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Surgical Technique

Comparative Analysis of Balloon Tract Dilator and Metal Telescopic Dilators for Percutaneous Nephrolithotomy in Thai Patient Population

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Abstract

Background: Balloon dilators for percutaneous nephrolithotomy (PCNL) have been adopted in various countries worldwide. However, its utilization remains limited in Thailand due to the equipment cost and the country's higher morbidity and complexity of renal stones. We performed a comparative study between the outcomes of balloon dilators (BD) and the commonly used metal telescopic dilators (MTDs) in Thai patients who underwent PCNL.

Methods: We conducted a retrospective review of 199 patients who underwent PCNL between Jan 2011 and July 2022. We excluded patients with risk for bleeding and active infection from our study. 144 patients were recruited in our study: 74 patients in the MTD group and 70 patients in the BD group. The success rate and complication of both methods of dilation were compared. Continuous demographic data was compared with an independent t-test. A generalized linear model was applied to assess the multivariable analysis's mean differences and risk differences.

Results: Demographic data of patients in both groups were not significantly different in size of stone, age, and history of kidney surgery. The success rate of dilatation was 95.5% and 98.6% for MTD and BD, respectively (p = 0.331). Renal pelvic injury was 8.1% for MTD and 10% for BD (p = 0.692). Stone clearance rates were 100% and 82.48% for MTD and BD, respectively (p = 0.098). LOS of both groups was not significantly different by multivariate analysis.

Conclusion: Both dilatation methods demonstrated comparable success rates, blood loss, and hospital stays in PCNL for renal stones. In the Thai population with a high prevalence of large renal stones, BD remains an effective option in most situations.

Keywords: Balloon dilator, Alken metal dilators, Percutaneous nephrolithotomy

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Introduction

Since 1976, PCNL has been established as the contemporary standard treatment for kidney stones larger than 2 cm in various types of patients, with multiple adaptations from the original methods to improve stone-free rates and reduce morbidities.[1-4] While some steps in PCNL may be omitted in specific conditions, tract dilation remains a crucial initial step to create a tract in the kidney parenchyma for the nephroscope and various types of stone breakers.

There are various techniques in tract dilation techniques for PCNL available in Thailand: Amplatz fascial dilators (AD), metal telescopic dilators (MTD), and balloon dilators (BD). The better method for tract dilation during PCNL is also controversial in the Thai population. In previous studies, Balloon dilator is considered the most effective and safe.[5] Due to the single-step technique, it decreased the tract dilation fluoroscopy time.[6] The mechanism of tract creation is by radial force against renal parenchyma after needle assessment and insertion of a guidewire. MTD utilizes both axial and radial force in multi-steps for tract dilation but is durable. Amplatz dilation is also multi-step in dilation but also practical and safe in patients who have previously had and did not have renal stone surgery.

In Thailand, the high prevalence and morbidity of kidney stones have prompted considerations on the choice of dilators.[7-8] Balloon and metal telescoping dilation are standard techniques developed over 30 years ago, but balloon dilation is still not widely popular in Asia.[9] Previous research indicates that BD may be associated with lower blood loss in patients without prior open renal surgery but demonstrates a lower success rate of dilation compared to MTDs in a limited study.[10-11]

This study aimed to compare the results of the use of BD and MTDs, as both devices have been extensively studied with mixed advantages and disadvantages. However, there is no definitive conclusion, and no studies have been conducted on kidney stone patients who underwent PCNL in the lower northern region of Thailand.

Patients and Methods

A total of 194 eligible patients who underwent PCNL at Naresuan University Hospital between January 2011 and July 2022 were included in this study. Without randomization, MTD was used for PCNL in the beginning period from January 2011 to December 2019, and then we used BD from January 2020 to July 2022 by two surgeons in our institute. The inclusion criteria comprised patients aged 15-80 who had undergone PCNL for kidney stones at the hospital during the specified period. Patients with a high risk of bleeding (e.g., cirrhosis, need for hemodialysis, or taking antiplatelet/anticoagulant drugs) were excluded, along with immunocompromised patients or those with active kidney infections that could lead to prolonged hospital stays. Patients with insufficient data due to medical record loss or loss of follow-up were also excluded. Out of the initial pool of samples, 144 patients were recruited and divided into two groups based on their tract dilation method. Group A (74 cases) underwent PCNL with MTD, while Group B (70 cases) received BD (as shown in Figure 1).

