

A Comparative Clinical Trial Study Between Hybrid Single Dilatation and Sequential Dilatation during Percutaneous Nephrolithotomy

Wael Sami Nasif¹, Ehab Jasim Mohammed^{2*}, Hayder I. Jawad³

¹FACMS (URO), Urologist in Al-Yarmok Teaching Hospital/Iraq

²Professor, FEBU, FABMS, FICMS, FRCS (GLASCOW), Consultant Urologist, Head of Department of Surgery/College of Medicine/ Ibn Sina University of Medical and Pharmaceutical Science/Iraq.

³Consultant Urologist, Head of Endourology Committee of Arab Board Specialization in Iraq, Head of Urology at Al-Yarmok Teaching Hospital/Iraq

Email: ehabgmh@yahoo.com

Abstract

Background: n important and integral step in percutaneous nephrolithotomy is renal puncture and tract dilatation with insertion of the access sheath. There are currently three standard methods for renal dilatation including telescopic metal coaxial dilators (Alken dilators), semirigid polyurethane fascial dilators (Amplatz dilators), and one-step balloon dilatation. **Aim:** To assess the differences between the Hybrid Single Dilatation and Sequential Dilatation during Percutaneous Nephrolithotomy regarding the effectiveness and complications. **Methods:** A comparative clinical trial study was conducted in the Department of Urology/Al-Yarmok Teaching Hospital/Iraq during the period from the 1st of January 2021 to the 1st of April 2022. A convenient sample of 100 patients with renal stones who presented with renal stones larger than 20 mm, staghorn or partial staghorn and were scheduled to have PCNL was included in the current study. The patients were submitted into two groups and were managed with hybrid single dilatation or with sequential dilatation. **Results:** Sequential dilatation was associated with a significantly longer duration of operation and x-ray exposure than hybrid single dilatation (P-value=0.003 and 0.001, respectively). Regarding the complications, the hybrid single dilatation was associated with a significantly lower mean of haemoglobin drop and hospital stay after the operation (Pvalue=0.001 for both). In addition, a higher proportion of patients with Clavien grading scores II and III were recorded in sequential dilatation than in hybrid single dilatation procedures. **Conclusion:** The hybrid single dilatation was significantly associated with a shorter time of operation and a shorter time of x-ray exposure compared to sequential dilatation. In addition, it was significantly associated with fewer complications including haemoglobin drop, and postoperative hospital stay.

1. Introduction

Nephrolithiasis, or renal calculi, can be considered as the consequence of crystallization and aggregation of highly concentrated urinary components, and they are caused by a disruption in the balance between solubility and precipitation of salts in the urinary tract and the kidneys. The lifetime prevalence of urinary tract stones has been estimated at 10-14%(1).

In the United Kingdom, renal colic is common, with 12% of men and 6% of women having at least one episode of renal colic in their lifetime, with an annual incidence of 1-2 per 1000 and incidence peaking at 40-60 years of age for men and late 20's for women. The difference between male and female risk is decreasing, this is likely due to the increase in obesity and the western diet(2).

The morbidity associated with urolithiasis includes colic pain and obstructive uropathy, which can lead to renal failure and severe urinary tract infections, leading in turn to pyonephrosis and septic shock(1). Conservative, medical, and surgical treatments are the treatment methods for stones in the urinary

system. Other options include percutaneous nephrolithotomy (PCNL), extracorporeal shock wave lithotripsy (SWL), and retrograde intrarenal surgery (RIRS), which are less invasive than open surgery. The primary goal in the treatment of kidney stones is to provide a maximally stone-free rate (SFR) with minimal morbidity(3).

The PCNL is currently the procedure of choice for treating large renal(4). The usual indications for PCNL are stones larger than 20 mm, staghorn, and partial staghorn calculi(5). This technique is associated with high success rates, decreased morbidity and fewer complications than conventional renal stone surgery(6). At the same time, it is associated with some complications such as renal haemorrhage, tract dilation failure, and collecting system perforation. The contraindications for PCNL include pregnancy, bleeding disorders, and uncontrolled urinary tract infections(5).

