




# BMJ Open Balloon versus Amplatz for tract dilation in fluoroscopically guided percutaneous nephrolithotomy: a systematic review and meta-analysis

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## ABSTRACT

**Objective** To compare the safety and efficacy of balloon and Amplatz for tract dilation in fluoroscopically guided percutaneous nephrolithotomy (PCNL).

**Method** EMBASE, PUBMED, MEDLINE and the Cochrane Central Register of Controlled Trials were searched for pertinent studies up until 30 October 2019. Pooled effects were calculated as ORs with 95% CIs or mean differences (MD) with 95% CIs. Endpoints included postoperative decrease in haemoglobin, transfusion rate, complication rate, successful dilation rate, stone-free rate, fluoroscopy time, access time, total operation time and length of postoperative hospitalisation (LPH). Bonferroni's correction was intercalated to reduce the likelihood of making a meta-analytical false positive.

**Results** One randomised controlled trial and five controlled clinical trials were included, which involved 1317 patients in total. We found a lower drop in postoperative haemoglobin for patients receiving balloon dilation compared with those in the Amplatz group (MD=−0.21, 95% CI −0.33 to 0.09, p=0.0005; Bonferroni correction  $\alpha=0.005$ ). Access time in the balloon group was also, on average, 2.61 min shorter than the Amplatz group (MD=−2.61, 95% CI −4.20 to 1.01, p=0.001; Bonferroni correction  $\alpha=0.005$ ). No significant differences were identified between the two dilation methods in terms of transfusion rate, complication rate, successful dilation rate, stone-free rate, fluoroscopy time, total operation time and LPH.

**Conclusion** Balloon dilation is a safe and effective tract dilation technique for access creation during fluoroscopically guided PCNL. Both of methods have similar success rates although balloon dilation is associated with significantly less postoperative haemoglobin decline and shorter access time. Therefore, balloon dilation appears to be the superior tract dilation technique, but further confirmatory research is required to confirm these findings.

## INTRODUCTION

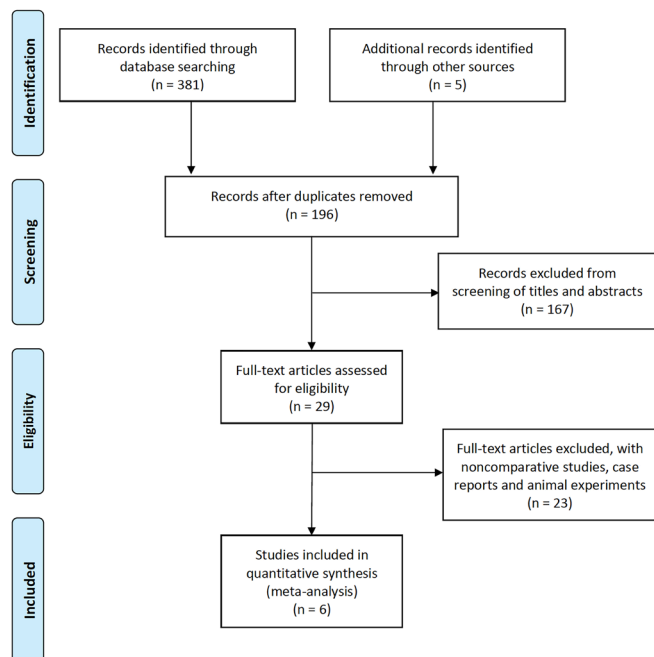
Percutaneous nephrolithotomy (PCNL) is the main approach for treating kidney stones and is the first-line treatment for both complex and larger stones.<sup>1</sup> One of the most fundamental procedures of PCNL is to ensure there

## Strengths and limitations of this study

- This study is a systematic comparison of balloon and Amplatz tract dilation techniques for fluoroscopically guided percutaneous nephrolithotomy.
- This present systematic review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.
- Most of the studies included here are clinically controlled trials that may decrease the overall standard of evidence, necessitating more high-quality randomised controlled trials.
- Language of included studies was restricted to English only, which may have a resulted in language bias.

is safe access which increases operative precision and therefore enhances surgical efficacy. However, complications in this process, such as tract dilation failure, haemorrhage and perforation of the renal parenchyma or collecting system, are not uncommon.<sup>2</sup> Finding the safest, most reliable tract dilation method is necessary to ensure patients suffer fewer complications and recover sooner.

