Original Article

A Retrospective Comparison of the Balloon Dilator and the Telescopic Metal Dilator for Tract Dilatation during Percutaneous Nephrolithotomy

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Background: Percutaneous nephrolithotomy (PCNL) is the procedure of choice for the management of large renal calculi. Nephrostomy tract dilatation is an essential step in PCNL. However, the types of dilatations used depend on the surgeon's preference.

Objective: To compare the effectiveness and safety of the balloon dilator (BD) against the telescopic metal dilator.

Materials and Methods: The present study involved 238 patients that underwent PCNL between January 2011 and February 2020. They were divided into two groups based on the adopted tract dilatation technique. The balloon dilatation group included 69 cases, and the telescopic metal dilator group included 169 cases. They were analyzed in terms of demographics and perioperative outcomes.

Results: The two PCNL groups were similar in age, stone burden, and stone density. There was no statistically significant differences in the stone-free status at 59.4% versus 56.8% (p=0.711), tract dilatation failure rates at 1.5% versus 0.6% (p=0.511), estimated blood loss at 200 mL versus 200 mL (p=0.311), blood transfusion rates at 11.6% versus 8.9% (p=0.520), and total operation time at 120 minutes versus 120 minutes (p=0.573) for the balloon dilatation group and the telescopic metal dilator group, respectively. The duration of the nephrostomy placement in the balloon dilatation group was significant longer than the telescopic metal dilator group at 3 days versus 4 days (p=0.005).

Conclusion: Both BD and telescopic metal dilator possess equivalent effectiveness and safety for PCNL.

Keywords: Percutaneous nephrolithotomy; Renal calculus; Balloon dilator; Telescopic metal dilator

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Kidney stone disease is caused by a concretion of minerals and organic matter that forms in the kidneys, and its worldwide prevalence, incidence, and recurrence rates have been increasing over the last few decades[1]. Because Thailand is in the tropical zone, high temperatures lead to dehydration. This is one of the environmental factors that contribute to the occurrence of urinary calculi in this area[2].

Before mid-1950s, open anatrophic nephrolithotomy and open pyelolithotomy were the standard treatments for patients with large kidney stones. However, because these procedures were accompanied by a decrease in renal function and large surgical wounds, the management of large renal calculi was changed to percutaneous nephrolithotomy (PCNL)[3]. One of the most important steps during PCNL is the dilatation of the nephrostomy tract. The instruments typically used are the balloon dilator (BD) and the telescopic metal dilator (TMD). However, the efficiency and safety of both types of equipment are unclear. The purpose of the present study was to evaluate the use of BD and TMD in terms of overall operative outcomes and complications.

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Materials and Methods

The present study protocol was approved by the Institutional Review Board of the Faculty of Medicine at Ramathibodi Hospital (COA MURA2020/1850). The present study was a retrospective analysis of 276 patients that underwent PCNL procedures conducted by highly experienced endourologists

between January 2011 and February 2020. Of these 276 patients, 238 patients met the inclusion criteria, were recruited into the study, and separated into two subgroups as BD with 69 cases and TMD with 169 cases. The inclusion criterion was that the patient had undergone a PCNL procedure performed using either BD or TMD. Patients excluded were those with uncorrected coagulopathies, active urinary infections, and pediatric patients below 18 years of age. Perioperative data, including the patient's medical history, physical examination, complete blood cell count, serum creatinine levels, coagulation profile, urinalysis, and urinary culture, were collected. For radiologic imaging, kidney, ureter, and bladder (KUB) plain film radiography and non-contrast computerized tomography (CT) scans were conducted. Two urology residents evaluated the CT scans, with one assessment per patient. Stone size was determined in the coronal axis using Picture Archiving and Communications System (PACS) imaging program. Skin-to-stone distance was described as the average vertical length from the midpoint of the stone to the skin at 0°, 45°, and 90°. Success rates were described as the patients having no residual stone or with clinically insignificant residual fragments less than 4 mm. An anesthesiologist estimated blood loss by the postoperative decrease in hematocrit, measured 24 hours before and 48 hours after the procedure, factored by the blood transfusion level. Blood transfusion was considered if indicated in patients experiencing hypovolemic shock due to blood loss with blood pressure below 90/60 mmHg or heart rate greater than 100 beats/minute, which significantly impaired the endoscopic view intraoperatively, or if severe hemorrhage occurred in the nephrostomy tube and a 1 g/dL decrease in Hb levels. All complications were recorded and classified according to the modified Clavien grading system.

