Suctioning Versus Traditional Access Sheath in Mini-Percutaneous Nephrolithotomy: A Systematic Review and Meta-analysis

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Purpose: The suctioning access sheath (SAS) is a novel access sheath connected to a negative pressure suction device and absorbs fragments. Some comparative studies have reported SAS with a higher stone-free rate and lower operative time. However, no higher-level evidence was published to support SAS. Hence, this systematic review and meta-analysis aimed to assess the clinical safety and efficacy of SAS versus traditional access sheath (TAS) for the treatment of renal stones in mini-percutaneous nephrolithotomy (MPCNL).

Materials and Methods: A systematic review of the literature was conducted using Pubmed, Embase (Ovid), Medline (EBSCO), Cochrane central register of controlled trials, and Sinomed to search comparative studies as recent as December 2020 that assessed the safety and effectiveness of SAS in PCNL. The quality of retrospective case-control studies (RCCs) and randomized controlled trials (RCTs) were evaluated by the Newcastle-Ottawa Scale (NOS) and the Cochrane risk of bias tool, respectively. The Oxford center set up evidence-based medicine was used to assess the level of evidence (LE). Statistical analyses were performed by the comprehensive meta-analysis program.

Results: Seven studies, with a total of 1655 patients, were included. Compared with the TAS group, the SAS group had a shorter operative time (MD = -17.30; 95%CI:-23.09,-11.51; $P \le .00001$), higher stone-free rate (OR = 2.37;95%CI:1.56,3.61; $P \le .0001$), fewer total complication rate (OR=0.50;95%CI:0.35,0.70; $P \le .0001$), lower auxiliary procedures rate (OR=0.48;95%CI:0.36,0.64; P<.00001), and lower postoperative fever rate (OR = 0.46;95%CI:0.34,0.62; $P \le .00001$).

Conclusion: The SAS can significantly improve MPCNL in the stone-free rate, operative time, and total complication rate, especially for auxiliary procedures and postoperative fever rates.

Keywords: suctioning access sheath; mini-percutaneous nephrolithotomy; systematic review; meta-analysis; efficacy; safety

INTRODUCTION

Urolithiasis is a common urinary disease. With a 10% recurrence rate in one year and 1.7%-14.8% prevalence rates^(1,2), the disease brings a severe burden to patients and society. Minimally invasive surgery, such as PCNL, extracorporeal shock wave lithotripsy (ESWL), and retrograde intrarenal stone surgery (RIRS), are used to remove stones and relieve obstruction in the clinic. Due to better safety and effectiveness, PCNL is the first-line treatment for larger than 2 cm or complex renal stones⁽³⁾. However, high renal pelvic pressure and damage still can be a tricky question to PCNL.

Many approaches are developed to decrease the complications, including the use of minimally access sheath. According to the access sheath size, PCNL is divided into minimally invasive percutaneous nephrolithotomy (MPCNL) and standard percutaneous nephrolithotomy (SPCNL). With a smaller access sheath, MPCNL has the advantage of lower bleeding, fewer transfusion rate, and shorter hospitalization⁽⁴⁾. However, minimally access sheath is reported with higher renal pelvic pressure and longer operative time, causing a high risk of postoperative urinary infection^(5,6). Recently, the application of continuous suctioning systems, such as SAS⁽⁷⁾, Swiss LithoClast@⁽⁸⁾, Cyberwand⁽⁹⁾, reported a lower renal pelvic pressure and less operative time than the standard perfusion system. SAS, retrofitted from a traditional minimally access sheath or a patented sheath, is inexpensive and cost-effective⁽¹⁰⁾. Keeping the advantage of minimally access sheath, the SAS can connect with a negative pressure aspirator. With the help of negative pressure, fragments and perfusate would be sucked out from patients immediately. Several RCTs have investigated the safety and effectiveness of SAS in PCNL. In 2017, a study conducted by Huang et al. reported the SAS group's stone-free rate is 96.7%, while that of the TAS group is 73.6% (P < 0.05) in the treatment of non-staghorn calculi⁽¹¹⁾. Xu et al. designed a study that included staghorn calculi cases to determine the operative time between TAS and SAS⁽¹²⁾. The result indicated that SAS could significantly improve complication, stonefree rate, and operative time in PCNL.

