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Comparıson of two dıfferent dılatatıon methods ın percutaneous nephrolıthotomy ın term of safety: One-shot dılatatıon versus stage dılatatıon

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Abstract
Background: To compare one-shot and standard stage amplatz dilatation techniques in percutaneous nephrolithotomy (PCNL) in terms of efficacy and safety method performed in the treatment of kidney stones.
Materials and Methods: Eighty patients who underwent PCNL were randomly divided into groups according to staged (group 1) or one-shot (group 2) amplatz dilatation. Amplatz dilatation was applied to the patients in group 1, starting from the 8F dilator, up to 30F in a standard manner. Patients in group 2 were dilated directly with a 30F amplatz dilator and both groups were compared in terms of efficacy and safety.
Results: Complete stone-free status was achieved in 35 (87.5%) of the patients in group 1 and in 36 (90%) of the patients in group 2 and no statistically significant difference was found between the two groups in terms of stone-free status (p: 0. 72). In group 2, the duration of surgery, dilatation time, and duration of fluoroscopy were significantly shorter (p: 0.001, p: 0.007, p: 0.001). There was no statistically significant difference between the two groups in terms of erythrocyte solution requirement (p: 0. 64). Total complication rates were 15% in both groups, and there was no statistically significant difference between the groups in terms of complication rates (p: 1.00).
Conclusions: One-shot amplatz dilatation method provided a significant advantage compared to the staged amplatz dilatation method by providing shorter dilatation time, scopy time and total operation time. In addition, it provided a similar rate of pain score, blood loss and hospital stay, resulting in the conclusion that it was a reliable method as safe as standard amplate dilatation.

Keywords: percutaneous nephrolithotomy, one-shot amplatz dilatation, efficiency, safety

Introduction

Urinary stone disease is one of the common and recurrent health problems. Percutaneous nephrolithotomy (PCNL) was first introduced in 1976 as an effective treatment option for the removal of renal calculi [1]. Over the years, parallel to advances in technology and increasing experience, it has achieved low complication and high stone-free rates, and has become the standard surgical method for the treatment of > 2 cm kidney stones [2].

One of the most important steps in PCNL is dilatation and it may be applied with one-shot or staged dilatation techniques [3]. In the dilatation step, amplatz, alken or balloon dilators may be used. In PCNL operations, the duration of surgery, complete removal of the stone, especially radiation exposure and complications are among the most emphasized issues [4]. Over the years, many studies have been done to improve the PCNL technique and it looks like more will also be done in the future [3-5].

In many studies, one-shot and staged amplatz dilatation methods in standart PCNL have been compared in terms of efficacy and safety, and it has been reported that one-shot amplatz dilatation method is a safe method even in patients with open stone surgery [3, 6-8]. Most of the studies on this subject in the literature are retrospective nature. There is limited study in the literature comparing only amplatz dilators with staged and one-shot techniques in a prospective-randomized manner (As the authors know). Although amplatz dilators are generally used for single use, they can be used reusable in many surgical procedures due to economic reasons and the material structure of the product. Many studies with reported comparative results are comparing different dilators, and it is difficult to get a clear idea of the staged or one-shot techniques for the most commonly used amplatz dilators.

The aim of this prospective-randomized study is to compare staged and one-shot amplatz dilatation PCNL techniques in terms of success or complications rate, total surgery duration, total fluoroscopy duration, dilatation duration, intraoperative and postoperative findings, patient and stone characteristics, duration of hospitalization and postoperative pain.

Material and Method

This prospective-randomized study was approved by the local Ethics Committee (HNEAH-KAEK 2018/KK/05, Date: 12.02.2018) and conducted according to the principles of the World Medical Association Declaration of Helsinki 'Ethical Principles for Medical Research Involving Human Subjects. Informed consent was obtained from all individual participants included in the study.

Patients older than 18 years with normal bilateral renal function, without any urological or nephrological additional disease were

included in the study. Exclusion criteria of the study were, being younger than 18 years old, lack of consent to participate in the study, previously undergone ipsilateral PCNL or open renal surgery, active urinary tract infection, bleeding/coagulation disorders, radiolucent stones, solitary kidney, kidney with anomaly and presence of nephrostomy tube.

A total of 80 patients who were admitted to our outpatient clinic between January 2018 and January 2019, who received the indication for PCNL surgery and were approved to participate in the study were randomized into two groups according to dilatation technique. After the surgery decision, the patients were given an opaque, sealed envelopes prepared by us and they were randomized into the two groups according to these envelopes.