Clinical information assessment included age, sex, body mass index, presentation symptoms, previous kidney surgery history, and co-morbidities such as diabetes, chronic kidney disease, and hypertension. Laboratory data, including complete blood count, creatinine, estimated GFR rate, and urine culture, were also collected for all patients. A plain KUB film and CT KUB were done on all patients.

PCNL was performed step-by-step, starting with inserting a ureteric catheter into the renal pelvis and then placing the patient in a prone position. Renal stones were accessed with an 18 G needle under fluoroscopy guidance, and tract dilation was performed over a 0.035-inch stiff guidewire.

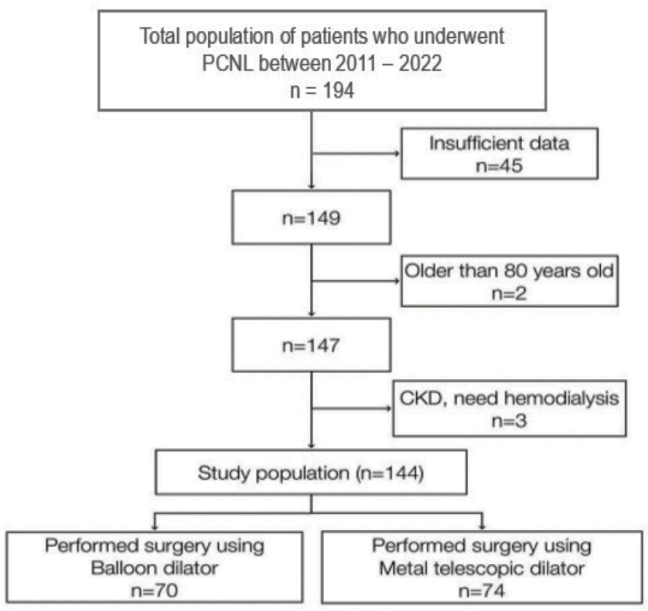

Figure 1 Population assignment description

Both brand new and re-sterilized balloon dilators (NephromaxTM, 30 Fr 12 cm) were used in the BD group, with inflation up to 10-12 ATM. Re-sterilized balloon dilators were used in 90% of patients. In the MTD group, dilation was performed from 9 to 30 Fr, followed by inserting a 30 Fr. working sheath. Stones were eliminated using pneumatic and ultrasonic lithotripters. A rigid nephroscope survey and fluoroscopic confirmation were conducted to assess stone clearance, and a nephrostomy tube was temporarily clamped in all cases.

The success rate of dilation, operative time, incidence of renal pelvis injury, postoperative ureteric stent need, blood transfusion, incidence of postoperative febrile UTI, postoperative hospital stays, and estimated blood loss were compared between the two groups. Stone clearance was calculated based on the average postoperative decrease in the maximum diameter of the renal stone from the KUB film at 1 month after PCNL. Failure of dilation is defined as the failure to insert an amplatz working sheath into the renal parenchyma or renal calyx.

Statistical analysis

Data were analyzed using Stata (version 18.0). Mean and standard deviation represented continuous variables, while frequency or percentage was used for categorical variables. Continuous variables were compared using an independent t-test, and a generalized linear model was employed to assess the mean difference and risk difference in the multivariable analysis.

Results

This study enrolled a total of 144 cases, with 74 cases in the MTD group and 70 cases in the BD group. Demographic data are presented in Table 1. Considering the gender observed between the two cohorts, the BD group showed a higher proportion of male patients than the MTD group. However, the gender distribution within the MTD group was contradictory. However, the p-value between the groups was 0.063, which is an insignificant difference. There are two significant differences in demographic data: chronic kidney disease and pre-operative imaging (CT /other imaging).