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Received March 2021 & Accepted October 2021

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Author Year	Period	Study type	LE	Quality	of study	Sheath size(F)	Sample (N)
				- •	·		SAS	TAS
Du et al. (20)	2018	2009-2014	RCT	1b	3a	16-18	311	304
Zhu et al. (10)	2019	2018-2019	RCC	3b	6b	20	256	256
Huang et al. (11)	2016	2011-2013	RCT	1b	4a	16	91	91
Ku et al. (12)	2020	2018	RCT	1b	4a	20	30	30
ai et al. (18)	2019	2017-2018	RCC	3b	6b	18	75	75
Song et al.(19)	2011	2008-2009	RCT	1b	3a	16	30	30
Lai et al. (7)	2020	2017-2018	RCT	1b	4a	20	38	38

Table1. Characteristics of the included studies

SAS suction access sheath, TAS traditional access sheath, RCT randomized controlled trial, RCC retrospective case control study, LE level of evidence, a Using the Cochrane risk of bias tools (score from 0 to 7), b Using the Newcastle-Ottawa Scale (score from 0 to 9)

Meta-analysis has a high level in evidence-based medicine and the advantage of overcoming samples' limitations from different studies. However, to date, the effectiveness and safety of SAS have not still been evaluated by systematic review or meta-analysis. Therefore, our systematic review and meta-analysis was performed to assess the safety and effectiveness between SAS and TAS in MPCNL.

MATERIALS AND METHODS

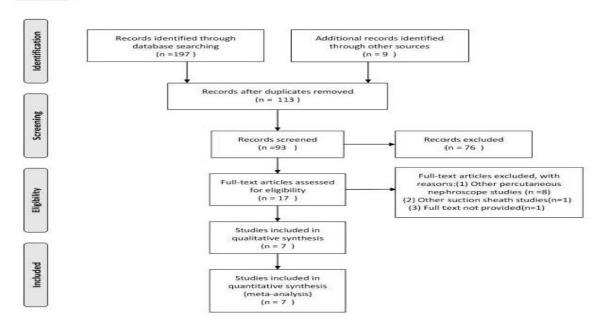
The meta-analysis was registered on the International Prospective Register of Systematic Reviews⁽¹³⁾ (PROSPERO, https://www.crd.york.ac.uk/prospero/, ID: CRD42021228513). According to the PRISMA guidelines⁽¹⁴⁾, our perspective protocol included an objective, study search strategy, selection criteria, level of

evidence, assessment of quality, data extraction, meta-analysis, sensitivity analysis, and publication assessment bias.

Study search strategy

A systematic review of studies, from published studies until December 2020, was performed from the following databases: Pubmed, Embase (Ovid), Medline (EBSCO), Cochrane central register of controlled trials, Sinomed. Besides, the references of all related studies were screened. Two authors independently performed the search of studies (Yu-run Xie and Zhi-hua Luo). When there were any disagreements, two previous authors cross-checked and then discussed with a third author (Chang-sheng Chen). MeSH terms were used in each database, and retrieval strategy used sequentially as follows:

PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Alman DG, The PRISMA Group (2009). Preferred Reporting Rems for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097 For more information, visit www.prisma-statement.org.

Figure 1. Study retrieval flow chart

uthor	Lithotripter	Stone burden SAS TAS	Staghorn calculi	Outcome indicators
Du et al. (20)	HL	$13.6\pm 5.2^{\rm b} \qquad 13.9\pm 4.7^{\rm b}$	Yes	SFR, PFR, APR
Zhu et al. (10)	HL	$15.23\pm 6.67^b\ 14.87\pm 6.32^b$	Yes	SFR, PFR, APR, TCR, OT
Huang et al. (11)	HL	$1.67\pm 0.58^{a} 1.51\pm 0.63^{a}$	No	SFR, PFR, APR, OT
Xu et al. (12)	HL	$4.2 \pm 1.0a$ 3.8 ± 1.4^{a}	Yes	SFR, PFR, APR, TCR, OT
Lai et al. (18)	HL	$6.76\pm 0.22^b 6.29\pm 0.34^b$	No	SFR, PFR, APR, TCR, OT
Song et al. (19)	HL	$8.57 \pm 2.25^{\rm b} 8.65 \pm 2.03^{\rm b}$	No	SFR, PFR, APR
Lai et al. (7)	HL	$2.34 \pm 0.73^{a} 2.02 \pm 0.65^{a}$	No	SFR, PFR, TCR, OT