All patients were evaluated after systemic examination, preoperatively; Complete blood count, comprehensive serum biochemistry, complete urine analysis, urine culture and bleeding/coagulation time tests were performed. Patients were evaluated preoperatively by stone protocol non-contrast abdominal tomography.

Patients who underwent PCNL with standard staged amplatz dilatation were referred to as group 1 and patients who underwent PCNL with one-shot amplatz dilatation were referred to as group 2. All operations were performed in our clinic by two experienced endourologists.

Before the PCNL, all patients received 1 gram intravenous Cefazolin as antibiotic prophylaxis. All the procedures were performed in prone position. In both groups, 6 French (F) ureteral catheter was inserted into the related renal unit, in the lithotomy position after general anesthesia. After the patient was placed in the prone position, retrograde pyelography was performed and access to the targeted calix was applied with 18 gauge access needle using a C-arm fluoroscopy device (monoplanar access). After a guide wire was sent through the access needle to the collecting system or to the ureter, different dilatation procedures were performed in group 1 and group 2. In group 1, amplatz dilatation was performed gradually starting from 8F dilator up to 30F dilator. In group 2 patients, one-shot access was carefully performed by a single 30F amplatz dilator over the 8F polyurethane dilator. As a final step, a 30F access sheath was placed in the collecting system under the guidance of a fluoroscopy in both groups. Infracostal access was performed to all patients. Dilatation time is defined as the time from entry with access needle to access sheath placement. After entry into the pelvicalyceal system with nephroscope, stones were fragmented with pneumatic lithotripter and removed with forceps. Postoperatively, all calyces and pelvis were checked for residual stone by rigid nephroscope and fluoroscopy. At the end of the operation, 12F malecot nephrostomy tube was placed in all patients. Transurethral catheters were withdrawn at the 24th postoperative hour. Nephrostomy catheters were withdrawn after antegrade nephrostography on the second postoperative day. Patients without leakage from the nephrostomy site and without colic pain were discharged. Postoperative 24th hour VAS pain scores were recorded. The absence of pain was 0 and the most severe was 10. Patients with postoperative renal colic complaints or nephrostomy site leakage after removal of the nephrostomy catheter were evaluated with USG and KUB, and Double-J (D-J) stent implanted when necessary. D-J stents were removed at postoperative 2nd - 3rd weeks. Urine and blood cultures were taken in patients with postoperative fever. Chest X-ray was performed to determine possible atelectasis. Postoperative complications were recorded. The Modified Clavien Classification used to evaluate the complications [9].

Patient groups were evaluated in terms of age, gender, stone localization, access failure, total stone size, operation time, duration of fluoroscopy, dilatation time, postoperative hemoglobin drop on the 24th hour, blood transfusion rates, hospital stay, postoperative Visual Analog Scale (VAS) scores on the 24th hour, additional treatment requirements, Clavien-Dindo complication grades. The duration of the fluoroscopy was defined as the number of minutes (min.) of radiation exposure demonstrated by the fluoroscopy device at the end of each surgery. Hemoglobin decline was calculated by subtracting the postoperative hemoglobin value at 24 hours from the preoperative hemoglobin value. Stone size was defined as the largest diameter of the stone on non-contrast computerized tomography (CT). In case of more than one stone, the stone size was calculated as the sum of the largest diameters of all stones. Access failure was defined as not to provide an access to the collecting system despite all attempts. Accesses provided after the first or multiple attempts were defined as successful access.

Statistical analyses were performed using SPSS Statistics 22.0 software (SPSS Inc., Chicago, IL, USA). The normality hypothesis was tested using the Shapiro Wilks test during data analysis. In the evaluation of the study data, besides the descriptive statistical methods (mean, and standard deviation), in the comparison of quantitative data; Independent-Samples T Test was used for intra-group comparisons of normally distributed parameters, and Wilcoxon sign test was used for intra-group comparisons of non-normally distributed parameters. Fisher's Exact test and Yates Chi-square tests were also used to examine the differences between categorical variables. Values of $p< 0.05$ were considered statistically significant.

Results

The mean age in group 1 is 48.77 ± 14.65 and 47.42 ± 13.35 in group 2. The mean BMI was 27.64 ± 4.25 in group 1 and 26.83 ± 3.82 in group 2. The stone was on the left side in 21 (26.25%) patients in group 1 and 26 (32.50%) patients in group 2. The mean total size of all stones of 80 patients was 30.9 (15 - 90) mm. The mean total stone size was 33.18 ± 19.34 mm in group 1 and 28.69 ± 12.95 mm in group 2 (Table 1).

