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The safety and efficacy of using Telescopic metal dilators for tract dilatation during percutaneous nephrolithotomy of staghorn renal calculi: (A local study)

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Abstract:

Background: In 1976 Fernstrom and Johansson were the first who introduced the method of percutaneous nephrolithotomy (PCNL). With advance of technology and mechanization in endourological equipment, PCNL quickly became a prevalent procedure in the last few decades and it has eventually became the first line of treatment of relatively sizable renal stones predominating open surgery technique. PCNL is considered as a fundamental technique in the treatment of complex renal calculi (multiple stones that are ≥2 cm in diameter), staghorn stones and large lower calyceal stones.

Aims: The main objective of this study was to assess the safety and effectiveness of using telescopic metal dilators (TMDs) for tract dilation during the procedure of PCNL of staghorn renal stones based on samples collected from Iraqi patients.

Patients and Methods: In this cross-sectional study patients with complex staghorn renal stones, but with no hydronephrosis were subjected to PCNL. Seventy-five patients, who were candidates for PCNL at Governorates hospitals and private hospitals in Baghdad, Iraq, were enrolled from April 2015 to March 2018. The main objective of this research was to compare the outcome of the use of TMD and balloon dilations (BD) in creating the tract for PCNL.

Results: In group A (40 patients) dilation using TMDs was successful in 39 (97.5%), but failed in only one patient, with successful re-dilatation in one (2.5%), and no failed procedures. In group B (35 patients) dilation using BD was successful in 19 (54.3%), but failed, necessitating prompt dilatation by TMDs, in 16 patients (45.7%). The failure rate of dilatation was 6.25% due to substantial extravasation.
Patients from Group A exhibited lower failure rate, shorter duration of operative , minimal blood loss, transfusion rate, and lower complications rate than group B (P values= 0.0001,0.002,0.0001,0.003,0.0001 respectively). Differences in fluoroscopic time exposure were statistically insignificant (p-value=0.058).

Conclusion: From the present study, we can conclude that TMD device has proven to have a better patient outcome compared with BD.

Keywords: Percutaneous , Nephrolithotomy, Staghorn, Dilators, Retrospective

INTRODUCTION:

Renal stones is considered as the third commonly occurring ailment of the urinary tract. Infections of the urinary tract and prostatic diseases surpass renal stone widely. These conditions are prevalent in humans and animals alike. (1)

Percutaneous Nephrolithotomy (PCNL) technique is the process of removal of renal stone via a tract generated between the surface of the skin and the collecting system (pelvis and calyces) (2).

Fernstrom and Johansson were the first ones to report the PCNL **procedure** of developing a percutaneous tract specially to extract a stone in 1976. Following reports have established PCNL as a common technique used to manage individuls who are suffering of big or complex calculi. The percutaneous approach to stone removal is superior to the open approach in terms of multiple factors. These factors involve cost, morbidity, and convalescence. As such, PCNL has taken the place of open surgical removal of large or complex calculi at most establishments (3). It has been the most favorable procedure in the management of complex renal calculi ≥2 cm in diameter.(4,5)

Staghorn stnes are know for their typical appearance featured with large branched calculi that conform to the shape of the calyceal anatomy and fill the collecting system. Partial staghorn calculi are smaller and only fill a portion of the collecting system.

According to the AUA, treatment for staghorn and partial staghorn calculi is best managed with PCNL**.** Overall, the stone-free rate with PCNL is 78%.(6)

Optimal dilatation method in PCNL is a controversial issue. The dilatation methods available are: telescopic metal dilators (TMDs), Amplatz polyurethane serial dilators (ASDs), and balloon dilators (BD). In a multicentric trial, Amplatz-assisted serial dilators have recently been proved to be supreme to balloon dilators techniques (5).

In 1985 Alken first introduced TMDs. They consist of a series of coaxial metal rods that enlarge sequentially and pass over an 8-F guide (central) rod. The most effective dilator is deemed to be the rigid metal dilator, particularly the findings of a perinephric adhesions from prior surgery. Moreover, its cost is lower than that of other disposable dilators, such as the balloon dilators (BD) and Amplatz. Nevertheless, if the dilation is not controlled well, it can result in perforation of the pelvicalyceal system (7).