Table 1 Demographic data

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Mean age (years)	56.14	56.68	0.401
Sex (%)			0.063
Male	34 (45.9)	43 (61.4)	
Female	40 (54.1)	27 (38.6)	
BMI (kg/m²) (%)			0.67
< 30	55 (95.9)	61 (88.4)	
≥ 30	9 (14.1)	8 (11.6)	
Diabetic Mellitus (%)	20 (27.0)	15 (21.7)	0.426
Gout (%)	7 (9.5)	7 (10.0)	0.913
Chronic kidney disease (%)	6 (8.1)	16 (22.9)	0.014
Hypertension (%)	40 (54.1)	33 (47.1)	0.407
Imaging pre-op (CT/other) (%)	21 (28.4)	53 (75.7)	< 0.001
Flank pain (%)	34 (45.9)	23 (32.9)	0.108
Hematuria (%)	16 (21.6)	12 (17.1)	0.497

Clinical data of the population are shown in Table 2. The average stone size was 2.89 cm in the MTD group and 2.95 cm in the BD group. No significant differences between the two groups were observed in skin-to-stone distance, preoperative Hb, HCT, and BUN. However, the BD group had a higher proportion of complex stones, such as staghorn calculi and multiple stones, as well as higher levels of creatinine (1.11 mg/dL vs. 0.99 mg/dL, $p = 0.013$) and lower pre-operative eGFR compared to the MTD group (70.38 ml/min/1.73 m^2 vs. 81.51 ml/min/1.73 m^2, $p = 0.003$).

Table 2 Clinical data of the population

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Stone size (cm.)	2.895 (1.82 - 4.03)	2.95 (2.1 - 4.31)	0.37
Skin-to-stone distance (cm.)	7.36 ± 2.035	6.90 ± 1.952	0.388
No. of stone (%)			0.035
1	41 (56.2)	27 (38.6)	
> 1	32 (43.8)	43 (61.4)	
Staghorn calculi (%)	28 (37.8)	39 (55.7)	0.032
Previous kidney surgery (%)	21 (28.4)	10 (14.3)	0.04
Hb pre-op (g/dL) mean ± SD	13.11 ± 1.68	13.31 ± 2.03	0.520
HCT pre-op (%) mean ± SD	39.245 ± 4.6	40.235 ± 5.8	0.261
BUN pre-op (mg/dL) median	13.5 (11.9 - 16.5)	14.4 (10.8 - 17.68)	0.816
Creatinine pre-op (mg/dL)	0.99 ± 0.285	1.11 (0.89 - 1.4)	0.013
eGFR pre-op (ml/min/1.73 m^2)	81.51 ± 21.43	70.38 ± 22.84	0.003

The incidence of renal pelvis injury and the need for a stent placement are not significantly different between the MTD and BD groups based on the data from Table 3. However, the MTD group had a slightly shorter operative time than the BD group; the BD group experienced less estimated blood loss during surgery. However, this study found no statistically significant differences in the incidence of renal pelvis injury, the need for a DJ stent during surgery, the amount of blood loss during surgery, and the time required between the two patient groups.

Table 3 Intraoperative data

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Renal pelvis injury (%)	6 (8.1)	7 (10)	0.692
Estimated blood loss (ml)	181.00 (50 - 300)	173.79 (30 - 262.50)	0.624
Stent needed (%)	19 (25.7)	18 (25.7)	0.996
Operative time (min)	50 (35 - 85)	55 (34 - 85)	0.834

Even though more patients in the MTD group had previous kidney surgery than in the BD group (28.4% vs. 14.3% respectively, $p = 0.04$), in postoperative data analysis, the success rates of dilation of the two groups were comparable, and the stone clearance rates did not differ significantly (Table 4). The postoperative fever rate, blood transfusion rate, and laboratory data, including Hb, Hct, and positive urine culture, did not show statistically significant variations. However, postoperative hospital stay was significantly shorter in the BD group compared to the MTD group (4.19 ± 2.14 days and 5.01 ± 2.36 days, respectively; $p = 0.029$) (Table 4).

