PCNL
<b>B)</b> Angioembolization for bleeding control								
Tubeles	PCNL Standa	rd PCNL			Ris	k Ratio	0	Risk Ratio

	Tubeless	PCNL	Standard	PCNL		Risk Ratio		Risk Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M–H, Random, 95% CI		M–H, Random, 95% Cl	
Challse	1	49	1	47	39,7%	0,96 [0,06, 14,90]			
Chol 2006	1	12	0	12	30,9%	3,00 [0,13, 67,06]			
Etemadian 2011	1	100	0	100	29,4%	3,00 [0,12, 72,77]			
Gonen 2019	0	30	0	30		Not estimable			
Llu 2017	0	31	0	31		Not estimable			
Sofikerim 2007	0	24	0	24		Not estimable			
Total (95% CI)		246		244	100,0%	1,91 [0,34, 10,74]		-	
Total events	3		1						
Heterogeneity: Tau <sup>2</sup> -	= 0,00; Chl <sup>2</sup>	= 0,40	df = 2 (P	= 0,82)	i <sup>2</sup> = 0%		0.001		1000
Test for overall effect	; Z = 0,73 (	P = 0,4	6)				0.001	Tubeless PCNI Standard PCNL	1000

Fig. 2 Meta-analysis of bleeding in studies comparing Tubeless PCNL vs Standard PCNL

-	Tube	eless PC	NL	Stan	dard PC	NL		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Agrawal 2008	31	4,6	101	59	5,1	101	8,6%	-28,00 [-29,37, -26,63]	+
Ali 2009	20	20,95	25	41,88	21,82	25	6,2%	-21,88 [-33,74, -10,02]	
Bhat 2017	4,76	1,2	25	6,64	1,4	25	8,7%	-1,66 [-2,60, -1,16]	-
Chol 2006	3	2,59	12	3,9	2,43	12	8,6%	-0,90 [-2,91, 1,11]	-
Cormio 2012	4,24	2,32	49	4,77	2,28	47	8,6%	-0,53 [-1,45, 0,39]	+
Feng 2001	3,8	0,5	8	3,7	0,4	10	8,7%	0,10 [-0,33, 0,53]	•
Gonen 2019	3,3	1,4	30	6,1	1,4	30	8,7%	-2,80 [-3,51, -2,09]	•
jiang 2017	4,6	1,7	30	5,8	1,6	30	8,6%	-1,20 [-2,04, -0,36]	-
Kirac 2013	3,28	1,4	25	5,38	1,3	36	8,7%	-2,10 [-2,79, -1,41]	•
Marchant 2011	5,5	1,1	40	5,9	1,2	45	8,7%	-0,40 [-0,89, 0,09]	
Shah 2008	27,87	18,95	33	37,18	14,08	32	7,3%	-9,31 [-17,41, -1,21]	<b>-</b> _
Shoma 2011	27,87	1,9	50	2,9	1,7	50	8,7%	24,97 [24,26, 25,68]	•
Total (95% CI)			428			443	100,0%	-3,14 [-8,75, 2,47]	•
Heterogeneity: Tau <sup>2</sup> =	94.51;	$Cht^2 = 6$	6507.0	4. df =	11 (P <	0.0000	(1); $f^2 = 1$	.00% -	da da da da da da
Test for overall effect:	Z = 1,1	0 (P = 0	),27)						Tubeless PCNL Standard PCNL
medication									

B) Patients requiring pain medication

	Tubeless	PCNL	Standard	PCNL		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Chol 2006	12	12	12	12	39,1%	1,00 [0,86, 1,17]	•
Cormio 2012	49	49	47	47	40,8%	1,00 [0,96, 1,04]	•
Desal 2004	0	10	10	10	2,6%	0,05 [0,00, 0,72]	
Feng 2001	5	6	5	10	17,5%	1,25 [0,55, 2,84]	_ <b>-</b>
Feng 2001	0	0	0	0		Not estimable	
Gonen 2019	0	30	0	30		Not estimable	
Llu 2017	0	31	0	31		Not estimable	
Total (95% CI)		140		140	100,0%	0,96 [0,61, 1,51]	
Total events	66		74				
Heterogeneity: Tau <sup>2</sup> =	0,13; Chr	= 44,41	8, df = 3 (F	< 0.00	001); 🖻 -	93%	
Test for overall effect:	Z = 0,18 (	P = 0,60	5)				Tubeless PCNL Standard PCNL

Fig. 3 Meta-analysis of postoperative pain in studies comparing Tubeless PCNL vs Standard PCNL

Meta-analysis from 6 studies (247 cases in Tubeless PCNL and 245 cases in Standard PCNL) showed that the incidence of postoperative urinary tract infection did not differ between the two groups (RR 0.74 95% CI 0.33–1.62, p=0.45) (Fig. 4B). There was no significant heterogeneity among the studies ( $I^2$  0%).