The stages of this operation are: obtaining access to the collecting system (guided by ultrasonography or fluoroscopy), dilatation of the tract, placement of the sheath, fragmentation of the calculus, and placement of the nephrostomy catheter(7).

The choice of puncture either fluoroscopic or ultrasound-guided is dictated by the calyceal anatomy and the surgeon's expertise in a particular technique. Regardless of the choice of access ureteric catheter is placed in all cases(5). Fluoroscopy is the standard guidance used in western countries; however, the associated radiation is a major drawback. Ultrasound-guided PCNL is gaining popularity because of its convenience and lack of X-ray exposure. One issue that minimizes the use of ultrasound guidance is the lack of monitoring during the tract dilation, as most previous ultrasound-guided PCNL studies have focused on the puncture, with the dilation completed either under fluoroscopy or blindly(8).

The conventional PCNL is done in a prone position. This allows direct access to the posterior calyx. In addition, the bowels do not come in the line of puncture(5). While the disadvantages of the prone position, such as anaesthetic, surgical, or logistical problems(9).

The PCNL can also be done in a supine position which has the advantages of combined antegrade and retrograde approaches easier switch of regional to general anaesthesia and usefulness in patients with cardiac co-morbidities. But in the supine position, we would not be able to establish multiple channels and the space is limited(5).

An important and integral step in PCNL is renal puncture and tract dilatation with insertion of the access sheath, but during these steps, bleeding can occur, although it usually responds to the tamponade effect provided by the access sheath(6). There are currently three standard methods for renal dilatation include telescopic metal coaxial dilators (Alken dilators), semirigid polyurethane fascial dilators (Amplatz dilators), and one-step balloon dilatation(7).

Metal telescopic dilators were first introduced by Alken in 1985. The dilation method is done by repeated insertion and withdrawal of a series of sequentially enlarging coaxial metal rods that pass over an 8-F guide (central) rod(4). The main advantages are economical benefits as they are reusable, more effective dilators especially if there are dense perinephric adhesions from previous renal surgery, and maintain a tamponade effect throughout the dilatation(6, 10). Disadvantages of Metal telescopic dilators include being more time-consuming, requiring a longer exposure to X-rays, and is associated with a higher risk of tract loss and collecting system perforation(11, 12).

Sequential fascial dilators (Amplatz) are passed one after the other, not coaxially like the rigid metal dilators but progressively, by advancing one dilator, removing it, advancing the next larger dilator, and so on until the final tract diameter is achieved(13). It has been suggested that during sequential dilator exchanges, the tamponade effect on the renal parenchymal tract is lost, which can lead to more blood loss during the exchange process. The dilation with the Amplatz set has moderate costs

close to those of balloon dilation(11). They are more time-consuming and require longer exposure to X-rays and increased the possibility of tract loss and collecting system perforation(10, 12).

In an attempt to reduce the blood loss from the repetitive passage of progressively larger dilators, the one-step balloon dilatation was developed. The reduced blood loss is thought to be due to the constant pressure applied on the renal parenchyma during dilatation before the sheath is advanced(6). The novel tract dilatation method 'one-shot' was first introduced by Frattini et al. in this method, the tract is dilated by a single 30-F Amplatz dilator(7). There is evidence from previous reports that balloon dilatation is associated with less bleeding and lower blood transfusion rates than other dilators(10).

One-step balloon dilatation is achieved with short dilation and scope time in addition to minimizing X-ray exposure(4, 14). In addition, they are associated with a lower risk of forwarding perforation compared with using Amplatz and Alken dilators(14). The main disadvantages include cost impact, lower efficacy than Metal telescoping dilators and Sequential fascial dilators, especially in cases with perinephric adhesions due to previous surgery, and can disrupt dilated structures(6, 10, 14).