 Table 2. Details of stone burden and outcome indicators

HL holmium laser, SAS suction access sheath, TAS traditional access sheath, ^aStone maximal diameter(cm), ^bStone surface area (cm²), SFR stone-free rate, PFR postoperative fever rate, APR auxiliary procedures rate, TCR total complication rate, OT operative time

(1): ((((((((Suctions) OR (Suctioning)) OR (Aspiration, Mechanical)) OR (Aspirations, Mechanical)) OR (Mechanical Aspiration)) OR (Mechanical Aspirations)) OR (Drainage, Suction)) OR (Drainages, Suction)) OR (Suction Drainage)) OR (Suction Drainages)

(2): (((Percutaneous nephroscope) OR (Nephrolithotomies, Percutaneous)) OR (Percutaneous Nephrolithotomies)) OR (Percutaneous Nephrolithotomy)
(3): (1) and (2)

Selection criteria

Searched studies were eligible if the following selection criteria were met. Inclusion criteria: (1) English language; (2) full text available; (3) Comparative study including RCT or RCC; (4) included renal calculus patients needed the treatment of MPCNL; (5) SAS and TAS used in two groups, respectively. Exclusion criteria: (1) included patients with anatomical malformation or coagulation function abnormalities; (2) repeated publication.

Quality assessment of eligible studies

The Oxford center set up evidence-based medicine was used to assess the $LE^{(15)}$. Furthermore, the NOS⁽¹⁶⁾ and the Cochrane risk of bias tool⁽¹⁷⁾ were applied to assess the quality of RCCs and RCTs, respectively. Two authors independently performed this step and compared consistencies (Yu-run Xie and Zhi-hua Luo). Any disagreements were resolved by a third author (Changsheng Chen).

Data extraction

Two authors browsed the full text of eligible studies and recorded related data (Di Chen and Chang-sheng Chen). Main outcome indicators were defined as follows:(1) at least three studies reported; (2) measurement or definition was similar. Finally, we extracted selected data as following: name of the first author, year of publication, the period of study, study type, stone burden, sheath size, lithotripter, sample, and main outcome indicators.

Meta-analysis

The meta-analysis was performed by Review Manager Software (RevMan V.5.2, Cochrane Collaboration, Ox-

		SAS			TAS			Mean Difference		Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C		IV, Random, 95% Cl	
1.1.1 Staghorn calcul	i										
Xu et al.2020	64.3	21.9	30	79.2	28.5	30	11.4%	-14.90 [-27.76, -2.04]			
Zhu et al.2019	106.2	18.4	256	132.1	22.2	256	23.8%	-25.90 [-29.43, -22.37]		*	
Subtotal (95% CI)			286			286	35.2%	-22.21 [-32.39, -12.03]		•	
Heterogeneity: Tau ² =	37.35; C	;hi² = 2.	61, df =	= 1 (P =	0.11); P	² = 62%	6				
Test for overall effect:	Z = 4.28	(P < 0.	0001)								
1.1.2 Non-staghorn c	alculi										
Huang et al.2016	54.5	14.5	91	70.2	11.7	91	23.4%	-15.70 [-19.53, -11.87]		*	
Lai et al.2019	32.4	9.6	75	46.2	11.8	75	23.9%	-13.80 [-17.24, -10.36]			
Lai et al.2020	56.3	19.83	38	70.4	14.83	38	17.6%	-14.10 [-21.97, -6.23]			
Subtotal (95% CI)			204			204	64.8%	-14.60 [-17.03, -12.16]		•	
Heterogeneity: Tau ² =	0.00; Cł	ni² = 0.5	4, df =	2 (P = 0).76); l²	= 0%					
Test for overall effect:	Z = 11.7	5 (P < (0.00001	1)							
Total (95% CI)			490			490	100.0%	-17.30 [-23.09, -11.51]		•	
Heterogeneity: Tau ² =	33.49; C	;hi² = 27	.46, df	= 4 (P	< 0.000	1); ² = ;	85%		H		
Test for overall effect:									-100		100
Test for subgroup diffe			,		= 0.15),	l² = 50.	.8%			Favours [SAS] Favours [TAS]	