Operative technique

All patients were placed under general anesthesia, and a 6F open-ended ureteral catheter was placed transurethrally. In the prone position, percutaneous renal access was achieved under fluoroscopic control using an 18-gauge needle passed into the desired calix. A 0.035-inch Sensor guidewire (Boston Scientific) was introduced into the renal pelvis. Before the needle was removed, a scalpel blade was used to incise the skin at the puncture site, and deep fascia was extracted using an arterial clamp. Dilatation of the percutaneous tract was accomplished using a BD (Nephromax, Boston Scientific, USA) or a TMD (Karl Storz, GmbH, Tuttlingen, Germany). The choice of dilatation technique was determined by the availability of surgical expertise. For the balloon dilatation technique, after the guidewire reached the pelvicalyceal system, the balloon was introduced over the guidewire and expanded using an inflator (LeVeen inflator, Boston Scientific). The pressure was increased to 18 atmospheric pressures. The metal telescopic dilator system consisted of eight stainless steel tubes with sizes ranging from 9 F to a maximum of 30 F and overlapping at 3 F intervals. After accomplishing dilatation using either technique, a 30 F working sheath was inserted into the pelvicalyceal system. A rigid nephroscope (Karl Storz, Munich, Germany) was then inserted under direct vision, and the kidney calculi were disintegrated and extracted. After complete clearance was confirmed using a fluoroscope and flexible endoscope, a 22 F silicone nephrostomy tube was placed for drainage. Nephrostomy tube was routinely withdrawn on the third postoperative day in the uncomplicated procedure.

Statistical analysis

Stata, version 14.1 (StataCorp LP, College Station, TX, USA) was used for analyses of the study results. Categorical factors were evaluated using Fisher's exact test, and the data generated were illustrated as numbers and percentages. Continuous factors were compared using a Wilcoxon rank-sum (Mann-Whitney) test, with the generated data illustrated as medians with interquartile ranges (IQRs). A p-value of less than 0.05 was accepted as statistically significant.

Results

Patient characteristics and clinical data that affected PCNL outcomes, such as age, stone size, stone density, and a history of open renal surgery, were comparable between the two groups (Table 1). Median ages in the BD group and TMD group were 60 years (IQR 52 to 69 years) and 60 years (IQR 51 to 65 years), respectively. The median stone size was 445 mm^2 (IQR 260 to 726 mm^2). Median stone density was 951 HU (IQR 636 to 1,270 HU). A history of open renal surgery was present in 4.3% (3 of 69) of the patients in the BD group, compared to 3.6% (6 of 169) of patients in the TMD group.

Table 2 presents a comparison of the post-operative outcomes. The overall stone-free rate was 57.6%, and there was no significant difference in the stone-free rates and rates of failure of tract

Table 1. Patient demographics for the two study groups

Variables	Balloon dilator (n=69); n (%)	Telescopic metal dilator (n=169); n (%)	Overall (n=238); n (%)	p-value
Age (years); median (IQR)	60 (52 to 69)	60 (51 to 65)	60 (52 to 67)	0.424
Sex				
Male	31 (44.9)	76 (45.0)	107 (45.0)	0.995
Female	38 (55.1)	93 (55.0)	131 (55.0)	
Body mass index (kg/m^2); median (IQR)	25.97 (21.93 to 28.89)	25.1 (23.05 to 28.13)	25.21 (22.81 to 28.25)	0.834
PCNL side				
Right	30 (43.5)	73 (43.2)	103 (43.3)	0.968
Left	39 (56.5)	96 (56.8)	135 (56.7)	
History of ipsilateral open stone surgery	3 (4.3)	6 (3.6)	9 (3.8)	0.770
Hypertension	41 (59.4)	87 (51.5)	128 (53.8)	0.265
Diabetes mellitus	23 (33.3)	40 (23.7)	63 (26.5)	0.125
Preoperative Hb (mg/dL); median (IQR)	13.3 (12.4 to 14.5)	13 (11.8 to 14.5)	13 (11.9 to 14.5)	0.314
Postoperative Hb (mg/dL); median (IQR)	12.4 (11 to 14)	11.9 (10.6 to 13.6)	12 (10.7 to 13.6)	0.376
ASA				
ASA 1	66 (95.7)	157 (92.9)	223 (93.7)	0.584
ASA 2	3 (4.4)	10 (5.9)	13 (5.5)	
ASA 3	0 (0.0)	2 (1.2)	2 (0.8)	
Stone burden (mm^2); median (IQR)	490 (329 to 820)	417 (225 to 690)	445 (260 to 726)	0.091
Stone density (Hounsfield unit); median (IQR)	990 (610 to 1,260)	909 (650 to 1,275)	951 (636 to 1,270)	0.662
Skin-to-stone distance (mm); median (IQR)	86 (70 to 102)	85 (71 to 95)	85 (70 to 98)	0.665