In some cases, BDs are known to be inferior to rigid TMDs and semigrid Amplatz dilators, due to their lower efficacy and higher cost. This is particularly apparent in patients with history of adhesions from earlier surgical management. Results of earlier studies shows that BDs is favorable in terms of reducing the need to blood transfusion and less bleeding compared to other dilators. (8-10)

In some cases, limited space around the stone makes tract dilation more challenging and increases the risk of guidewire slippage, as well as following failure to dilate the tract. Normally, this problem affects patients with staghorn calculi, calyceal stones but no hydronephrsosis, and an anteriorly situated targeted calyx. (11)

The primary objective of this research was to determine the safety and efficacy of using TMDs in creating the tract for PCNL in patients with staghorn calculi (with a limited area surrounding the stone but with no hydronephrosis). We emphasized on perioperative assessment and follow up of all parameters including success rates of the dilatation.

PATIENTS AND METHODS:

Seventy-five patients with complex staghorn renal stones who were candidates for PCNL at Governorates hospitals and private hospitals in Baghdad, Iraq were enrolled in this retrospective study from April 2015 to March 2018, to compare the results of the use of TMDs and BDs in creating the tract for PCNL in patients with complex staghorn renal stones, but with absence of hydronephrosis.

The selected patients were assigned to one of two groups; group-A for TMDs and group-B for BDs as a first option dilatation technique used.

Parameters assessed included demographic details of the patient, complex staghorn renal stone side, and operative and recovery variables, operative time, success rate of dilatation, fall in haemoglobin concentration, fluoroscopic time, and transfusion

rate. Moreover, complications were compared between group A and group B.

The exclusion criteria were significant medical comorbidities, uncorrected coagulopathies, severe infection, hydronephrosis or renal pelvic stones with the targeted calyx free of stones, congenital renal malformations, former renal surgery, or past intercostal (supracostal) access, as it was documented previously that TMD is superior to BD in these patients.

The ethical committee approved this study and the patients of the two groups read and signed an informed consent form.

The patients were evaluated using non-contrast computed tomography (CT) scan. Basic investigations including complete blood picture, renal function test, blood sugar, viral screen test, coagulopathy blood tests were all routinely done before surgery. In some patients who showed evidence of infection documented by urine cultures or when there was a suspicion of infected stones, urine culture was routinely done before surgery and appropriate antibiotics were given for the duration of seven days before PCNL.

The patients were operated using standard procedure. ‘‘The operation began with induction of anaesthesia, followed by lithotomy positioning and rigid cystoscopy-assisted non-ballon 8F ureteric catheter placement to the level of the ipsilateral pelviureteric junction. Afterwards, the patient was put in a prone position and underwent a fluoroscopy-assisted puncture. The position of the calculus and anatomical factors determined the desired calyx, preferring the subcostal lower pole posterior calyx. This was followed by an insertion of a hydrophilic guidewire (0.98 mm) into the system with optimal placement down the ureter. Another guidewire was then passed, using a 10F dilator (Boston Scientific)’’.

In group A the first stage in tract dilatation was to pass the 8-F guide (central) rod over a stiff guidewire. Then , for every consecutive metal rod was telescopically passed until the intended tract was reached, mostly up to 26 F. There was limited exposure to fluoroscopy with the subsequent dilation, in order to reduce the fluoroscopy time.

In group B, we applied two fascial dilators (6 and 8 F) were used, then it was followed by the balloon dilators (BD) (30 F, length 55 cm, balloon length 15 cm; Cook, Spencer, Indiana, USA) inflated up to 1.4 MPa. In order to confirm full inflation of the balloon to its maximum length, contrast medium was used for inflation. Thirty seconds later the sheath (30 F, 17 cm) was emerged over the inflated balloon. The balloon was then expelled and taken off.

On the first postoperative day the patients underwent an abdominal radiograph and an ultrasonography; haemoglobin concentration was measured. Following the removal of the nephrostomy, the patient was discharged on the condition that the haematuria cleared and residual fragments were not shown on the abdominal radiograph. In the case of a stone burden of ≥5 mm being present on the prompt postoperative X-Ray, the patients had to undergo a relook PCNL via the established tract of the third day.

It was postulated that the low level of haematocrit has caused the bleeding. Each blood transfusion that was required either during or after the surgery was recorded. There was record of total operative duration, the dilation time, as well as success rates. Success rate was defined as the patient being rendered stone-free, or with residual fragments of <4 mm that are clinically insignificant.