Meta-analysis from 9 studies (384 cases in Tubeless PCNL and 380 cases in Standard PCNL) showed that the incidence of postoperative sepsis did not differ between the two groups (RR 0.86 95% CI 0.44–1.67, p = 0.66) (Fig. 4C). There was no significant heterogeneity among the studies ( $l^2$  0%).

# Meta-analyses of urinary fistula, perirenal fluid collection, and pleural breach

Meta-analysis from 14 studies (466 cases in Tubeless PCNL and 464 cases in Standard PCNL) showed that the incidence of the postoperative urinary fistula was significantly lower in the Tubeless PCNL group (RR 0.18 95% CI 0.07–0.47, p = 0.0005) (Fig. 5A). Heterogeneity among the studies was not important ( $I^2$  11%).

Meta-analysis from 13 studies (478 cases in Tubeless PCNL and 474 cases in Standard PCNL) showed that the incidence of the postoperative perirenal fluid collection did not differ between the two groups (RR 1.00 95% CI

0.42–2.40, p = 0.99) (Fig. 5B). There was no significant heterogeneity among the studies ( $I^2 0\%$ ).

Meta-analysis from 14 studies (449 cases in Tubeless PCNL and 468 cases in Standard PCNL) showed that the incidence of pleural breach did not differ between the two groups (RR 0.01 95% CI -0.01–0.03, p = 0.49) (Fig. 5C). There was no significant heterogeneity among the studies ( $I^2$  0%).

#### Meta-analyses of hospital readmission and stone-free rate

Meta-analysis from 8 studies (268 cases in Tubeless PCNL and 278 cases in Standard PCNL) showed that the incidence of hospital readmission for any reason did not significantly differ between the two groups (RR 1.02 95% CI 0.46–2.27, p = 0.96) (Fig. 6A). There was no significant heterogeneity among the studies ( $I^2 0\%$ ).

Meta-analysis from 18 studies (573 cases in Tubeless PCNL and 583 cases in Standard PCNL) showed that the stone-free rate did not differ between the groups (RR 1.03 95% CI 0.99–1.07, p = 0.13) (Fig. 6B). There was no significant heterogeneity among the studies ( $I^2$  0%).



Fig. 4 Meta-analysis of infection complications in studies comparing Tubeless PCNL vs Standard PCNL



Fig. 5 Meta-analysis of urinary fistula, perirenal fluid collection, and pleural breach in studies comparing Tubeless PCNL vs Standard PCNL

A) Re

A) Readmission	Study or Subgroup	Events	Tota	Events	Tot	al Weigh	t M-H, Random, 95% CI	M–H, Random, 95% CI
	Chalise	2	49	) 3	4	7 21,0	0,64 [0,11, 3,66]	
	Chol 2006	4	12	2	1	2 28.55	2.00 [0.45, 8.94]	
	Etemadian 2011	1	100	) 0	10	6.3	3.00 [0.12, 72,77]	
	Kara 2010	1	30	3	3	0 13.1	0.33 [0.04, 3.03]	<b>_</b>
	Kirac 2013	2	25	í á		6 24 4	6 0 72 10 14 3 631	
	Mishra 2010	1	11	. n	1	1 6.7	3 00 10 14 66 531	
	Softkarim 2007	ñ	24	i ñ	2		Not estimable	.
	Tefekli 2007	ŏ	17	ŏ	1		Not estimable	
	Total (95% CI)		269	,	27	78 100 0	1 02 10 46 2 27	
	Total (55% CI)		200	, 	21	8 100,07	1,02 [0,40, 2,27]	
	Total events	11		12				
	Heterogeneity: Tau* =	0,00; Chr	= 3,13	, df = 5 (	P = 0,6	8); P = 0%	í	0.005 0.1 1 10 200
	Test for overall effect:	Z = 0,05 (	P = 0.9	6)				Tubeless PCNL Standard PCNL
		Tubeless		Standard			Risk Ratio	Risk Ratio
D) Change Constants	Study or Subgroup	Events	Total	Events	Total	Weight N	A-H Random 95% CI	M-H Random 95% CI
<b>B</b> ) Stone free rate	Chol 2006	12	12	11	12	2.0%	1 00 0 87 1 361	
	Cormin 2012	43	10	41	47	6 3 4	1 01 0 86 1 17	
	Etemadian 2011	92	100	90	100	19.0%	1 02 0 94 1 121	
	Feng 2001	7	8	7	10	0.6%	1.25 [0.77, 2.03]	<b>`</b>
	Goldberg 2020	34	38	29	37	3.6%	1.14 [0.93, 1.40]	
	Gonen 2019	27	30	25	30	3.6%	1 08 10 88 1 321	
	llang 2017	28	30	29	30	10.7%	0.97 [0.86, 1.08]	
	Kara 2010	29	30	27	30	7.7%	1.07 [0.94, 1.23]	
	Kirac 2013	21	25	31	36	3.18	0.98 [0.79, 1.21]	
	Llu 2017	30	31	29	31	11.4%	1.03 [0.92, 1.16]	_ <b>_</b>
	Mishra 2010	8	11	9	11	0.7%	0.89 [0.56, 1.40]	
	Sebaev 2016	37	40	33	40	5.1%	1.12 [0.95, 1.33]	
	Shah 2008	29	33	28	32	4.4%	1.00 [0.84, 1.21]	
	Shoma 2011	46	50	42	50	6.6%	1.10 [0.95, 1.27]	
	Singh 2008	27	30	28	30	6.2%	0.96 [0.83, 1.12]	
	Sofikerim 2007	19	24	20	24	1.9%	0,95 [0,72, 1,25]	
	Tefekii 2007	16	17	16	18	3.5%	1.06 [0.87, 1.30]	
	Zhao 2016	13	15	14	15	2,5%	0,93 [0,73, 1,18]	
	Total (95% CI)		573		583	100,0%	1,03 [0,99, 1,07]	•
	Total events	518		509				
	Heterogeneity: Tau <sup>2</sup> =	0,00; Chl <sup>2</sup>	- 8,01,	df = 17 (P	= 0,97	);		
	Test for overall effect:	Z = 1,50 (F	- 0,13	•				Tubeless PCNL Standard PCNL