Figure 2. Forest plot of the operative time of the suctioning access sheath (SAS) group and the traditional access sheath (TAS) group

	SAS		TAS	;		Odds Ratio	Odd	s Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% C	I M-H, Rar	dom, 95% Cl
1.2.1 Staghorn calcul	i							
Du et al.2018	252	311	225	304	26.3%	1.50 [1.02, 2.20]		 ∎-
Xu et al.2020	24	30	16	30	9.5%	3.50 [1.11, 11.02]		_ -
Zhu et al.2019	201	256	177	256	25.8%	1.63 [1.09, 2.43]		
Subtotal (95% CI)		597		590	61.6%	1.63 [1.25, 2.13]		◆
Total events	477		418					
Heterogeneity: Tau ² =	0.00; Chi ²	= 1.89	df = 2 (F	P = 0.39	9); l ² = 0%			
Test for overall effect: 2	Z = 3.58 (P = 0.0	003)					
1.2.2 No-staghorn cal	culi							
Huang et al.2016	88	91	67	91	8.5%	10.51 [3.04, 36.37]		—
Lai et al.2019	67	75	58	75	13.0%	2.45 [0.99, 6.10]		— —
Lai et al.2020	32	38	24	38	10.2%	3.11 [1.04, 9.28]		— —
Song et al.2011	27	30	22	30	6.7%	3.27 [0.77, 13.83]		<u>+</u>
Subtotal (95% CI)		234		234	38.4%	3.75 [2.00, 7.06]		-
Total events	214		171					
Heterogeneity: Tau ² =	0.08; Chi ²	= 3.70	df = 3 (F	P = 0.30); l ² = 19%			
Test for overall effect: 2	Z = 4.11 (P < 0.0	001)					
Total (95% CI)		831		824	100.0%	2.37 [1.56, 3.61]		•
Total events	691		589					
Heterogeneity: Tau ² =	0.14; Chi ²	= 12.1	6, df = 6 (P = 0.0)6); l ² = 51	%		
Test for overall effect: 2	Z = 4.05 (P < 0.0	001)				0.01 0.1	1 10
Test for subgroup diffe			,	(P = 0	(12) $12 = 8^{10}$	2 204	Favours [TAS	Favours [SAS]

Figure 3. Forest plot of the stone-free rate of the suctioning access sheath (SAS) group and the traditional access sheath (TAS) group

ford, UK). Two categorical variables of main outcome indicators, SFR and complication, were calculated as the summary statistic using the pooled odds ratios with 95% confidence intervals (CIs). Due to continuous variables, mean differences (MDs) with 95%CI were performed for statistical analysis of operative time. With $P \leq .05$ considered statistically significant, the Z test was used to determine all the pooled effects. The pooled heterogeneity of statistics was assessed by the Cochrane Chi-squared test and inconsistency(I²). The random-effects model was adopted when the heterogeneity was significant (P < .05 or $I^2 > 50\%$). Otherwise, a fixed-effects model was used for the pooled. Subgroup analyses and sensitivity analysis was performed to assess the cause of significant heterogeneity. Furthermore, a funnel plot was used to examine publication bias when eligible studies less than ten.

RESULTS

Characteristics of studies

According to the previous search strategy, 206 studies were identified. Then, 113 duplicate studies were excluded. Finally, a total of seven studies^(7,10-12,18-20), with 1655 cases, were included in the meta-analysis (**Figure 1**). The characteristics, level of evidence, and quality assessment of eligible studies are reported in **Table 1**. Five RCTs and two RCCs were 1b and 3b levels of evidence, respectively. Simultaneously, the quality assessment of RCCs was high (NOS: 6 of 9 points). **Table2** exhibits lithotripter, stone burden, and main outcome indicators. Only three eligible studies reporting staghorn calculi cases included.