There was no statistically significant difference between the two groups in terms of age, gender distribution, BMI, stone side, total stone size, dilatation failure, decrease in hemoglobin, postoperative blood transfusion, postoperative fever, complication rates, residual stone, hospitalization time and VAS scores ($p>0.05$). Total surgery, fluoroscopy and dilatation time were significantly lower in group 1 ($p<0.05$) (Table 1).

Stone-free rates in the staged and one-shot amplatz dilatation group were found to be 87.5% and 90% respectively. There was no statistically significant difference between the two groups in terms of stone-free rates (p: 0.72)

Complications such as blood transfusion, prolonged postoperative pain, postoperative fever, urinary extravasation at the site of nephrostomy, insertion of a D-J catheter due to obstruction, and bleeding requiring angioembolization were observed in 21 patients. No postoperative complications were

encountered in 59 patients. Overdilatation, injury to pelvicalyceal system or postoperative chest complication in PCNL were not observed in any patient. In one patient, after the lower calyx and pelvis were cleared, the procedure was terminated without interfering with the upper calyceal stones due to bleeding. There was no statistically significant difference between the two groups in terms of Modified Clavien Grade I, II, III, IV and V complication rates (p:0.762) (Table 1).

Table 1: Demographic characteristics, stone characteristics, residual stone rates, modified Clavien grade complications and statistical evaluation results of both groups in Group 1 and II patients.

	Dilatation Groups	Mean ±SD or n (%)	p
Age (Years)	Group 1	48.77±14.65	0.66
	Group 2	47.42±13.35	
BMI (kg/m2)	Group 1	27.64±4.25	0.37
	Group 2	26.83±3.82	
Stone size (mm)	Group 1	33.18±19.34	0.22
	Group 2	28.69±12.95	
Dilation failure	Group 1	3 (3.75%)	0.077
	Group 2	0 (0.00%)	
Total operation time (min.)	Group 1	80.62±30.80	0.001
	Group 2	59.82±23.10	
Duration of fluoroscopy (min.)	Group 1	3.34±2.60	0.007
	Group 2	2.00±1.58	
Duration of dilatation (min.)	Group 1	6.82±3.98	0.001
	Group 2	4.00±3.72	
Hg drop (mg / dl)	Group 1	1.94±1.34	0.289
	Group 2	1.61±1.40	
Postoperative Blood Transfusion	Group 1	3 (3.75%)	0.644
	Group 2	2 (2.50%)	
Postoperative Fever	Group 1	0 (0%)	0.314
	Group 2	1 (1.25%)	
Postoperative Residual Stone	Group 1	5 (6.25%)	0.723
	Group 2	4 (5.00%)	
Duration of hospitalization (Days)	Group 1	4.45±1.50	0.792
	Group 2	4.57±2.58	
VAS score	Group 1	3.97±1.60	0.230
	Group 2	3.57±1.33	
Grade I complication	Group 1	0 (0%)	0.762
	Group 2	1 (1.25%)	
Grade II complication	Group 1	5 (6.25%)	
	Group 2	4 (10%)	
Grade IIIA complication	Group 1	0 (0%)	
	Group 2	1 (1.25%)	
Grade IIIB complication	Group 1	1 (1.25%)	
	Group 2	1 (1.25%)	
Grade IVA, IVB, V complication	Group 1	0 (0%)	
	Group 2	0 (0%)	

Discussion

One-shot dilatation technique applied during PCNL compared to the standard staged dilatation technique can present shorter dilatation time, fluoroscopy time and total surgery time with similar stone-free and complication rates. In the literature, the number of prospective-randomized studies on comprasion of dilatation technique in PCNL as one-shot versus standart staged amplatz dilatation is limited. Therfore we think that balloon dilatation technique should be also evaluated as the most suitable method to compare methodologically. However, the previous studies report that the one-shot amplatz dilatation technique is at least as effective and safe as the other three techniques and it causes less radiation exposure [3, 4, 9]. Stone-free rates for one-shot amplatz dilatation are reported between 84% and 94% in different series [9-11]. A study by Dehong *et al*. reported that no significant difference was found between the one-shot dilatation and metal telescopic dilatation methods in terms of stone-free rates [3]. According to our data, stone-free rates in the staged and one-shot amplatz dilatation group were found to be 87.5% and 90% respectively, which was consistent with the literature. One-shot amplatz dilatation technique had no negative effect on stone-free status. In different studies have reported that when one-shot dilatation technique has compared with staged dilatation techniques in terms of complications, it has concluded that the results were similar [11-14]. In our study, total complication rate was equal to 16.25% in group 1 and 2, similar to other studies. In the one-shot amplatz dilatation group, a 5% lower blood transfusion ratio is noteworthy, although not statistically significant. In the literature balloon dilatation has been reported to cause less bleeding than other techniques as in the one-shot technique [15, 16]. More bleeding in the staged amplatz dilatation group may be due to the possibility of further damage to the renal collecting system and the parenchyma during successive dilatations. A retrospective study which compared staged amplatz dilatation, Alken dilatation and balloon dilatation has reported that dilatation failure in Alken and balloon dilatations were lower than in staged amplatz dilatation but not statistically significant (%5.35, %4.2 and %7.36 respectively) [6]. In our study, less dilatation failure was detected in the one-shot amplatz dilatation group, but no statistically significant difference was found between the group 1 and group 2 (% 3.75 and % 0 respectively) (p>0.05). One-shot amplatz dilatation technique is as safe as all other dilatation methods.

