A comparison of balloon and amplatz dilators in percutaneous nephrolithotomy: a retrospective evaluation

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ABSTRACT

Objective: In this study, we compared our experience using balloon and amplatz dilatation in percutaneous nephrolithotomy (PCNL). We also evaluated peri- and postoperative variables, including success rates.

Material and methods: Two hundred renal stone patients (123 men/77 women) underwent PCNL at the Urology Clinic of İzmir Atatürk Training and Research Hospital from September 2005 to May 2011. The nephrostomy tract was dilated using a balloon (128 patients) or amplatz (72 patients) dilator. The groups were compared by age, total operating time, treatment success rate, retreatment rate, pre- and postoperative hematocrit values, mean decrease in hematocrit values, blood transfusion rate, stone burden, tract dilatation failure, hospital stay and nephrostomy removal times, stone localization, previous stone operation and the cost of the dilatation system.

Results: There was no statistically significant difference in the operative time (97.9 ± 45.3 minutes in balloon group vs. 98.5 ± 43.4 minutes in the amplatz group; $p=0.43$), preoperative hematocrit value (39.04 ± 4.21 vs. 38.94 ± 4.49 ; $p=0.87$), postoperative hematocrit value (32.74 ± 4.86 vs. 32.48 ± 5.43 ; $p=0.73$), decrease in hematocrit values (6.30 ± 2.60 vs. 6.45 ± 2.64 ; $p=0.68$), blood transfusion rate (15.6% vs. 16.7%; $p=0.84$) or treatment success rate (78.9% vs. 79.2%; $p=0.96$) between balloon and amplatz groups. Differences in other variables were also not observed between the two groups.

Conclusion: The balloon or amplatz dilatation methods have similar results with regard to efficacy, speed, and safety. However, the cost of the balloon dilator is higher than that of the amplatz dilator.

Key words: Balloon dilatation; percutaneous nephrolithotomy; renal calculi.

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Introduction

Urinary system stone disease has been encountered frequently in various communities. Treatment of urinary system stone disease has been managed using conservative, medical or surgical methods depending on the characteristics of the patient, and the stone.

Percutaneous nephrolithotomy (PCNL) firstly described in 1976 by Fernström and Johansson is a minimally invasive surgical method used for the treatment of urinary stone disease.^[1,2] Nowadays in the management of renal stone, extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS), and their combinations, and laparoscopic techniques have been used. With the use of invasive, and noninvasive techniques, open surgery has been used only at

a rate of 1-2% in the management of renal stones.^[3]

Despite developments in the treatment of renal stones, and very frequent use of ESWL, especially in cases with higher stone burden (in the older publications 2 cm², and in recent publications >500 mm²) PCNL is recommended as a gold standard management modality.^[4,5] The advancements in intracorporeal lithotripters, and nephrostomy tract creation techniques, have decreased operative times, and complications at the expense of increased cost. Optimal dilatation method is debatable. Many dilatation methods including Amplatz, balloon, and metal telescopic dilatation are available.^[6,7]

In many international multicentered studies Amplatz dilators have been shown to be superior over balloon dilators.^[7] With the development in balloon dilators, some studies also

have demonstrated superiority of balloon dilators over Amplatz dilators.^[8]

In this article, we compared use of Amplatz, and balloon dilators in consideration of pre-, and postoperative values.

Material and methods

Two hundred (123 men, and 77 women) patients who had undergone PCNL operations in Izmir Atatürk Training and Research Hospital between September 2005, and May 2011 after obtaining their written consent forms, were included in the study. Amplatz (n=72), and balloon (n=128) dilatation methods were used.

Demographic characteristics, location, and size of the stone, success rate, pre-, and postoperative hematocrit level, decrease in the hematocrit level, transfusion rate, complication(s) during dilatation procedures, hospital stay, nephrostomy removal time, and previous renal stone operation were compared between groups.

Besides stones were classified according to their locations as simple, and complex stones. Stone burden was measured on direct urianry system radiograms (DUSR) with a ruler. Multiplication of two largest diameters of the stone perpendicular to each other was recorded as stone burden.^[9,10]

Operative time was calculated from the beginning of the cystoscopic examination up to the achievement of nephrostomy tube placement, and its fixation to the skin.

Hospital stay was calculated from the day of the operation up to the day of discharge.