Operative time

Five eligible studies^(7,10-12,18), three of which were RCTs and two were RCCs, reported operative time (from the insertion of the ureteroscope to the placement of ne-phrostomy tube). With 490 cases in the SAS group and

the same cases in the TAS group, the result indicated operative time in the SAS group was shorter than that of the TAS group (MD=-17.3;95%CI: -23.09, -11.51; P < .00001; Figure 2). The result had significant heterogeneity (P < .0001; $I^2 = 85\%$). Stone burden was an important factor affecting operative time. Duo to large size and complex morphology, staghorn stones require more time to remove. Therefore, a subgroup analysis based on stone burden was performed. In the subgroup analysis, two studies were assigned in a staghorn calculi group and the other three studies in a non-staghorn calculi group. As shown in Figure 2, the SAS group of staghorn calculi was shorter than that of the TAS group in operative time (MD = -22.21;95%CI: -32.39, -12.03; P < .0001). The non-staghorn calculi subgroup had a similar result (MD = -14.60;95%CI: -17.03, -12.16; P < .0001). Test for subgroup differences was significant (P $= .15; I^2 = 50.8\%$).

Stone-free rate

All eligible studies reported stone-free rate after one session, and the stone-free state was defined as no residual stones > 4 mm evaluated by no-contrast CT or KUB. Five studies informed that the evaluation was performed on postoperative one week. As presented in Figure 3, the SAS group was higher than the TAS group in stone-free rate. (OR=2.37;95%CI:1.56,3.61; P < .0001). However, a subgroup analysis was performed due to heterogeneity (P = .06; $I^2 = 51\%$). Stone burden was a factor affecting stone-free rate, suggesting may affects heterogeneity in our meta-analysis. In subgroup analysis, three studies in the staghorn calculi group and four in the non-staghorn calculi group. With low heterogeneity (P = .39; $I^2 = 0\%$) in the staghorn calculi subgroup, the SAS group had a higher stonefree rate (OR=1.63;95%CI:1.25,2.13; P = .0003). The non-staghorn calculi subgroup also had a similar result (OR=3.75;95%CI:2.00,7.06; P < .0001). Test for subgroup differences was significant (P = .02; $I^2 = 82.3\%$).

	SAS		TAS			Odds Ratio	Odds Ratio
Chudu an Cubanau					Malaka		
Study or Subgroup	-	Total	Events	Total	Weight	M-H, Fixed, 95% C	I M-H, Fixed, 95% CI
1.3.1 Staghorn calcul	i						
Xu et al.2020	4	30	11	30	10.2%	0.27 [0.07, 0.96]	
Zhu et al.2019	43	256	70	256	62.4%	0.54 [0.35, 0.82]	· · · · · · · · · · · · · · · · · · ·
Subtotal (95% CI)		286		286	72.7%	0.50 [0.33, 0.75]	◆
Total events	47		81				
Heterogeneity: Chi ² = 1	.03, df = '	1 (P = ().31); I ² =	3%			
Test for overall effect: 2	Z = 3.37 (F	P = 0.0	007)				
1.3.2 No-staghorn cal	culi						
Lai et al.2019	11	75	21	75	19.2%	0.44 [0.20, 1.00]	
Lai et al.2020	6	38	9	38	8.1%	0.60 [0.19, 1.91]	
Subtotal (95% CI)		113		113	27.3%	0.49 [0.25, 0.95]	◆
Total events	17		30				
Heterogeneity: Chi ² = 0).19, df = '	1 (P = 0).66); I ² =	0%			
Test for overall effect: 2	Z = 2.11 (P = 0.0	4)				
Total (95% CI)		399		399	100.0%	0.50 [0.35, 0.70]	◆
Total events	64		111				
Heterogeneity: Chi2 = 1	.22, df = 3	3 (P = 0).75); l² =	0%			
Test for overall effect: 2	Z = 3.98 (F	P < 0.0	001)				0.01 0.1 1 10 10
Test for subgroup diffe	rences: Cl	hi² = 0.	00, df = 1	(P = 0)	.97), l ² = 0	%	Favours [SAS] Favours [TAS]