Standard PCM

Rick Ratio

Tubalass DCNI

Fig. 6 Meta-analysis of hospital readmission for any reasons and stone-free rate in studies comparing Tubeless PCNL vs Standard PCNL

# Discussion

PCNL was first described in 1976 by Fernström and Johansson, and has evolved and revolutionized the way renal calculi are managed [31] and is the current standard in stones larger than 2 cm across international guidelines [32, 33]. In 1999, Goh et al. described PCNL using a 30-34 Ch Amplatz sheath with this trend carrying into the early 2000s [34]. In 2007, Brusky et al. performed mini-PCNL through a 20 Ch percutaneous access starting the trend for miniaturization in PCNL [35]. After initial skepticism, miniaturized PCNL is now an accepted way forward with tract sizes dropping from 30 to 24 Fr for a standard PCNL and sizes less than 20 Fr being considered a mini-PCNL surgery [36].

This led to the belief that miniaturized PCNL should ideally replace standard PCNL; however, as seen in our review, many centers continue using standard access in both arms of their study (Supplementary Fig. 3). Our study is the only systematic review that has looked at tract size, and only two studies out of 26 studies used a 16 Fr and 14 Fr tract, respectively [21, 24]. Postprocedure, the most common nephrostomy tube placed was 20 Fr and above. Only two studies placed an 8 Fr nephrostomy tube as an exit in a 34 Fr tract [9, 25]. Supplementary Fig. 3 shows the correlation between the tract size and the nephrostomy tube used in studies included in this review.

In our analysis, no specific trends were noted between tract size and nephrostomy tube size based on stone volume. Most series were comparable in the stone volume included in both groups, and these often included partial and complete staghorn stones. However, the specific number of these cases was not available in individual studies to consider a subset analysis to see if this has any impact on outcomes.

Our findings suggest that a tailored and personalized approach is the need of the day for modern PCNL, and urologists should not shy away from using bigger tracts to achieve a good outcome [37]. Significant advancements in miniaturization [36], adoption of new positions [38], and technological enhancements have provided a plethora of choices for lithotripsy, ranging from ballistic to laser to combined energy devices [39]. The aforementioned improvements tackle any stone composition and volume, with minimal complications and maximum efficacy, making PCNL feasible for a day surgery/ambulatory procedure in a select group of patients.

The first work about tubeless PCNL was published in 1997 by Bellman et al. without significant complications and early discharge of all 50 patients [40]. Limb et al. tried to specify discharge criteria to objectively compare the length of stay between standard and tubeless PCNL [41]. They reported different factors that may bias this variable such as health care system policies, patient's concomitant morbidities, and the variability of subjective pain assessment.