In order to assess this, an ultrasonography and a non-contrast abdominal imaging was used in particular patients by CT. If a reduction in haematocrit to <28% was specified, blood transfusion was considered. The modified Clavien grading system was used to collect and categorise postoperative complications (11).

Several months after the procedure stone-free status was established on repeat non-contrast CT evaluation. Fragments of ≤4 mm were not treated, as they were considered insignificant, unless patient and anatomical factors inhibited a conservative approach.

Student-t-test and the Pearson Chi-square test were used to statistically analyse the data. Significance level was set at 0.05.

RESULTS:

The demographics of the seventy-five patients included in the study are shown in (Table 1). The mean age of the patients in group A was 44.2+-7.8 years, and 47.0+-9.1 years in group B (Table 1).

Table 1: The patients’ number, age, gender, renal stone side, success or failure of dilatation, operative data, and complications.

	Group A (TMD) Telescopic Metal Dilators		Group B (BD) Balloon Dilators		P value
Number of patients	40		35		
Age (years)	44.2±7.8 (32-67)		47.0± 9.1 (29-69)		0.156
Gender Male	27	(67.5%)	21	(60.0%)	0.500
Female	13	(32.5%)	14	(40.0%)	
Staghorn stone Side Right	19	(47.5%)	18	(51.4%)	0.734
Side Left	21	(52.55)	17	(48.6%)	
Success rate of dilatation	39	(97.5%)	19	(54.3%)	0.0001#
Failed dilatation (TMD+Failed procedure)	1	(2.5%)	16	(45.7%)	
Operative time (minutes)	87.0± 5.3 (72-96)		82.7± 5.9 (67-93)		0.002*
Fluoroscopy time (minutes)	5.9± 0.4 (4.8-6.5)		6.1± 0.5 (4.5-6.6)		0.058
Haematocrit decrease (%)	2.9± 0.3 (1.6-3.4)		3.6± 0.6 (1.8-4.1)		0.0001*
Blood transfusion need	2	(5.0%)	11	(31.4%)	0.003#
Complications	7	(17.5%)	29	(82.9%)	0.0001#
Complications Grade I	3		10		0.883
Grade II	2		11		
Grade IIIa	2		8		
Complications Grade I→When there is postoperative pain, transient urine leakage, tube reclamping.					
Grade II→When bleeding requiring blood transfusion.					
Grade IIIa→If there is persistent urine leakage which need insertion of ureteric stent.					
*P value for Students-t-test is significant at 0.05 .					
# P value for Pearson Chi-square test is significant at 0.05.					

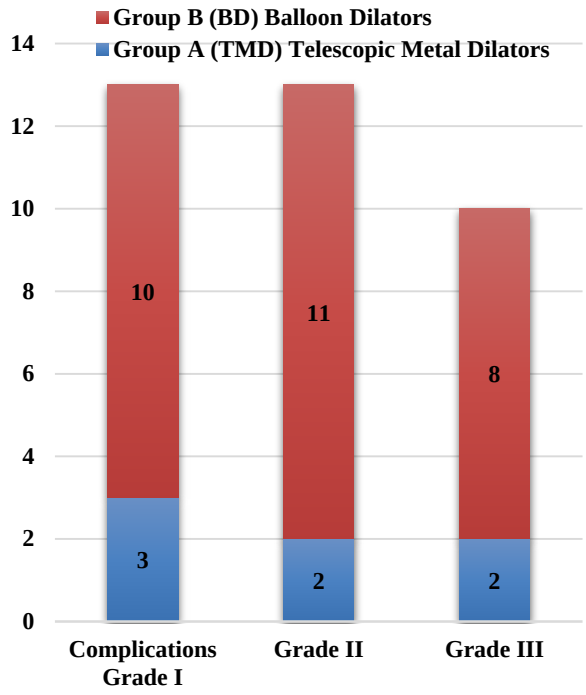

Fig.1:The complications(Grade 1,2,and 3) according to the modified Clavien grading system.

In group A (40 patients) the use of TMDs was successful in 39 (97.5%), but failed in only one patient, with successful re-dilatation in one (2.5%), and no failed procedures (Table-1). In group-B (35 patients) the use of BD was successful in 19 (54.3%), but failed, necessitating a prompt dilatation by TMDs, in 16 (45.7%). The balloon outside the pelvicalyceal system caused the failure just after inflation slipping and retracting, due to the lack of space around the stone. The dilation failure was identified in one of the 16 patients due to considerable extravasation. A week later, this particular patient had an unintended second PCNL.