There are currently a number of tract dilation options for PCNL, which mainly include sequential Amplatz dilation, balloon dilation and one-shot dilation (OSD).<sup>3–5</sup> OSD is generally considered a safe, effective technique which is relatively uncomplicated and associated with less fluoroscopy time,<sup>6–10</sup> although this is based on only a few studies. Further high-quality randomised controlled trials (RCTs) are currently under way to confirm these findings. Presently, the Amplatz dilation method is considered the standard technique and most widely used, although, balloon dilation which is also generally considered safe and effective, has been increasingly implemented by urologists as a component of PCNL.



**Figure 1** Flowchart of study selection.

Several studies have directly compared outcomes of balloon and Amplatz for tract dilation in fluoroscopically guided PCNL. However, the advantages and risk factors of balloon dilators and Amplatz dilators have not been compared with develop guidelines, therefore a systematic review and meta-analysis is required. The purpose of this study was to synthesise current clinical evidence and compare the safety and efficacy of balloon versus Amplatz for tract dilation in PCNL. This evidence base is relatively unsophisticated and therefore this study may be used to guide clinical decisions and provide the best urological solutions for patients suffering the debilitating effects of kidney stones.

## METHODS

### Patient and public involvement statement

This is a systematic review and meta-analysis of pooled secondary data extracted from published studies. As such, no patients or the public were involved in the design or conduct of this report.

### Literature search

Embase, PubMed, Medline and the Cochrane Central Register of Controlled Trials were searched for pertinent studies up until 30 October 2019. The following terms were used: nephrolithotomy, percutaneous PCNL, tract, Amplatz, balloon and dilation. These search terms were used singly and in various combinations. The following search strategy was adopted for each database: (“percutaneous nephrolithotomy”[Mesh] OR “PCNL”) AND (“tract dilatation”[Mesh] OR “tract dilation” OR “access creation”) AND (“balloon dilation”[Mesh] OR “balloon dilatation”) AND (“Amplatz dilation” [Mesh] OR “Amplatz dilatation”) (see online supplementary file 1 for details).

Manual searching of citations and references was also conducted to ensure related studies were not overlooked. The search and selection strategy was applied according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>11</sup> The specific search and selection process for this study is provided as [figure 1](#).

### Inclusion criteria and study endpoints

Eligibility was assessed according to the following criteria: (1) all prospective RCTs and controlled clinical trials (CCTs) comparing outcomes of balloon dilation and Amplatz dilation in fluoroscopically guided PCNL were included; (2) all patients were required to be in relatively good health prior to surgery; (3) language was restricted to English only and full-text, or related data, must be readily available from within each report.

Two authors independently reviewed titles and abstracts for initial consideration, and differences of opinion were discussed with a third author in order to reach an agreement. Endpoints, included: postoperative decrease in haemoglobin, transfusion rate, complication rate, successful dilation rate, stone-free rate, fluoroscopy time, access time, total operation time and length of postoperative hospitalisation (LPH).

### Data extraction and quality assessment

Two authors independently extracted demographics and outcomes data and assessed study quality by reading full-texts. Data were extracted from RCTs and CCTs which met our prerequisite inclusion criteria. Where there were multiple publications based on the same sample, the latest full report was included. Any differences in data extraction were resolved through discussion and consultation with senior authors.

In addition, we assessed the methodological quality of each of the included RCTs, using the Jadad scale.<sup>12</sup> Scores for each study ranged from 0 to 5. Studies with scores of less than 3 were considered low quality, while those with scores greater than or equal to 3 were considered high quality. Likewise, the Newcastle-Ottawa Scale<sup>13</sup> was used to assess the quality of the included CCTs. Scores of each study ranged from 0 to 9. Studies with scores less than 5 were considered low quality, while those with scores greater than or equal to 5 were considered high quality.