Rick Ratio

Albeit limited, evidence from the past on this topic has shown that these are the key areas to consider for any PCNL outcome apart from stone and patient characteristics [2–4, 42]. Our review confirmed that the mean hospital stay (MD—1.10 days, 95% CI – 1.48 to – 0.71, p < 0.00001) and shorter operative time significantly favored the tubeless PCNL group (MD—5.18 min, 95% CI – 6.56 to – 3.80, p < 0.00001). However, the SFR in our analysis, defined in most studies as residual fragments <4 mm and/or no fragment seen on table inspection or at first imaging, did not differ between the two groups. Generally, a 100% SFR is preferable for PCNL, but this is not a reason to delay or postpone hospital discharge. Since the SFR did not differ, it could be interpreted that achieving a 100% SFR should not be a precluding factor for a tubeless PCNL.

With regards to postoperative pain and analgesic requirements, similar or better outcomes favored tubeless PCNL in previous systematic reviews [2–4, 43]. Maheshwari et al. proposed that even in a Standard PCNL by just leaving a small pigtail in situ as a nephrostomy tube, patients can be discharged earlier, pain score is better, complications are less, and recovery is faster [44]. Interestingly, Eslahi et al. also found that the amount of narcotic use and pain were significantly lower in totally tubeless PCNL (no ureteral stent and no nephrostomy tube) as compared with standard and tubeless PCNL [45]. Our meta-analysis on postoperative pain favored the tubeless cohort; however, it was not statistically significant. Furthermore, the need for postoperative pain medication was not different between the two groups. This reiterates the concept that tubes probably have minor effects on postoperative pain. We could not identify if intraoperative tract infiltration for pain management is now a common trend, but this could aid in immediate postoperative pain management and analgesic requirements, especially if a patient is being considered for same-day discharge [25]. Same-day discharge PCNL is indeed a reality today as shown recently by a 500-patient study by Chong et al., where they reported the use of a standard tract dilation (24–30 Fr) in 77% of cases, and 99% of cases had a ureteral stent as the only form of drainage [46]. However, 2.4% required early readmission, and the 30-day readmission rate was 4.2% [46]. While systematic reviews in the past have shown that Tubeless PCNL allowed for a faster return to work, and this is an important aspect to take into account if patients are getting readmitted which defeats the purpose of a day surgery [2, 4].

Complications are a dreaded part of PCNL. In the past systematic reviews, no statistical differences for hemoglobin drop and blood transfusion were seen [3, 4]. In our analysis, 19 studies did not show any difference in the rate of blood transfusion, and in the 6 studies that reported incidence of angioembolization post-PCNL, no absolute difference was noted. Most studies in our review had tract size greater than 20 Fr and serial dilatation was the preferred approach in 10 of the 13 reported series. These findings have practical utility for urologists while planning a desired tract size and technique of renal access. Complications like fever, sepsis, urinary infections, pleural injury, and incidence of perirenal fluid collections did not differ between the two groups in our analysis, but the incidence of postoperative urinary fistula was significantly lower in the Tubeless PCNL group (RR 0.18 95% CI 0.07-0.47, p = 0.0005). There was no trend noted for using sealants and only 4 of the 26 studies used some tract sealants, but the use of sealants disappeared after 2016. Another important finding of our meta-analysis was that the incidence of hospital readmission for any reason did not significantly differ between the two groups (RR 1.02 95% CI 0.46–2.27, p = 0.96). This is very important as it allows urologists full flexibility in choosing any approach feasible to their realm of practice and is the quintessential for counseling patients during preoperative planning.

While our review has the inherent bias associated with patient selection that may vary across the world, we have a significantly higher number of included studies as compared to any past similar meta-analysis, and this allows us to dive deeper and compare the pros and cons of Tubeless PCNL vis-a-vis Standard PCNL. Hence, this could account for the differences from other reviews. The lack of reported outcomes such as the number of staghorn stones prevented any form of subset analysis. We also could not perform a cost analysis and assess quality of life of patients.

## Conclusions

Our review shows that the standout benefits of Tubeless PCNL are shorter operative time, shorter hospital stay, and a lower rate of postoperative urinary fistula. However, pain scores, need for readmission, use of analgesia, and complication rates did not differ between the groups, making Tubeless PCNL a safe option that deserves further studies to assess its role in a same-day discharge approach.

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Author contributions VG and DC conceived the study. JCT, VG, VWSC, and DC designed the study protocol. VG and DC led the development of the manuscript. DC performed statistics. EGR, EJL, SS, MPP, EP, DC, VG, MLW, MC, performed data extraction and analysis. BKS, OT, HYT, JdlR and CTH reviewed the paper for critical intellectual content. All authors participated in manuscript writing, review, and approval of the final version of the manuscript for submission.

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#### Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

Ethical approval No ethical concerns.

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