There was a statistically significant difference (P = 0.0001) in the failure rate of primary dilation between the groups as shown in (Table-1).

The variation in patient age, patient gender, renal stone side and mean fluoroscopy time were statistically insignificant (p=0.156, 0.500, 0.734, 0.058 respectively). The mean of operating time was significantly higher in group A, while the reduction in haematocrit was significantly higher among B group along with need for hemotransfusion (p=0.002, 0.0001, 0.003 respectively) as shown in (Table-1).

Regarding complications in accordance with the modified Clavien grading system, it was found that the proportion of complications(Grade I, II or III) was statistically higher among group B than group A patients (p-value=0.0001), as seen in (Table-1) and in Fig-1. However, There was significant difference in the proportion of VI or V complications (bleeding requiring angioembolisation; nephrectomy; sepsis; or death).

DISCUSSION:

PCNL is a minimally invasive technique, and just like other similar operations, it evolves constantly. In 1955 Goodwin and associates described the first nephrostomy placement. In the 1970s, Stables *et al.* rendered its use more popular, as the technique and equipment have advanced considerably, thus improving patient outcome (12-14).

Since the introduction of PCNL a few decades ago, there has been a significant progress in its equipment and technique, and it is presently the most common method for treating large renal stones (>2 cm). Reports showed that PCNL favorable for treating staghorn calculi, and large renal stones. The procedure has a high stone-free rate and a relatively low complication rate (15-17). The AUA guidelines (2005) for staghorn stones show that the overall approximated stone-free rate after treatment is the highest for PCNL (78%) (6).

Dilation techniques have been an essential advancement in the filed of urology. BD approaches have decreased the rate of haemorrhage, fluoroscopic exposure time and operative time (18). Nonetheless, this has been objected.

Despite the fact that PCNL is a less traumatic managment option and has a high stone-free rate, it still poses a great challenge for the urologist. The most difficult aspects of the procedure are establishment of appropriate to the pelvicalyceal system, as well as reducing the burden on complicated and serious patient who to achieve stone-free status free of stone. (19-21)

The different access dilators are Amplatz, TMDs and BD, also known as “one-shot” dilators. BDs are reported to be superior to TMDs and Amplatz in terms of shorter dilation time and consequently shorter fluoroscopy time because of lesser bleeding (22). Nevertheless, according to some studies, TMDs cause less bleeding than BD (23).

In our study the limited fluoroscopy exposure during the use of TMDs might have caused the difference to be small enough not to reach the statistical and clinical significance in fluoroscopy exposure time.

Restricted space around the stone in patients with complex staghorn renal calculi made it difficult to establish access to the pelvicalyceal system. Introducing a guidewire and then advancing the tip of the dilator into the pelvicalyceal system can be challenging if hydrocalyx is absent (23).

Currently, there is a lack of high quality and highg level of evidence from the available reports which compare different dilation techniques (24). According to Joel *et al.* the dilation failure rate for BD as a primary dilation method is 17% (from 99 patients). As reported by Osman *et al.* (23) a serious of >300 patients who underwent the TMD treatment had a failure rate of <3.5%.

Likewise the current study documented a significantly lower success rate with using BD. Our hypothesis is that in staghorn renal stones and calyceal stones the limited space between the site of puncture and the stone in the targeted calyx renders the dilation more difficult than expected. TMD is more efficient for dilation than BD because of its flat metal end. BD on the other hand has a conical tip and it carrys risk of penetration of the pelvicalyceal system during the inflation of the balloon. These findings were observed in our patients and they are in agreement with other reports (8,24).

The transfusion rates due to percutaneous renal surgery from various series have ranged from 1%-34% (25).

Our findings were encouraging, as blood loss, duration of operation, and blood transfusion rate were lower in the TMD group. In BD group there was lower rate of successful dilations, higher complication and retreatment rates.

The limitations of the current study were primarily due to its retrospective nature and a relatively small number of patients. However, this study is considered as a pioneer study that compare competing dilation methods in a rather complicated patients. In order to draw stable conclusions more randomized controlled studies need to be carried out.

To conclude, the study showed that TMDs are a more successful and effective method of tract dilation compared to BD when using PCNL for complex renal stones (with no hydronephrosis). The two techniques were compared in terms of operative time duration, complication rates and dilation success rate.

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