ASA=American Society of Anesthesiologists; eGFR=estimated glomerular filtration rate; Hb=hemoglobin, IQR=interquartile range; PCNL=percutaneous nephrolithotomy

Table 2. Postoperative outcomes and complications

Variables	Balloon dilator (n=69); n (%)	Telescopic metal dilator (n=169); n (%)	Overall (n=238); n (%)	p-value
Stone-free status	41 (59.4)	96 (56.8)	137 (57.6)	0.711
Operation time (minute); median (IQR)	120 (90 to 150)	120 (80 to 150)	120 (90 to 150)	0.573
Estimated blood loss (mL); median (IQR)	200 (100 to 400)	200 (50 to 400)	200 (100 to 400)	0.311
Blood transfusion rate	8 (11.6)	15 (8.9)	23 (9.7)	0.520
Hb drop (mg/dL); median (IQR)	0.8 (0.5 to 1.5)	0.8 (0.5 to 1.4)	0.8 (0.5 to 1.4)	0.578
Percent change in eGFR; median (IQR)	6.98 (2.22 to 13.79)	4.17 (2.22 to 12.16)	4.5 (2.22 to 12.5)	0.130
Duration of nephrostomy (days); median (IQR)	3 (2 to 4)	4 (3 to 5)	3.5 (3 to 5)	0.005*
Hospital stays (days); median (IQR)	7 (5 to 8)	6 (5 to 8)	6 (5 to 8)	0.309
Dilatation tract failure	1 (1.5)	1 (0.6)	2 (0.8)	0.511
Total complication rate				
Clavien 1	15 (21.7)	31 (18.3)	46 (19.3)	0.547
Clavien 2	9 (13)	15 (8.9)	24 (10)	0.333
Clavien 3	1 (1.5)	4 (2.4)	5 (2.1)	0.654
Clavien 4	0	4 (2.4)	4 (1.7)	0.197

eGFR=estimated glomerular filtration rate; Hb=hemoglobin; IQR=interquartile range

* Statistically significant

dilatation between the groups. There was similarity in the estimated blood loss and blood transfusion rate for both groups. A necessitated pack red cell (PRC) transfusion was received by eight patients in the BD group and 15 patients in the TMD group. Perioperative complications were observed in 79 (33.2%) patients and categorized according to the modified Using the Clavien grading system, 46 patients (19.3%) had grade 1 complications, with grade 2, grade 3, and grade 4 complications in 24 (10%), five (2.1%), and four patients (1.7%), respectively. No significant differences were detected between

the two dilatation methods in terms of complication rate, and no reported iatrogenic or accidental injuries to any perirenal organs. The present study results showed no statistically significant differences with respect to operation time and the duration of hospital stay. The median duration of the nephrostomy placement was longer for the BD group compared with the TMD group at 3 days versus 4 days (p=0.005).

Discussion

PCNL is the first-line treatment option for large, multiple, and staghorn calculi. The primary goal of this management technique is to ensure maximum stone clearance with minimal morbidity. The size and hardness of the stones are significant factors affecting the success of the procedure[4]. Bleeding is the most common and most significant complication in PCNL, with the reported incidences of hemorrhage requiring blood transfusion being 0.7% to 55%, depending on the literature reviewed[5-7]. The percutaneous access and dilatation procedure is associated with kidney bleeding occurring during PCNL[8]. Presently, there are different dilatation pieces of equipment such as BD, TMD, Amplatz, and one-shot dilators, and equipment selection depends on the surgeon's experience. The difference in the mechanical process between BD and other dilatation methods is that all the other methods apply longitudinal shearing forces during their advancement, while balloon dilatation does not[9].