The hybrid described by us is applicable to both the bull's eye and the triangulation method. It describes the three most important things needed to achieve a successful percutaneous renal puncture: the site of skin entry, the angle of entry and the depth at which the puncture is achieved. It relies on simple tools. There could be some errors which could creep in, especially if the protractor is not held parallel to the operating table, but this could be overcome easily with minimal experience (and the assistant telling that the protractor is parallel to the table or not)(13).

2. Aim of the Study

To assess the differences between the Hybrid Single Dilatation and Sequential Dilatation during Percutaneous Nephrolithotomy regarding the effectiveness and complications.

3. Patients and Method

A comparative clinical trial study was conducted in the Department of Urology/Al-Yarmok Teaching Hospital/Iraq during the period from the 1st of January 2021 to the 1st of April 2022.

A convenient sample of 100 patients with renal stones who presented with renal stones larger than 20 mm, staghorn or partial staghorn and were scheduled to have PCNL was included in the current study. The patients were submitted into two groups that were matched in age, gender, and body mass index of the patients:

Group A: Included 60 patients who were managed with hybrid single dilatation.

Group B: Included 60 patients who were managed with sequential dilatation.

Exclusion criteria include previous renal surgery on the same side body mass index of >35 kg/m², uncorrected coagulopathies, and age of less than 18 years or older than 65 years.

A structured questionnaire was prepared to gather information and included the following variables:

Age and gender of the patients

The weight and height with consequent calculated body mass index.

The size, site, and burden of the stones.

The operative duration (calculated from the time of cystoscopy to securing the 30-F nephrostomy tube to the skin) and that of fluoroscopic exposure were recorded at the end of the procedure.

Haemodynamic changes and any need for transfusion were evaluated and recorded during the first 24 h after surgery.

Any perioperative complications were classified according to the modified

Clavien grading system as grade I, II, or III.

Any organ injury

The total hospital stay was evaluated for each

group.

The research proposal was discussed and approved by the Scientific Council of Urology of the Arabic Board of Medical Specializations. Fully informed consent was obtained from the patients verbally after explaining the aim of the study thoroughly and clearly with ensuring the confidentiality of information

The data was collected and analyzed using Microsoft Excel software, version 2016 and Statistical Package for the Social Sciences (SPSS), version 22. The descriptive analysis focused on frequencies and percentages, Chi-square test was used to calculate the significance of the difference in proportion between the study groups. The independent samples t-tests was utilized to determine the differences in the mean between the study groups. A P-value less than 0.05 was considered statistically significant

4. Results

A total of 120 patients were enrolled in the current study, there was no significant association between the study groups regarding age, gender, and body mass index (Table 3.1).

Table 3.1: Distribution of age, gender, and body mass index according to the study groups

| Age, gender, and body mass index | | Groups | | Total | P-value |
|----------------------------------|------------|---------------|---------------|-----------|---------|
| | | Group A N (%) | Group B N (%) | | |
| Age (years) | 18-30 | 10 (16.7) | 12 (20.0) | 22 (18.3) | 0.730 |
| | 31-40 | 19 (31.7) | 22 (36.7) | 41 (34.2) | |
| | 41-50 | 25 (41.7) | 19 (31.7) | 44 (36.7) | |
| | >50 | 6 (10.0) | 7 (11.7) | 13 (10.8) | |
| Gender | Male | 45 (75.0) | 44 (73.3) | 89 (74.2) | 0.835 |
| | Female | 15 (25.0) | 16 (26.7) | 31 (25.8) | |
| Body mass index | Normal | 39 (65.0) | 36 (60.0) | 75 (62.5) | 0.561 |
| | Overweight | 15 (25.0) | 14 (23.3) | 29 (24.2) | |
| | Obese | 6 (10.0) | 10 (16.7) | 16 (13.3) | |

Regarding the characteristics of the stone, there were no significant differences between the study

groups regarding the laterality, location, and burden, as shown in table 3.2.