### Data analysis

Pooled effects were calculated as ORs with 95% CIs for dichotomous data and mean differences (MD) with 95% CIs for continuous data. The random effects model was used to perform statistical analysis.<sup>14</sup>  $I^2$  statistics were used to assess heterogeneity. When  $I^2 < 50\%$ , heterogeneity was considered low. When  $I^2 \geq 50\%$  and  $< 75\%$ , heterogeneity was considered moderate and when  $I^2 \geq 75\%$ , this was considered substantial heterogeneity. When  $I^2 \geq 50\%$ , sensitivity analysis was conducted in order to try to identify the source of heterogeneity but also to assess the reliability of findings. Given the multiple endpoints of interest, Bonferroni correction was performed to avoid

potential over-estimation, thus the significance level  $\alpha=0.005$ . Review Manager was used for statistical analysis (RevMan, V.5.3; Cochrane Collaboration, Copenhagen, Denmark).<sup>15</sup>

### RESULTS

A total of 386 pertinent studies were retrieved through preselected meta-databases. According to our eligibility criteria, one RCT and five CCTs were included in this systematic review and meta-analysis.<sup>16-21</sup> Basic study design characteristics and quality assessments of the included studies are provided in [table 1](#). In each of the included studies, groups were relatively homogeneous in terms of stone location, size and shape. PCNL for all patients were performed by senior urologists.

#### Postoperative decrease in haemoglobin and transfusion rate

Three of the included studies reported postoperative decreases in haemoglobin,<sup>16 19 21</sup> although, two studies conversely found no significant difference between balloon dilation and Amplatz dilation.<sup>19 21</sup> One further study also reported that balloon dilatation can significantly reduce the extent of postoperative haemoglobin decline in patients,<sup>16</sup> and pooled analysis appears to confirm that there is a lower decrease of approximately 2.1 g/L in postoperative haemoglobin levels in patients whom received the balloon dilation technique as part of the standard PNCL procedure (MD=-0.21, 95% CI -0.33 to 0.09,  $p=0.0005$ ). Although, this difference was statistically significant and there was no significant heterogeneity ( $I^2=0\%$ ,  $p=0.87$ ), there were only two studies included ([figure 2A](#)).

All studies reported transfusion rates<sup>16-21</sup> but only one reported that balloon dilation can significantly reduce the need for blood transfusion.<sup>21</sup> The remaining five studies did not verify this finding and therefore could not reach the same conclusion.<sup>16-20</sup> Pooled analysis also suggests that there is no statistically significant difference in terms of transfusion rate between the two groups (OR=0.69, 95% CI 0.47 to 1.01,  $p=0.06$ ), overall. No significant heterogeneity was observed ( $I^2=0\%$ ,  $p=0.67$ ) (see [figure 2B](#) for further details).

#### Complication rate

Five studies reported complication rates<sup>16-20</sup> and only one reported having observed a significant difference in the rate of complications between these two dilation techniques. This meta-analysis also appears to confirm that complications rates may be similar for each of the components of PNCL analysed here (OR=0.74, 95% CI 0.51 to 1.08) although this was not a significant finding ( $p=0.12$ ). Absolutely no heterogeneity was observed which suggests this may be a stable finding although this was also not considered statistically significant ( $I^2=0\%$ ,  $p=0.73$ ) (see [figure 2C](#) for further details).

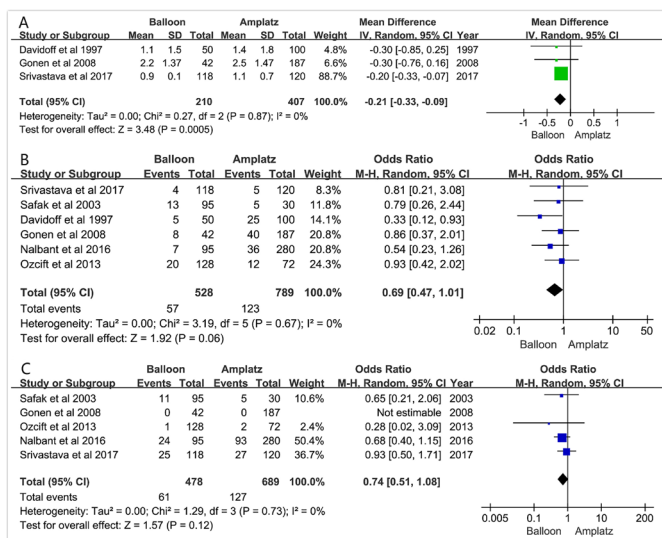
#### Successful dilation rate and stone-free rate

Successful dilation rates were reported in five of the included studies.<sup>16-20</sup> The results of these studies and our