Figure 4. Forest plot of the total complication rate of the suctioning access sheath (SAS) group and the traditional access sheath (TAS) group

Total complications rate

Four eligible studies reported total complications rate^(7,10,12,18). Modified Clavien classification was used to evaluate total complications in three studies. One study assessed total complication by the Clavien grade classification. The total complication rate between the SAS group and the TAS group is presented in Figure 4. Compared with the TAS group, the SAS group had a lower total complication rate (OR=0.50;95%CI:0.35,0.70; *P* < .0001). Furthermore, the heterogeneity was low (*P* = .75; $I^2 = 0\%$). In subgroup analysis, two studies in the staghorn calculi group and two in the non-staghorn calculi group. With low heterogeneity (P > .05; $I^2 > 50\%$) and subgroup differences (P = .97; $I^2 = 0\%$), two subgroup results reported that the SAS group had a lower total complication rate (P < .001).

Auxiliary procedures rate

Auxiliary procedures, such as shockwave lithotripsy, 2nd PCNL, and retrograde intrarenal stone surgery, were reported in six eligible studies^(10-12,18-20). In the meta-analysis, the auxiliary procedures rate was significantly lower in the SAS group than the TAS group (OR = 0.48;95%CI :0.36,0.64; P < .00001; Fig.5). The result exhibited a low heterogeneity (P = .15; I² = 39%). In

	SAS	;	TAS	5		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	M-H, Fixed, 95% Cl
Du et al.2018	38	311	49	304	30.1%	0.72 [0.46, 1.14]	-8-
Huang et al.2016	0	91	14	91	10.0%	0.03 [0.00, 0.50]	←
Lai et al.2019	8	75	17	75	10.5%	0.41 [0.16, 1.01]	
Song et al.2011	3	30	8	30	5.0%	0.31 [0.07, 1.29]	
Xu et al.2020	6	30	14	30	7.8%	0.29 [0.09, 0.90]	
Zhu et al.2019	34	256	61	256	36.6%	0.49 [0.31, 0.78]	-
Total (95% CI)		793		786	100.0%	0.48 [0.36, 0.64]	◆
Total events	89		163				
Heterogeneity: Chi2 =	8.15, df =	5 (P = (0.15); l² =	39%			
Test for overall effect:	Z = 5.11 (P < 0.0	0001)				0.01 0.1 1 10 100 Favours [SAS] Favours [TAS]

Figure 5. Forest plot of the auxiliary procedures rate of the suctioning access sheath (SAS) group and the traditional access sheath (TAS) group

	SAS		TAS	;		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C	M-H, Fixed, 95% Cl
1.5.1 Staghorn calculi							
Du et al.2018	25	311	45	304	33.1%	0.50 [0.30, 0.84]	
Xu et al.2020	2	30	6	30	4.4%	0.29 [0.05, 1.55]	
Zhu et al.2019	19	256	35	256	25.6%	0.51 [0.28, 0.91]	
Subtotal (95% CI)		597		590	63.1%	0.49 [0.34, 0.71]	◆
Total events	46		86				
Heterogeneity: Chi ² = 0).41, df = :	2 (P = 0).81); I ² =	0%			
Test for overall effect: 2	Z = 3.71 (I	P = 0.0	002)				
1.5.2 No-staghorn cal	culi						
Huang et al.2016	10	91	25	91	17.6%	0.33 [0.15, 0.73]	
Lai et al.2019	6	75	15	75	10.9%	0.35 [0.13, 0.95]	
Lai et al.2020	5	38	8	38	5.5%	0.57 [0.17, 1.93]	
Song et al.2011	3	30	4	30	2.8%	0.72 [0.15, 3.54]	
Subtotal (95% CI)		234		234	36.9%	0.40 [0.24, 0.67]	◆
Total events	24		52				
Heterogeneity: Chi ² = 1	1.17, df = 3	3 (P = 0).76); l ² =	0%			
Test for overall effect: 2	Z = 3.44 (I	P = 0.0	006)				
Total (95% CI)		831		824	100.0%	0.46 [0.34, 0.62]	◆
Total events	70		138				
Heterogeneity: Chi ² = 1	.95, df = 6	6 (P = 0).92); I ² =	0%			0.01 0.1 1 10
Test for overall effect: 2	Z = 5.03 (I	> < 0.0	0001)				0.01 0.1 1 10 Favours [SAS] Favours [TAS]
Test for subgroup differ	rences: C	hi² = 0.3	38. df = 1	(P = 0)	54), $l^2 = 0$	%	Favours [SAS] Favours [TAS]