Table 3.2: Characteristics of the stones

| Characteristics | | Groups | | Total | P-value |
|-----------------|------------------|---------------|---------------|-----------|---------|
| | | Group A N (%) | Group B N (%) | | |
| Laterality | Right | 44 (73.3) | 46 (76.7) | 90 (75.0) | 0.673 |
| | Left | 16 (26.7) | 14 (23.3) | 30 (25.0) | |
| Location | Calyceal | 16 (26.7) | 9 (15.0) | 25 (20.8) | 0.273 |
| | Pelvic | 16 (26.7) | 14 (24.3) | 30 (25.0) | |
| | Upper ureter | 17 (28.3) | 19 (31.7) | 36 (30.0) | |
| | Multiple | 11 (18.3) | 18 (30.0) | 29 (24.2) | |
| Stone burden | Staghorn | 45 (75.0) | 47 (78.3) | 92 (76.7) | 0.666 |
| | Partial staghorn | 15 (25.0) | 13 (21.7) | 28 (23.3) | |

Sequential dilatation was associated with a significantly longer duration of operation and x-ray exposure than hybrid single dilatation (P-

value=0.003 and 0.001, respectively), as shown in table 3.3.

Table 3.3: Characteristics of the procedures

| Characteristics | | Groups | | Total | P-value |
|-------------------------------|------------|-------------------|-------------------|------------|---------|
| | | Group A N (%) | Group B N (%) | | |
| Access | Successful | 57 (95.0) | 55 (91.7) | 112 (93.3) | 0.464 |
| | Failed | 3 (5.0) | 5 (8.3) | 8 (6.7) | |
| | | Mean (±SD) (N=57) | Mean (±SD) (N=55) | | |
| Operation time (minutes) | | 104 (±10.3) | 111 (±12.3) | | 0.003* |
| X-ray exposure time (minutes) | | 10.2 (±0.57) | 11.3 (±0.9) | | 0.001* |

There was no significant difference between the study groups regarding the results of the operation

(clearance of the stones), as shown in figure 3.1.