Table 4 Postoperative outcomes

	MTD Group (n = 74)	BD Group (n = 70)	*P*-value
Success of dilation (%)	71 (95.5)	69 (98.6)	0.331
Stone clearance rate: mean ± SD	83.149 ± 2.57	74.432 ± 28.96	0.045
Postoperative febrile UTI (%)	9 (12.2)	15 (22.1)	0.116
Blood transfusion (%)	7 (9.5)	9 (12.9)	0.517
Post-op. hospital stays (days): mean ± SD	5.01 ± 2.36	4.19 ± 2.14	0.029
12 hr. Hb post-op (g/dL): mean ± SD	11.55 ± 2.03	11.83 ± 1.91	0.384
12 hr. HCT post-op (%): mean ± SD	35.03 ± 4.75	35.88 ± 5.37	0.328
Urine culture positive (%)	3 (33.3)	6 (66.7)	0.263
Mean different Hb (%)	1.88 ± 2.65	1.96 ± 3.52	0.439

In assessing stone clearance, we classified it into two categories: "stone-free," representing cases with 100% clearance, and "residual stone," representing any remaining stone after the procedure. The BD group had 41.4% of patients classified as stone-free, while the MTD group had 51.4% of stone-free cases, but there was no statistically significant difference between the two groups (p-value = 0.247) (Table 5).

Table 5 Stone clearance rate determined by the number of patients with residual stones or classified as stone-free, compared to the MTD and BD groups

	MTD Group A (n = 74)	BD Group (n = 70)	Total	*P*-value
Stone-free (%)	38 (51.4)	29 (41.4)	67	0.247
Residual stone (%)	36 (48.6)	41 (58.6)	77	0.247
Total	**74**	**70**	**144**	

Figure 2 illustrates the number of patients and length of hospital stay in both groups. The Crude analysis of generalized linear model for mean difference revealed that the BD group had a significantly shorter hospital stay by 0.827 days than the MTD group (p-value = 0.028). However, after accounting for other factors affecting the duration of hospital stay, such as the period of surgery, history of previous kidney surgery, and chronic kidney disease, the multivariable analysis showed that the post-operative hospital stays for patients using BD was only 0.374 days less than the MTD group. This difference is statistically insignificant (adjusted mean difference = -0.374, p = 0.512) (Table 6 and Figure 2).

Figure 3 illustrates the number of patients and their stone clearance outcomes. Additional analysis of the stone clearance rate, using a generalized linear model for risk difference with the result of stone clearance (yes or no revealed a 9.9% lower chance of stone clearance in the BD group compared to the MTD group. However, when other factors that may affect the stone clearance rate, such as stone size, history of previous kidney surgery, type of kidney stone, and number of stones, were considered, multivariable analysis showed that the BD group had a 3.9% lesser chance of stone clearance than those who used the MTD method (95% CI - 0.20 to 0.12, p = 0.627) (Table 6).

Table 6 Results of the multivariable analysis of postoperative hospital stay and stone clearance rate

Outcomes	Crude difference (BD – MTD)	95% (CI)	*P*-value	Effect size (adjusted difference)	95% (CI)	*P*-value
Post-operative hospital stays (Mean difference)	-0.827	- 1.564 - 0.091	0.028	- 0.374	- 1.490 - 0.745	0.512
Stone clearance rate (Risk difference)	-0.099	- 0.262 - 0.064	0.234	- 0.039	- 0.200 - 0.120	0.627