**Table 1** Study characteristics of balloon versus Amplatz for tract dilation in PCNL

Authors	Year	Institution location	Types	Cases (N)		Gender (M:F)		Mean age (Years)		Mean stone size (mm <sup>2</sup> )		PORS		Size of access sheath		Jadad scores
				Balloon	Amplatz	Balloon	Amplatz	Balloon	Amplatz	Balloon	Amplatz	Balloon	Amplatz	Balloon	Amplatz	
Davidoff and Bellman <sup>21</sup>	1997	USA	CCT	50	100	-	-	47	47	-	-	-	-	30F	30F	4
Şafak et al <sup>20</sup>	2003	Turkey	CCT	95	30	59:36	18:12	47.2	46.2	-	-	0	0	32F	32F	5
Gönen et al <sup>19</sup>	2008	Turkey	CCT	42	187	28:14	121:66	45.2	49.4	1079.1	951.1	8	23	34F	34F	5
Özçift et al <sup>18</sup>	2013	Turkey	CCT	128	72	-	-	48.25	44.84	708	786	24	18	30F	30F	5
Nalbant et al <sup>17</sup>	2016	Turkey	CCT	95	280	55:40	188:92	44	47	678.05	748.96	0	0	30F	30F	5
Srivastava et al <sup>16</sup>	2017	India	RCT	118	120	59:59	62:58	42.1	40.1	31.1	29.7	18	19	30F	30F	5*

\*Newcastle-Ottawa Scale. CCT, clinical controlled trial; F, female; M, male; PCNL, percutaneous nephrolithotomy; PORS, previous open renal surgery; RCT, randomised controlled trial.



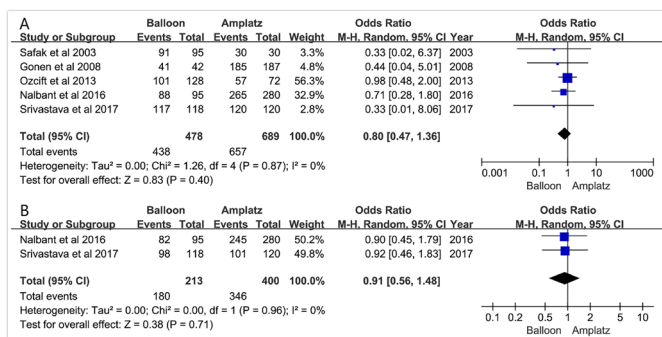
**Figure 2** Forest plots illustrating the meta-analysis of outcomes with balloon dilation versus Amplatz dilation in percutaneous nephrolithotomy.

meta-analysis did not identify significant differences in successful dilation rate between these two dilation techniques (OR=0.80, 95% CI 0.47 to 1.36, p=0.40). No significant heterogeneity was observed ( $I^2=0\%$ , p=0.87) which suggests this finding is relatively stable (see figure 3A for further details).

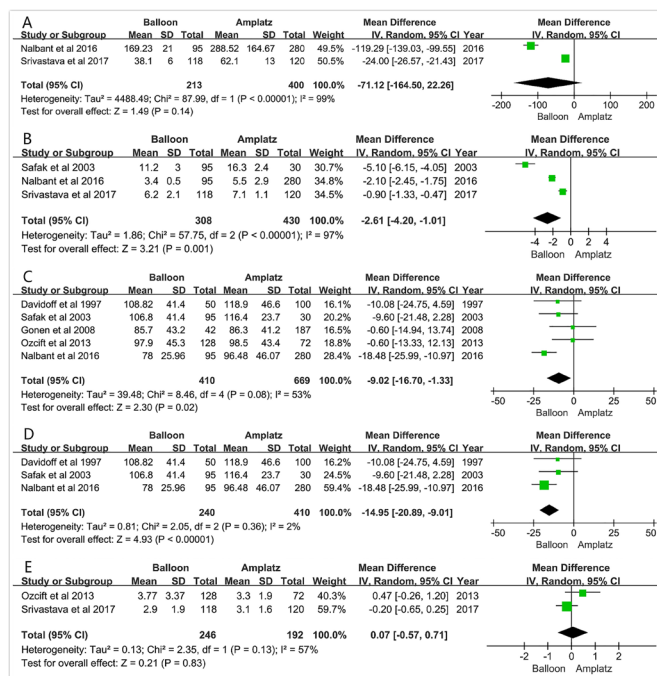
Stone-free rate was reported in two studies<sup>16 17</sup> and both found that stone-free rates related to each of these two techniques was comparable. Pooled analysis also suggests that there may be no significant difference in stone-free rate between the balloon dilation and Amplatz dilation groups (OR=0.91, 95% CI 0.56 to 1.48) although this cannot be considered a significant finding (p=0.71). No significant heterogeneity was observed ( $I^2=0\%$ , p=0.96) (see figure 3B for further details).