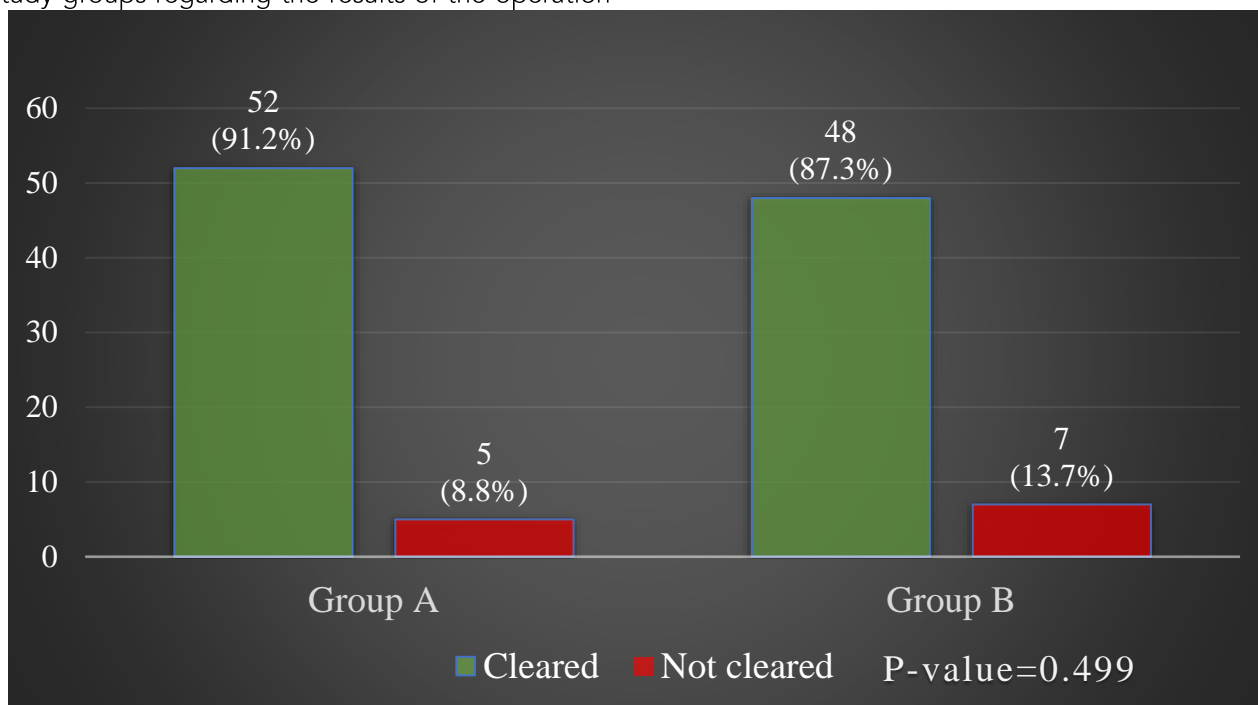


Figure 3.1: Clearance of the stones

Regarding the complications, the hybrid single dilatation was associated with a significantly lower mean of haemoglobin drop and hospital stay after the operation (Pvalue=0.001 for both). In addition, a

higher proportion of patients with Clavien grading scores II and III were recorded in sequential dilatation than in hybrid single dilatation procedures (Table 4).

Table 4: Complications of the operation

| Complications of the procedure | Groups | | Total | P-value |
|--------------------------------|-------------|-------------------|-------------------|---------|
| | Group A (%) | Group B N (%) | | |
| Clavien grading System | I | 46 (80.7) | 34 (61.8) | 0.036* |
| | II | 9 (15.8) | 12 (21.8) | |
| | III | 2 (3.5) | 9 (16.4) | |
| Organ injury | Yes | 0 (0.0) | 1 (1.8) | 0.491 |
| | No | 57 (100.0) | 54 (98.2) | |
| | | Mean (±SD) (N=57) | Mean (±SD) (N=55) | |
| Haemoglobin drop | | 0.34 (±0.1) | 0.98 (±0.2) | 0.001 |
| Hospital stay (days) | | 2.2 (±0.4) | 2.6 (±0.4) | 0.001 |

5. Discussion

Over the last three decades, PCNL has become a common and well-tolerated procedure. The tract creation and dilatation is the prime fundamental step of PCNL(4). This study was among other studies that tried to assess the effectiveness and safety of different options of PCNL.

In the current study, most participants were male with an age of 41-50 years, followed by patients aged 31-40 years. In comparison, the same results were obtained in another study that was done by Xiong et al. in China(11). This agreed with other studies that were done in China by Wang et al(8), and Turkey by Necmettin et al.(7).

Most of the patients in the current study had renal stones in the upper ureter of the right side. In comparison, the same results were obtained by another study that was done in Turkey by Necmettin et al.(7). In Egypt, a study was done there by Hani et al revealed that most of the renal

stones were in the right side(6). In contrast, in another study that was done in China by Xiong et al., most of the stones were on the left side of the renal pelvis(11).

No significant difference was obtained between the study groups regarding the successful access rate and clearance rate of the stone. This agreed with another study that was done in Turkey(7). In China, a study was done there that revealed that the successful access rate was not significantly different between the one-shot group and the sequential group(11). In India, loke et al. revealed the same results in their study that was done there.

An important finding of the current study was that the procedure in group B was significantly associated with shorter operation and time and shorter time of x-ray exposure. This agreed with another study that was done in China by Xiong et al.(11). In India, a study done there by Loke et al. revealed the same results.

Postoperatively, a higher proportion of patients with

stage III Clavien grading system was obtained in sequential dilatation compared to those in group A with hybrid single dilatation. The same results were obtained by another study that was done in China(8).

The current study revealed that the haemoglobin drop postoperatively was significantly lower in group A with hybrid single dilatation use compared to group B with sequential dilatation. In comparison, the same results were obtained by another study that was done in India by Alok et al.(4). This agreed with another study that was done in China by Wang et al.(8).

The final finding in the current study was that the duration of hospital stay after the operation was significantly lower among patients with hybrid single dilatation use compared to those with sequential dilatation. In comparison, the same results were obtained in another study that was done in India by Alok et al.(4).