Figure 6. Forest plot of the postoperative fever rate of the suctioning access sheath (SAS) group and the traditional access sheath (TAS) group

subgroup analysis, three studies in the staghorn calculi group and three in the non-staghorn calculi group. With low heterogeneity (P > .05; $I^2 < 50\%$) and significant subgroup differences (P = .03; $I^2=79\%$), two subgroup results reported that the SAS group had a lower auxiliary procedures rate (P < .001).

Postoperative fever rate

All eligible studies reported postoperative fever. Six studies defined postoperative fever as postoperative temperature > 37.5°C. As presented in **Figure 6**, the postoperative fever rate was found to be significantly lower in the SAS group than the TAS group(OR = 0.46; 95%CI:0.34,0.62 ;P < .00001).The result exhibited a low heterogeneity (P = .76; $I^2 = 0\%$). Notably, subgroup analysis also exhibited similar results.

Sensitivity analysis and bias of publication

To test the stability of the result, we performed a sensitivity analysis with an article-by-article culling method. After the research by Zhu et al. was excluded in operative time, the I² value changed from 85% to 0%. Simultaneously, the I² value of stone-free rate changed from 51% to 0% by Huang et al. was excluded. While the result of operative time and stone-free rate was still stable. Therefore, the analysis suggested that both studies were the major cause of the heterogeneity, and our result is convincing. However, the funnel plot, used to assess publication bias, was unbalanced and indicated some publication bias.

DISCUSSION

Higher safety and effectiveness are still the goals for urologists to improve PCNL. Although MPCNL has the advantage of being minimally invasive, the increased operative time and renal pelvic pressure > 30mmhg are high-risk postoperative infection factors^(21,22). Therefore, accelerated suctional speed of perfusate and fragments may be a rational approach to reduce complications. In 2011, Song et al.'s RCT firstly reported a patented SAS, which can connect to a negative aspirator and keep a 16 F size⁽¹⁹⁾. The result indicated that patients in the SAS group had a higher stone-free rate than the TAS group (stone-free rate: 90% vs. 73.3%; P < .05). However, the SAS was not further investigated and used in clinical practice widely.

Recently, SAS has gradually been concerned and used in clinics since other simplified or purchasable SAS reported⁽²³⁾, such as ClearPetra⁽⁷⁾ and homemade SAS⁽¹⁰⁾. Many scholars have conducted related clinical studies. In 2019, Lai et al. performed a feasibility study that reported the ClearPetra with the function of suction and store fragments⁽¹⁸⁾. Next year, Xu et al. conducted an RCT that included staghorn stones to assess the safety and effectiveness of ClearPetra⁽¹²⁾. The result suggested that compared with TAS, ClearPetra can significantly improve renal pelvic pressure, stone-free rate, and complications in MPCNL. Similarly, Zhu et al. reported a simplified and homemade SAS in a case-matched comparative study, which had a lower operative time and lower complication rate⁽¹⁰⁾. However, to date, the SAS has not been evaluated by a systematic review or meta-analysis.