Preoperatively, hemogram, blood biochemistry, and urine culture test results of the patients were evaluated. Patients with bacterial growth detected in their urine cultures were treated with appropriate antibiotics, and operated when negative culture results were obtained. Operation of aspirin or other anti-coagulant users were delayed for 7-10 days. Average decrease in hematocrit levels was evaluated in consideration of pre-, and postoperative hemogram values, and total amount of transfused blood (according to our accepted criteria, every unit of blood transfused increases hematocrit levels at a rate of 3 percent).^[11]

PCNL technique applied

Preoperative antibiotic prophylaxis was achieved with 1 g IV cephazolin. After administration of anesthesia while the patient was lying on the operating table in the supine position, he/she was placed in the lithotomy position, and through a 22 F cystoscope inserted transurethrally, an open-ended 6F ureteral

catheter was advanced up to the kidney with a stone. Then the patients were placed in the prone position.

Access into renal collecting system

Under the guidance of fluoroscopy, radiopaque agent was delivered through ureteral catheter to opacify pelvicalyceal system. An 18 Gauge (G) percutaneous access needle was advanced into the calyx from which maximal number of stones can be retrieved with minimal risk of bleeding. After observation of urine outflow through the needle, guidewire was delivered through the needle into pelvicalyceal system. The skin was incised with 20 G scalpel. Over the guidewire, 6F, then 10 F co-axial dilators were advanced to dilate the access tract. Balloon dilator (Nephromax®, Boston Scientific, USA) was passed over the guidewire into the pelvicalyceal system which was inflated up to 15 kg/cm² atmospheric pressure using radiopaque agent and with the aid of an inflator (LeVeen™ Inflator, Boston Scientific). Over balloon dilator, a 30 F working sheath was advanced into the pelvicalyceal system. After deflation of the balloon, dilator was withdrawn from the working sheath. When Amplatz dilators were used, the access tract was dilated over guidewire with Amplatz dilators up to 28 F, then 30 F Amplatz sheath (Amplatz Sheath Boston Scientific, USA) was advanced over the co-axial dilator into the pelvicalyceal system.

Fragmentation, and extraction of the stones

Pelvicalyceal system was entered with a 25 F nephroscope. Stones were extracted either only with forceps or fragmented with pneumatic or ultrasonic lithotripter, and then extracted with a forceps. In case of need, for complete stone clearance more than one entry was achieved. During operation at first opportunity ureteral catheter was taken out, and a guidewire was delivered through the catheter. At the end of the operation a re-entry Malecot catheter was engaged into pelvis.

After termination of the operation, operative site of the patient was compressed during his/her transport on the same stretcher. from the operating table to his bed in the ward. Nephrostomy tubes of the patients with haemorrhage access tract were kept clamped during their transport to the service. Dependent on the color of the drainage bag, foley catheter was withdrawn the next morning. The patients received antibiotherapy with a quinolone group antibiotic. The next day direct urinary radiograms were obtained from all patients with radiopaque stones. On postprocedural 1., and 2. days nephrostomy tube was clamped, and withdrawn in patients without fever, residual stones, and apparently disturbing pain. In the presence or suspicion of extravasation, and ureteral stones, retrograde nephrostograms were obtained. If free passage of radiopaque agent into the bladder was observed, then nephrostomy tubes were removed. Double-J ureteral stents were implanted in patients with sustained urine

leakage or residual stones which migrated into ureter during postoperative period.

The patients were evaluated with intravenous urograms (IVUs) at 3. month of the postoperative period. The operation was deemed to be successful if stone-free state was achieved or the nonobstructive, asymptomatic, noninfectious, clinically insignificant residual fragments (CIRFs) less than 4 mm were observed postoperatively in the urinary tract.

Statistical analysis

For the evaluation of outcomes of our study data, SPSS 16.0 program was used. Data obtained were compared with *chi*-square, and Mann-Whitney U -t-tests. Correlations between paired variables were calculated using Pearson correlation analysis. Numerical values were expressed as mean±standard deviation (SD). P<0.05 was accepted as statistically significant.

Results

Age range (15-73 yrs), median age (49 yrs), and mean age (47.03±13.24 yrs) of the patients were also calculated. Mean

ages in the Amplatz, and balloon dilatation groups were 44.84±13.21, and 48.25±13.15 years, respectively (p=0.08) (Table 1).