In conclusion, the hybrid single dilatation was significantly associated with a shorter time of operation and a shorter time of x-ray exposure compared to sequential dilatation. In addition, it was significantly associated with fewer complications including haemoglobin drop, and postoperative hospital stay.

References

1. Shalini S, Arunachalam VK, Varatharajaperumal RK, Mehta P, Thambidurai S, Cherian M. The role of third-generation dual-source dual-energy computed tomography in characterizing the composition of renal stones with infrared spectroscopy as the reference standard. *Polish Journal of Radiology*. 2022;87(1):172-6.
2. Tyson M, Grimes N, McAuley L, Hennessy D, Pahuja A, Young M. Renal and Ureteric Stone Composition: A five year retrospective study for Northern Ireland. *Ulster Med J*. 2019;88(1):21-4.
3. Senel S, Ozden C, Aslan Y, Kizilkan Y, Gokkaya CS, Aktas BK. Can the Stone Scoring Systems Be Used to Predict Infective Complications of Retrograde Intrarenal Surgery? *Medical Principles and Practice*. 2022;31(3):231-7.
4. Srivastava A, Singh S, Dhayal IR, Rai P. A prospective randomized study comparing the four tract dilation methods of percutaneous nephrolithotomy. *World journal of urology*. 2017;35(5):803-7.
5. Ganpule AP, Vijayakumar M, Malpani A, Desai MR. Percutaneous nephrolithotomy (PCNL) a critical review. *International Journal of Surgery*. 2016;36:660-4.
6. Nour HH, Kamal AM, Zayed AS, Refaat H, Badawy MH, El-Leithy TR. Single-step renal dilatation in percutaneous nephrolithotomy: A prospective randomised study. *Arab journal of urology*. 2014;12(3):219-22.
7. Penbegul N, Dede O, Daggulli M, Hatipoglu NK, Bozkurt Y. A novel percutaneous nephrolithotomy (PCNL) set: The 'Economical One-shot PCNL Set'(Ecoset). *Arab journal of urology*. 2017;15(3):199-203.
8. Wang S, Zhang Y, Zhang X, Tang Y, Xiao B, Hu W, et al. Tract dilation monitored by ultrasound in percutaneous nephrolithotomy: feasible and safe. *World journal of urology*. 2020;38(6):1569-76.
9. Birowo P, Raharja PAR, Putra HWK, Rustandi R, Atmoko W, Rasyid N. X-ray-free Ultrasound-guided Percutaneous Nephrolithotomy in Supine Position Using Alken Metal Telescoping Dilators in a Large Kidney Stone: A Case Report. *Res Rep Urol*. 2020;12:287-93.
10. Elshazly M, Salem S, Allam A, Hathout B. Balloon dilator versus telescopic metal dilators for tract dilatation during percutaneous nephrolithotomy for staghorn stones and calyceal stones. *Arab Journal of Urology*. 2015;10.
11. Xiong J, Shi Y, Zhang X, Xing Y, Li W. Chinese one-shot dilation versus sequential fascial dilation for percutaneous nephrolithotomy: A feasibility study and comparison. *Urology Journal*. 2019;16(1):21-6.
12. Falahatkar S, Neiroomand H, Akbarpour M, Emadi SA, Khaki N. One-shot versus metal telescopic dilation technique for tract creation in percutaneous nephrolithotomy: Comparison of safety and efficacy. *Journal of endourology*. 2009;23(4):615-8.
13. Sharma GR, Maheshwari PN, Sharma AG, Maheshwari RP, Heda RS, Maheshwari SP. Fluoroscopy guided percutaneous renal access in prone position. *World Journal of Clinical Cases: WJCC*. 2015;3(3):245.
14. Ozok HU, Sagnak L, Senturk AB, Karakoyunlu N, Topaloglu H, Ersoy H. A comparison of metal telescopic dilators and Amplatz dilators for nephrostomy tract dilation in percutaneous nephrolithotomy. *Journal of endourology*. 2012;26(6):630-4.