Various factors influence adverse PCNL outcomes[10,11]. Kukreja et al[12] demonstrated that during percutaneous access, differences in the location of the calyx puncture and the number of attempts before a successful puncture had no impact on bleeding complications. In contrast, the tract dilatation method was associated with blood loss (p<0.0001). Furthermore, a subgroup analysis of the present study to investigate three types of dilators, including Amplatz, TMD, and BD, found that there was a lower bleeding rate with Amplatz dilators when compared with TMDs and BDs. However, other studies reported that BD had advantages over Amplatz. Davidoff and Bellman[13] demonstrated that using a BD led to less renal hemorrhage and lower transfusion rates than using Amplatz dilatation. Likewise, Safak et al[14] demonstrated that the balloon dilatation method achieved less blood loss than Amplatz fascial dilators (13.7% vs. 16.6%). Nonetheless, in the literature, there were studies reporting that BD did not show any significant advantages over TMD. For example, Stoller et al[15] could not find any significant difference between telescopic metal dilatation and balloon dilatation in terms of blood loss (p=0.197). Similarly, in the present study, the authors demonstrated that necessitated PRC transfusions, which were 8.9% for the TMD group and 11.6% for the BD group, showed no statistical difference (p=0.520).

Unsuccessful percutaneous tract dilatation can be caused by guidewire slippage or kinking during dilatation, a hypermobile kidney, or the presence of extreme retroperitoneal scarring from a previous surgery[16,17]. Open renal stone surgery leads to fibrosis covering the kidney postoperatively, which may adversely affect the introduction of an access needle and prevent proper dilatation of the tract. Joel et al[18] reported a high dilatation failure rate using BD, which was 17% of the total PCNL cases. Safak et al[14] reported four cases among 95 patients using the balloon dilatation method failed to form a tract due to difficulties introducing the balloon over the guidewire because of excess fibrotic scar tissue. However, dilatation was then achieved by switching to fascial Amplatz dilators in three cases and to a metal coaxial dilator in one case. In a TMD study, Osman et al[19] reported their experience with over 300 patients who underwent PCNL with a TMD, with a failure dilatation rate of lower than 3.5%. In the present study, these were two cases of access failure. Severe dense adhesion following a previous open anatrophic nephrolithotomy was present in one of the patients with access failure using a TMD, and percutaneous access was successfully achieved using 550-micron fiber with a holmium laser to incise the scar via a nephroscope. For the other patients, there was access failure using a BD, but success was achieved by switching to a TMD. Postoperative insertion of a percutaneous nephrostomy drainage tube was conducted under the belief that it decreases bleeding along the tract, prevented urinary extravasation, and preserved competence of kidney drainage[20]. Retainment of the drainage tube for 48 hours after PCNL is still a common practice in various centers, even in non-complicated procedures that did not have residual stones[21]. However, the present study utilized a longer nephrostomy drainage tube placement with a median of 3.5 days.

The present study has some limitations. First, the study utilized a retrospective design, so radiation exposure and duration of dilatation were not evaluated. Second, the stone free rate was low in the present study due to the limited number of cases. Third, the selection of BD or TMD depended on the physician's preference, and thus, there may be a

selection bias. Finally, data collection from multiple surgeons may have affected the reliability and validity of the present study. Therefore, further large, randomized, and controlled studies are required to draw firm conclusions.

Conclusion

BD and TMD are efficient instruments of tract dilatation with low failure rates. Both techniques possess equivalent levels of safety in terms of comparisons of estimated blood loss, blood transfusion rates, and complications. The authors recommend the use of both pieces of dilatation equipment to patients undergoing PCNL.

What is already known on this topic?

Establishment of nephrostomy tract is the essential step during PCNL. The equipment commonly used are BD and TMD. Nonetheless, effectiveness and safety of both instruments are not clear.

What this study adds

The authors proved that BD and TMD are equivalent levels of effectiveness and safety in term of low failure rates and lack of complications.

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Conflicts of interest

There are no conflicts of interest.

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