Another factor that is considerable as stone-free and complication rates during PNCL is radiation exposure. Dilatation methods by Alken dilators or semirigid amplatz dilators take more time and cause longer fluoroscopic exposure time compared to the use of balloon dilators [5]. A study by Hani H. Nour *et al*.; the mean operation time of patients who underwent Alken dilatation and one-shot amplatz dilatation was 124.9 (29.3) min. and 100.9 (29.3) min, and X-ray exposure times were 11.8 (0.42) min and 10.5 (4.7) min, respectively. According to this study, the mean duration of surgery and fluoroscopy was shorter in the one-shot amplatz dilatation group [11]. In our study, durations of the radiation exposure in the one-shot amplatz dilatation group were shorter that standart staged dilatation method and similar to balloon dilatation results in the literature. Total operation time, duration of anesthesia and length of hospital stay are also important in the evaluation of PCNL for all patients. In a study comparing amplatz, Alken, and balloon dilatation PCNL datas which collected from 3 centers; Average tract formation times have been reported as 328.67 ± 172.99, 325.14 ± 175.70 and 203.50 ± 32.76 seconds, respectively. Total operation time and tract formation times were significantly lower in the balloon dilatation group [6]. In a study by Khorrami *et al*., which compares progressive metal telescopic dilatation with one-shot amplatz dilatation; No significant difference was reported between the two groups in terms of length of hospital stay [17]. In our study; There was no statistically significant difference between the two

groups in terms of duration of hospitalization time ($p>0.05$). It is understood that PCNL performed with one-shot amplatz dilatation technique does not cause additional cost burden due to prolonged hospital stay. This is consistent with the fact that the complication rates prolonging hospital stay were similar in both groups. Although the length of hospital stay is similar, it should not be forgotten that the one-shot technique is more comfortable for patients as it has better results in terms of postoperative pain. The balloon dilatation technique may be comfortable, but its cost will be higher. The limited number of patients and the absence of all dilatation techniques can be considered as limitations of this study. In addition, not investigating long term results and cost-effectiveness, not recording the stone localization in our study can be considered as additional disadvantages. Prospective study number comparing the one-shot amplatz dilatation technique with all other dilatation techniques are limited in the literature. We think that our study will contribute to medical science with its prospective-randomized nature which comparing the staged amplatz dilatation and one-shot amplatz dilatation techniques.

Conclusions

Finding the ideal dilatation method in the standard PCNL will have significant contributions in terms of operative time, radiation exposure, morbidity, efficacy and cost. In this study that we conducted for these reasons, we found that one-shot amplatz dilatation technique has a shorter dilatation time and therefore has a shorter total surgery and radiation exposure time compared to staged amplatz dilatation technique. In addition, we concluded that the one-shot amplatz dilatation method was similar to the staged amplatz dilatation method in terms of efficacy, complication, pain score and length of hospital stay. According to these results, one-shot amplatz dilatation technique seems to be an effective, safe and applicable method in terms of patients and urologists. Urologists performing standard stage amplatz dilatation can reduce the radiation exposure time, operation and dilatation time by applying one shot amplatz dilatation in their daily practice. At the same time, they will not face off any increase in peroperative complications and risks.

Compliance with Ethical Standards

This manuscript was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. In our manuscript, patients have given their written informed consent for the publication of this study. We have obtained the ethical approval from our local institute's committee on human research (Haydarpaşa Numune Education and Research Hospital Ethical committe, Date:12.02.2018, HNEAH-KAEK 2018/KK/05).

Conflict of Interest

The authors, “Muhammed Cihan Temel, Ömer Yılmaz, Ferhat Ateş, Caner Ediz, Sezgin Okçelik, Serkan Akan” declares that they have no conflict of interest.

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