Mean stone burden of the patients was found to be 7.36±6.31 cm². Mean stone burden was 7.86±8.03 in the Amplatz, and 7.08±5.11 cm² in the balloon groups, respectively (p=0.4). The patients had either simple (n=91) or complex (n=109) stones (coraliform, partial coraliform, pelvicalyceal stones or multiple calyceal sytones). In the Amplatz group 31 (43.1%) simple, and 41 (56.9%) complex, and in the balloon group 60 (46.9%), and 68 (53.1%) complex stones were found (p=0.6).

Mean operative time in the balloon, and Amplatz groups was 97.9±45.3, and 98.5±43.4 minutes, respectively without any statistically significant difference between groups (p=0.43).

Preoperatively, mean hematocrit levels were 39.04±4.21, and 38.94±4.49, in the balloon, and Amplatz groups, respectively (p=0.87). Postoperatively, corresponding hematocrit values were 32.74±4.86, and 32.48±5.43, respectively (p=0.73). Postoperative decrease in hematocrit values was

Table 1. Comparisons between balloon, and Amplatz dilatation groups

	Amplatz	Balloon	p value
Median age (years)	44.84	48.25	0.08
Median duration of operation (mins)	98.5	97.9	0.43
Previous operation (n. %) pyelolithotomy/nephrolithotomy /PCNL	18 (25%)	24 (18.8%)	0.36
Median stone burden (mm ²)	7.86	7.08	0.4
Median decrease in hematocrit (%)	6.45	6.30	0.68
Median time to the removal of the nephrostomy tube (days)	2.15	2.00	0.38
Median hospital stay (days)	3.30	3.77	0.28
Success rate (%)	81.9	83.6	0.84
Success rate before additional treatment (%)	79.2	78.9	0.96
Additional treatment n, %	11 (15.3%)	13 (10.2%)	0.28
Additional treatments (n)			
PCNL ¹	1	1	
URS ²	0	4	
ESWL ³	9	7	
Double J stenting	1	1	
Stone location (n)			
Simple	31 (43.1%)	60 (46.9%)	0.6
Complex	41 (56.9%)	68 (53.1%)	
Complication during dilatation (n)	2	1	

¹PCNL, percutaneous nephrolithotomy; ²URS, ureterorenoscopy; ³ESWL, extracorporeal shock wave lithotripsy

6.45 ± 2.64 , and 6.30 ± 2.60 in the Amplatz, and balloon groups, respectively ($p=0.68$). Blood transfusions were also applied in the balloon ($n=20$; 15.6%) and Amplatz ($n=12$; 16.7%) groups ($p=0.84$).

Postoperative success rates were 79.2% in the Amplatz, and 78.8% in the balloon groups ($p=0.96$). Twenty-four patients received additional therapy after PCNL operation because of residual stone disease. These cases were managed using extracorporeal shock wave lithotripsy (ESWL) ($n=16$), ureterorenoscopic intervention ($n=4$), PCNL ($n=2$) or double J stenting ($n=2$). Need for additional treatment emerged both in the balloon (10.2%), and Amplatz (15.3%) groups ($p=0.28$). Success rates after additional treatment were 83.6, and 81.9% in the balloon, and Amplatz groups, respectively ($p=0.84$).

The patients stayed in the hospital for a mean period of 3.61 ± 2.93 days. Mean hospital stay was 3.30 ± 1.90 days in the Amplatz, and 3.77 ± 3.37 days in the balloon groups. ($p=0.28$). Nephrostomy tube was withdrawn after a mean postoperative period of 2.00 ± 1.12 , and 2.15 ± 1.25 days in the balloon, and Amplatz groups, respectively ($p=0.38$).

In the balloon group, 24 (18.8%), and in the Amplatz group 18 (25%) patients had been previously operated for their ipsilateral renal stones. ($p=0.36$). This difference in incidence rates might be explained by failure to advance balloon dilator into collecting system over guidewire because of development of perirenal fibrotic tissue during the postoperative healing period. In these cases Amplatz dilator was used instead of balloon dilator.