Stone-free rate and operative time are valid indicators to assess the effectiveness of PCNL. Because of the high recurrence rate in fragments $> 4mm^{(24)}$, fragments < 4mm are regarded as clinically insignificant residual fragments (CIRFS) and the symbol of stone-free⁽²⁵⁾. However, the removal of renal stone fragments still remains a tricky problem. Clinically, graspers or baskets were commonly used to remove fragments, but repetitive mechanical operation will cause mucosa damage and is time consuming. In order to improve fragments removal, several modalities have been proposed. Panah et al. reported a technique to flush out renal stone fragments by refluxed infusion⁽²⁶⁾. Subsequently, Kati

et al. performed a comparative study between aspiration method and irrigation method⁽²⁷⁾. They found that stonefree rate was higher in aspiration method, containing the advantage of high efficiency and convenience. In our study, the stone-free rate and operative time were better in the SAS group. The result may relate with the characteristic of SAS. With the advantage of continuous negative pressure suction, SAS can gather around fragments and then suck out, avoiding escape to other renal calyces. Due to the gravity, the lower pole calyx is a common and tricky position for deposited fragments. SAS, with continuous suction, may improve the treatment of fragments deposited in the lower pole calyx. Du et al. performed a multicenter RCT and reported a similar opinion that SAS could immobilize stone and limit the movement of fragments, causing a higher stonefree rate and less operative time(20). Furthermore, SAS may reduce the necessity of powder fragments. Several studies revealed that fragments < 5mm could be sucked out⁽¹⁹⁾. Lai et al. reported that fragments with a maximum diameter of 6.3mm can be aspirate by a 20F SAS, which decreases operative time in shattering stone⁽⁷⁾. Moreover, when the holmium laser smashes stone, SAS can accelerate perfusate mobile speed and keep a clear visual field, which is an important cause of operative time shorted. Although our result had significant heterogeneity, subgroup analysis and sensitivity analysis were performed and found the cause of heterogeneity. After reducing the heterogeneity, our result still indicated that the SAS group had a higher stone-free rate and less operative time than the TAS group.

When evaluating the safety of PCNL, the postoperative complication rate is a credible indicator. Currently, the Modified Clavien-Dindo system is a rational and validated complication classification system widely used to assess urology surgery complications⁽²⁸⁾. Postoperative fever is a grade I complication in the Modified Clavien-Dindo system. Although only four eligible studies reported total complications assessed by the Clavien-Dindo system, all seven included studies reported postoperative fever risk. The present result suggested that the SAS group showed much less total complication rate than the TAS group, especially in postoperative fever and auxiliary procedures. These results may be the following causes: (1) A lower interoperative renal pelvis pressure in the SAS group. High renal pelvis pressure contributes to absorbed bacterial endotoxin and damages the collecting system, causing high operative fever and even urinary tract infection. Zhong et al. informed that high RPP (> 30mmhg) and accumulated time of high RPP (> 50 s) are risk factors of postoperative fever⁽²⁹⁾. Xu et al.'s RCT assessed the renal pelvis pressure of different puncture poles and period reported that SAS can significantly decrease renal pelvis pressure and pressure-related complications⁽¹²⁾. Several studies reported operative time is a dependent risk factor of postoperative fever or urosepsis^(22,29). With a continuous negative pressure state, SAS accelerated the speed of fragments removal, decreased operative time. Additionally, because the heterogeneity of total complication rate, postoperative fever rate, and auxiliary procedures rate is low, we achieved a convincing result that the SAS can improve complications compared with TAS.

Our study also had some limitations:(1) Even if we had found the cause of heterogeneity in our result, the definition of some outcomes among included studies was not completely consistent or clear, causing the increase of heterogeneity.⁽²⁾ Although two RCCs included in the study were of high quality, more related RCTs are needed to be included.⁽³⁾ Because all included studies were independent studies and came from the same country, included high-quality RCT from different countries may improve credibility further.⁽⁴⁾ All included studies in our research used holmium laser lithotripsy. Different lithotripsy techniques may impact the effectiveness and safety of PCNL due to crushing mechanisms differences⁽³⁰⁾, and thus our conclusions may not apply to other types of lithotripsy.

CONCLUSIONS

Above all, our study results found that compared with the TAS group, patients in the SAS group had higher stone-free rate, less operative time, lower total complication rate, lower postoperative fever rate, and lower auxiliary procedure rate. Therefore, SAS is a safe and effective method in MPCNL.

COMPETING INTERESTS

The authors declare that they have no competing interests

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