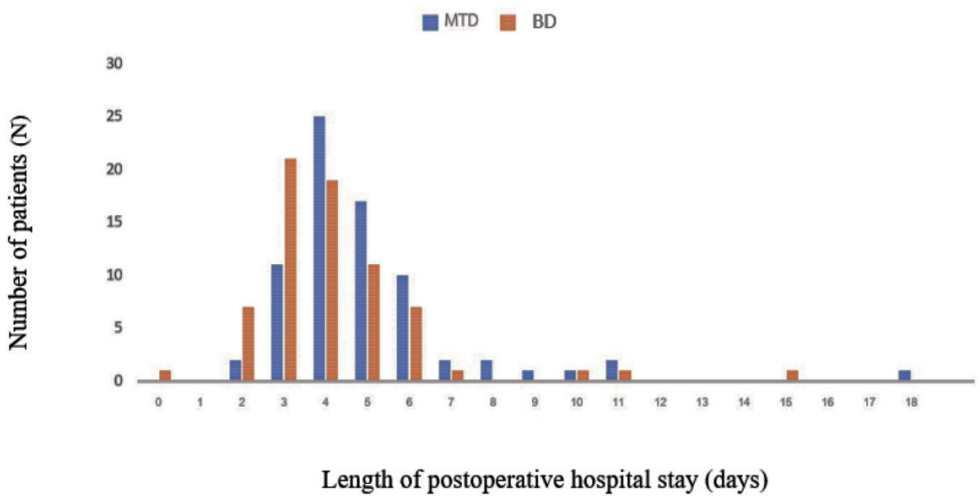

Figure 2 Number of patients and length of hospital stay in both groups

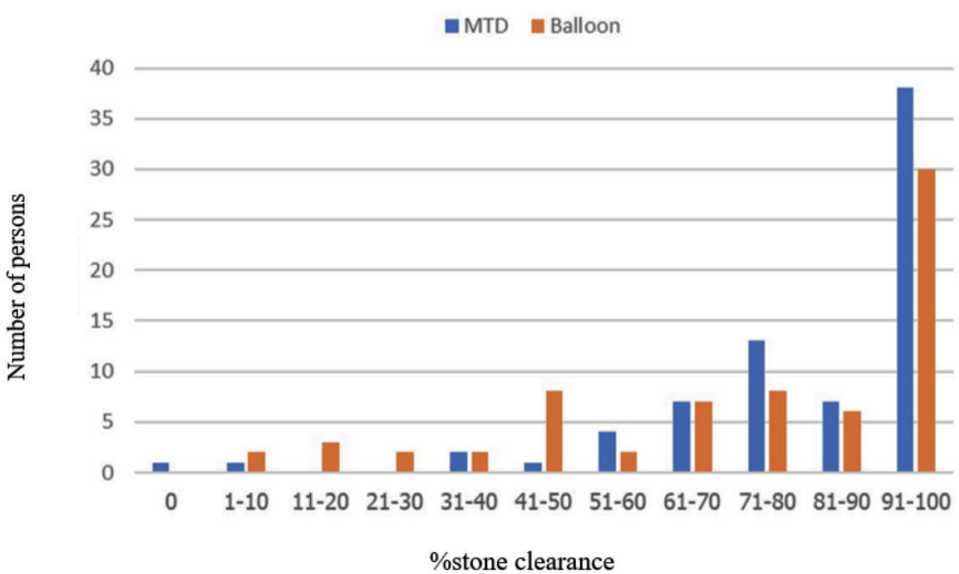

Figure 3 Number of patients and stone clearance rate in both groups

Discussion

The data from the two study groups showed remarkable similarity, with the difference being pre-operative imaging and underlying chronic kidney disease. Recently, non-contrast CT KUB was used as a standard study before PCNL. Therefore, the BD group had a higher rate of CT than the MTD group. However, we found that this factor had no significant association with the operative outcome in PCNL.

In the BD group, patients had slightly higher stone burden and lower estimated GFR in their clinical profiles. However, there were no differences in intraoperative results such as operative time, blood loss, and renal pelvic injury. The significant outcomes in this study were related to post-operative results in univariable analysis, specifically stone clearance and length of hospital stay. Still, the multivariable analysis showed no significant differences between the two groups.

BD involves a single-step dilation with radial force acting on kidney parenchyma, while MTD utilizes axial and radial force in multi-step for tract dilation. Both techniques aim to expand the parenchymal tract in the kidney and soft tissue up to 30 Fr. in standard PCNL. Different mechanisms of dilation may affect the result of PCNL.

Previously, MTD had the advantage of being durable and reusable, with a higher success rate in patients who had undergone previous kidney surgery.[12] However, it also carried the risk of forward perforation, necessitating the surgeon's awareness and frequent fluoroscopic checks during MTD dilation.

Eventually, there is no difference in the success rate of dilation in our study. However, according to the significant patients who had previous kidney surgery and increasing popularity of BD, we recommend preparing MTD spare for patients with prior surgery.

The use of balloon dilators was claimed to expedite the dilation process, but no significant difference in operative time was observed between the 2 groups. It appears that the disparity in stone burden between the groups had a more substantial impact on the total procedure time than the type of dilator used.