Double J-catheter was applied in 8 cases because of prolonged drainage ($n=8$; 4%) and (or) extravasation which occurred following Amplatz ($n=3$) or balloon ($n=5$) dilatation. Postoperative ureterorenoscopy, and/or double-J catheter implantation were/ was performed in 6 (3%) patients because of passage of residual stones into ureter during the postoperative period.

During management of upper pole stones using either Amplatz ($n=1$) or balloon dilatation ($n=1$) pneumo/hydrothorax occurred because of injury to the diaphragm. Double J stent was applied in one patient in the Amplatz group because of pelvic laceration during Amplatz dilatation.

Discussion

PCNL has become an applicable procedure in the management of all renal stones with its treatment success, and advantages as shorter hospital stay, earlier recovery, minimal invasiveness and decreased procedural cost.

Percutaneous nephrolithotomy is in continuous evolution just like other minimally invasive procedures. Dilatation is one of the most important steps in the PCNL procedure. From the first application of nephrostomy in 1955, developments in its technique, and equipment have improved patient outcomes.^[12-14]

Kukreja et al.^[15] demonstrated that during intrarenal access, the selection of the appropriate calyx had not any impact on the development of complications, on the contrary following optimal access with a needle the dilatation technique used had effected rates of bleeding. In 1994, Stoller et al.^[16] investigated the effects of telescopic metal, and balloon dilatation on blood loss, and couldn't find any significant difference between both methods. Michel et al.^[17] demonstrated that balloon dilatation method had decreased operative times, blood loss, and exposure to fluoroscopy. Davidoff et al.^[8] revealed that Amplatz dilatation had led to higher incidence of bleeding episodes relative to balloon dilatation. In a study by Kukreja et al.^[15], Amplatz dilators, Alken telescopic metal dilators, and balloon dilators were compared, and lesser blood loss was reported with Amplatz dilators relative to other dilators without any statistically significant difference between dilators regarding blood loss. In our series, balloon, and Amplatz dilators were used. Comparatively higher cost is the most important disadvantage of balloon dilators despite their easy, and safe use. Besides, balloon dilators decrease radiation exposure significantly.^[17,18]

The Clinical Research Office of the Endourological Society (CROES) has recently published the outcomes of a study related to PCNL performed in 5803 patients from 96 centers worldwide.^[7] Observational analyses demonstrated that when compared with the patients who had undergone Amplatz dilatation, in patients who had experienced balloon dilatation lower bleeding (9.4 vs. 6.7%) and transfusion rates (7 vs. 4.9%) were detected. Procedural failure rate was higher in the balloon dilatation group.^[7] However, very frequent use of balloon dilators in the management of larger staghorn stones, and operations performed in different medical centers with various indications were limitations of this study.

When compared with the Amplatz dilators, recently developed balloon dilators decrease operative time, exposure to fluoroscopic radiation, and morbidity rates.^[17,18]

Our results have demonstrated that operating time, bleeding, transfusion rate, additional intervention, and complication rates were proportionally lower in the balloon dilatation group. However any statistical difference was not seen in all variables.

Bleeding episodes related to Amplatz dilatation have been associated with perforation of the collecting system which increases

morbidity rates.^[19,20] These bleeding episodes are known to lead to deterioration of the endoscopic vision. Lesser bleeding appears to effect success rate of PCNL favorably, and shorten hospital stay.^[19]

Contrary to CROES study, our study demonstrates that in patients with comparable indications, and similar stone burden, balloon dilatation is proportionally but not statistically superior relative to the Amplatz dilatation. However, shorter hospital stay has been demonstrated in the Amplatz group.

[12,13,18,21,22]

Higher cost of balloon dilators, disadvantages of their dynamic features, and single-use, need for Amplatz dilators when more than one access tract must be created for multiple, and staghorn stones demonstrate superiority of Amplatz dilators in terms of cost-effectiveness.^[22,23]

Since our study had a retrospective design, duration of dilatation, and radiation exposure were not evaluated.

In conclusion, balloon dilatation yields comparable outcomes with Amplatz dilatation regarding rapidity of its application, effectiveness, and safety. With development of its technology, balloon dilatation have demonstrated comparatively superior postoperative outcomes. However generally operative outcomes carry very close similarities. However Amplatz dilators are more cost-effective than balloon dilators. Nowadays, when we have taken the importance of cost-effectiveness into account, use of Amplatz dilators apparently reduce the treatment expenditures to very low levels.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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