### Fluoroscopy time and access time

Only two of the included studies reported intraoperative fluoroscopy times,<sup>16 17</sup> although, both found that balloon dilation can significantly reduce time taken for fluoroscopy. Controversially, our meta-analysis suggests there



**Figure 3** Forest plots illustrating the meta-analysis of outcomes with balloon dilation versus Amplatz dilation in percutaneous nephrolithotomy. The outcomes analysed were (A) successful dilation rate and (B) stone-free rate.



**Figure 4** Forest plots illustrating the meta-analysis of outcomes with balloon dilation versus Amplatz dilation in percutaneous nephrolithotomy. The outcomes analysed were (A) fluoroscopy time, (B) access time, (C) total operation time, (D) sensitivity analysis of total operation time and (E) length of postoperative hospitalisation.

may be no difference between the balloon dilation and Amplatz dilation group; however, this finding cannot be considered significant (MD=-71.12; 95% CI -164.50 to 22.26, p=0.14). Heterogeneity was also significant and extreme ( $I^2=99\%$ , p<0.001) although, the high heterogeneity observed may be the manifestation of differences in methodological design (figure 4A). Even though, heterogeneity was significant in this instance, sensitivity analysis was not performed due to the limited number of included studies.

Three studies compared access times taken for balloon and Amplatz tract dilation.<sup>16 17 20</sup> Two studies found that access times for balloon dilation were shorter than for Amplatz dilation.<sup>17 20</sup> One study did not find significant differences in access times between these two groups.<sup>16</sup> However, our pooled analysis revealed that access time in the balloon group was on average 2.61 min shorter than in the Amplatz group (MD=-2.61, 95% CI -4.20 to 1.01, p=0.001), although heterogeneity was again significant and extreme ( $I^2=99\%$ , p<0.001) (see figure 4B for details).

### Total operation time and LPH

Five studies reported time take for surgeries,<sup>17 18 20 21</sup> one of which found that surgery time taken in the balloon dilation group was significantly less than that in the Amplatz dilation group,<sup>17</sup> but the remaining four studies did not verify this finding.<sup>18 20-22</sup> Our pooled analysis showed that the balloon dilation technique took approximately 9.02 min less than Amplatz dilation; however, there was

no significant difference (MD=-9.02, 95% CI -16.7 to 1.33,  $p=0.02$ ; Bonferroni correction  $\alpha=0.005$ ). There was moderate heterogeneity ( $I^2=53\%$ ,  $p=0.008$ ) (see figure 4C for details). In order to identify the source of this heterogeneity we removed two studies,<sup>18 19</sup> which had enrolled patients having undergone previous open renal surgery. The heterogeneity decreased substantially ( $I^2=2\%$ ,  $p=0.36$ ) but the result of this sensitivity analysis changed (MD=-14.95, 95% CI -20.89 to 9.01,  $p<0.001$ ; Bonferroni correction  $\alpha=0.005$ ) (see figure 4D for details).

Two studies reported comparisons of postoperative hospitalisation although no significant differences were observed. Our meta-analysis confirmed there may be not a substantial difference in postoperative hospitalisation related to these two dilation techniques (MD=-0.07, 95% CI -0.57 to 0.71,  $p=0.83$ ). Moderate heterogeneity was observed ( $I^2=57\%$ ),  $p=0.13$ ) (see figure 4E for details). The sensitivity analysis was not performed due to the limited number of included studies.