A previous study by Lopes et al. showed conflicting results regarding the efficacy of balloon and MTD methods in managing intraoperative blood loss. Kukreja et al. proposed various factors that affect significant blood loss during PCNL. Their review suggested that using Amplatz and balloon dilators demonstrated an observed correlation with reduced blood loss.[13] In contrast, our findings indicate a lack of apparent difference in hemoglobin change between the two groups.

In this study, balloon dilators were disinfected using Ethylene Oxide sterilization. Approximately 90% of patients in the balloon group received re-sterilized BD. Unfortunately, non-inflated reused BDs often had larger diameters than the new ones. Additionally, we had to dilate the tract with fascial dilators up to 14 Fr before inflating the balloon for insertion. However, there is no subgroup comparison between re-used and brand-new balloon dilators.

Non-randomized dividing of the population could be our limitation and might have some bias in patient selection.

Conclusion

Based on our experience, both metal and balloon dilators can safely be used for PCNL in treating large renal stones without compromising procedural efficacy. There is no significant difference in success rate and complications in both groups. Further studies with a larger population may be conducted to improve liability and decrease selective bias.

REFERENCES

1. Fernström I, Johansson B. Percutaneous pyelolithotomy. A new extraction technique. Scand J Urol Nephrol. 1976;10:257-9. doi:10.1080/21681805.1976.11882084.
2. EAU Guidelines. Edn. presented at the EAU Annual Congress Milan 2023. ISBN 978-94-92671-19-6.
3. Lojanapiwat B. Previous open nephrolithotomy: does it affect percutaneous nephrolithotomy techniques and outcome? J Endourol. 2006;20:17-20. doi:10.1089/end.2006.20.17.
4. Sabler IM, Katafigiotis I, Gofrit ON, et al. Present indications and techniques of percutaneous nephrolithotomy: What the future holds? Asian J Urol. 2018;5:287-294. doi:10.1016/j.ajur.2018.08.004.
5. Davidoff R, Bellman GC. Influence of technique of percutaneous tract creation on incidence of renal hemorrhage. J Urol. 1997;157:1229-31.
6. Nouri M, Tligui M, Flahaut A, et al. La dilatation pariéto rénale au ballonnet dans la chirurgie percutanée du rein [Balloon catheter parieto-renal dilatation in percutaneous kidney surgery]. Prog Urol. 2000;10:1131-4.
7. Yanagawa M, Kawamura J, Onishi T, et al. Incidence of urolithiasis in northeast Thailand. Int J Urol. 1997;4:537-40. doi:10.1111/j.1442-2042.1997.tb00304.x.

8. Lopes T, Sangam K, Alken P, et al. The Clinical Research Office of the Endourological Society Percutaneous Nephrolithotomy Global Study: tract dilation comparisons in 5537 patients. J Endourol. 2011;25:755-62. doi:10.1089/end.2010.0488.
9. Wezel F, Mamoulakis C, Rioja J, et al. Two contemporary series of percutaneous tract dilation for percutaneous nephrolithotomy. J Endourol. 2009;23:1655-61. doi:10.1089/end.2009.0213.
10. Dehong C, Liangren L, Huawei L, et al. A comparison among four tract dilation methods of percutaneous nephrolithotomy: a systematic review and meta-analysis. Urolithiasis. 2013;41:523-30. doi:10.1007/s00240-013-0598-z.
11. El-Shazly M, Salem S, Allam A, et al. Balloon dilator versus telescopic metal dilators for tract dilatation during percutaneous nephrolithotomy for staghorn stones and calyceal stones. Arab J Urol. 2015;13:80-3. doi:10.1016/j.aju.2014.12.004.
12. Kumar V, Keeley FX Jr. Percutaneous nephrolithotomy: why do we use rigid dilators? J Endourol. 2008;22:1877-9. doi:10.1089/end.2008.9785.
13. Kukreja R, Desai M, Patel S, et al. Factors affecting blood loss during percutaneous nephrolithotomy: prospective study. J Endourol. 2004;18:715-22. doi:10.1089/end.2004.18.715.