## DISCUSSION

Though Amplatz and balloon tract dilation techniques continue to be widely used in our daily clinical work, the current evidence does not overwhelmingly support one method over the other one regarding the safety and efficacy. To the best of our knowledge, only one similar systematic review was conducted in 2013, which yielded no statistically significant or clinical relevant results.<sup>23</sup> However, our study identified statistically significant reductions in postoperative haemoglobin decrease, transfusion rate, access time and operation duration with balloon dilation although there appears to be no difference between balloon dilation and Amplatz dilatation in terms of transfusion rate, complication rate, successful dilation rate, stone-free rate, fluoroscopy time and postoperative hospitalisation.

In PCNL, the degree of haemoglobin decline, transfusion rate and complication rate are important factors which not only indicate but also influence, surgical safety. To some extent, the effect on haemoglobin decline after PCNL reflects both blood loss and bleeding which is also a common complication of PCNL.<sup>24</sup> Kessar *et al* found that the amount of intraoperative blood loss caused by the tract dilation techniques accounted for approximately half of the total amount of blood loss.<sup>25</sup> The correct puncture pathway and selecting the most appropriate tract dilation methods are key decisive factors which determined the amount of intraoperative blood loss.<sup>6</sup> Of the included studies, Srivastava *et al* found balloon dilation was associated with less post-surgical haemoglobin decline,<sup>16</sup> and Davidoff and Bellman found that the balloon dilation technique may reduce transfusion rate.<sup>21</sup>

The results of this meta-analysis appear to confirm that the use of balloon dilation results in less bleeding. Although, no significant difference was found between the two groups in terms of transfusion rate, the balloon seems to have a tendency to reduce the possibility of transfusion.

Reductions in the blood transfusion rate could therefore greatly reduce the number of complications associated with blood transfusions, for instance, blood transfusion reactions, infections and so on. Davidoff and Bellman believed that Amplatz serial dilation causes greater tract trauma, while balloon dilation is less time-consuming and can maintain a constant pressure on the surrounding blood vessels during surgery.<sup>21</sup> For damaged blood vessels, balloon has the effect of oppression and haemostasis, and therefore may represent a distinct advantage of balloon dilation. Benway and Nakada recommended balloon dilation as the best modality for dilating percutaneous tracts due to fewer bleeding complications and collecting system damage<sup>26</sup> which appears to evidence this advantage although further research is required.

In this study, the primary complications involved in PCNL included double-J stent insertion, postoperative urinary tract infections, urine leakage, haemorrhage, blood transfusion, collection system perforation and postoperative fever. Unfortunately, the classification of complications is not completely uniform among these studies, which may affect the results of statistical analysis. The rate of complication was 16.1% overall, with a lower rate (ie, 12.8%) in the balloon dilation group and 18.4% in the Amplatz dilation group; although, this was not considered a statistically significant difference. Fewer collecting system injuries and lower transfusion rate may be the main reasons for the reduced incidence of complication with balloon dilation. Through clinical experience, we know that injury to the collecting system is an important complication of PCNL and can have a negative impact on outcomes. The probability of collecting system perforation was suggested to be higher when rigid and semirigid dilation methods are used.<sup>27</sup> Şafak *et al*<sup>20</sup> and Nalbant *et al*<sup>17</sup> reported collecting system damage rates were 11.6% versus 16.6% and 3.1% versus 2.5% between balloon group and Amplatz group, respectively. However, Şafak *et al*<sup>20</sup> found that the decrease in collecting system damage rate was related to increased surgeon's experience. This meta-analysis was unable to intercalate length of surgical experience due to the lack of reporting. This is likely to be a key issue and therefore we would encourage authors to collect and report this potentially influential factor in future studies.

Successful dilation rate and stone-free rate are important indicators of the efficacy in PCNL. In our study, successful dilation rate and stone-free rate of balloon dilation group were slightly lower than the Amplatz dilation group with 91.6% versus 95.4% and 84.5% versus 86.5%, respectively. However, pooled analysis did not identify significant differences between these two groups. Tomaszewski *et al* also found balloon dilation had a comparable stone-free rate among patients undergoing PCNL.<sup>28</sup> Patients' body mass index, stone location, size, shape, surgery history and the experience of surgeons are important factors affecting the successful dilation rate. Although, Joel *et al* reported a failure rate of 25% for balloon dilation in previously operated patients,<sup>29</sup> while Ren *et al* found that balloon



dilation had a higher tract success rate for staghorn stones in patients without history of open renal surgery.<sup>30</sup> These findings combined suggest efficacy maybe reduced in patients with previous open renal surgery who underwent balloon dilation during access creation. Critically speaking, fibrosis around the kidney, scar formation and severe fascial resistance which can prevent the passage of the balloon dilator, may be responsible for balloon dilation failure. Therefore, implementing the Amplatz dilation method for patients with a history of renal surgery may be a more appropriate.

One further issue which ought to be considered is that prolonged exposure to radiation can cause genetic mutations and increase the risk of cancer to both patients and surgeons administering PCNL.<sup>31</sup> Unfortunately, our study did not find a significant reduction intraoperative fluoroscopy time associated with either technique. Nevertheless, two of the included studies revealed that balloon dilation can significantly reduce the fluoroscopy time<sup>16 17</sup> which demands further research. Differences in methodology may be the main cause of the significant heterogeneity observed here. Although again, further high quality RCTs are required to garner insight into this area. In addition, X-ray-free ultrasound-guided PCNL or totally ultrasound-guided PCNL are increasingly being used.<sup>22 32-34</sup> The safety and efficacy of PCNL solely guided by ultrasound have already been reported<sup>22 30 34 35</sup> and this marks an important step forward for our patients and for urologists alike.

Access time is of course, one of the factors which influence operation times, and perhaps reflects the complexity of tract dilation techniques. Three of the included studies reported that the tract could be dilated more rapidly and in one step using balloon dilators and therefore generally is less time-consuming in terms of access<sup>16 17 20</sup> and the overall surgical procedure.<sup>17</sup> Our pooled analysis also highlighted that the balloon dilation technique is less time consuming for X-ray-guided PCNL in the length of access. Although, no statistical difference was observed in operation time between the two groups, sensitivity analysis showed that balloon dilation significantly reduced surgery time for patients without a history of open renal surgery. A reduction in surgery time would certainly decrease the risk of anaesthesia, help patients recover sooner after surgery, reduce bleeding and therefore the likelihood of requiring postoperative blood transfusion which should provide clinicians with assurances for decision-making although gaining access is only one step in the procedure.

In terms of recovery, this synthesis did not identify a significant difference in postoperative hospitalisation between these two techniques, which is consistent with other previous studies.<sup>16 17</sup> Although, it is worth noting that the cost may be an important factor influencing this technical choice. The price of Amplatz dilation is considerably lower than the balloon dilation method,<sup>16</sup> which reduces the economic burden on patients or more generally on the health system. Reductions in treatment costs can optimise the allocation of medical resources but there

is a counterbalancing issue here. It is therefore crucial to evaluate the cost effectiveness of the two tract dilation techniques in clinical practice, and perhaps especially for less developed countries.

Despite the evidence presented here, we must point out that this system review and meta-analyses in general, have certain limitations. First, the number of studies included was relatively small and most of them were retrospective cohort studies with varying degrees of quality. These issues will have impacted each individual study and therefore our synthesis. Second, due to limited data, we could not report age-gender adjusted OR or MD and failed to perform subgroup analyses based on stone burden, previous open renal surgery and surgeon experience to further investigate the association between these factors and tract dilation techniques. Third, in the included studies, the definitions of some outcomes were not explicitly mentioned or were not completely consistent, which may bias the results. Additionally, telescopic Alken dilation and OSD are also used for tract creation. A comparison among multiple tract dilation methods of PCNL may better demonstrate the advantages and disadvantages between different techniques. Finally, studies were deemed ineligible based solely on the language used which may result in language bias. Further clinical research should be designed to overcome some of these problems to ensure this evidence base is more comprehensive and reliable.

## CONCLUSION

In general, Balloon dilation is a safe and effective tract dilation technique for access creation in fluoroscopically guided PCNL. Both of methods have similar success rates although balloon dilation appears to reduce the degree of postoperative haemoglobin decline and access times. Therefore, balloon dilation may be the superior tract dilation technique; but more high-quality RCTs are necessary to confirm this, before balloon dilation can be recommended as a key component of PCNL.

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**Contributors** P-xP, S-cL and GZ conceived and designed the experiments. Y-hH and HZ extracted the data. P-xP, SS and S-cL analysed the data. SS, Y-hH, X-mW and HZ contributed materials/analysis tools. P-xP and S-cL wrote the manuscript. Then, GZ and SS critically revised this report.

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