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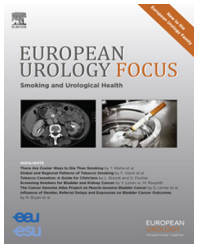

Stone Disease

Comparing the Efficacy and Safety of Ultrasonic Versus Pneumatic Lithotripsy in Percutaneous Nephrolithotomy: A Randomized Clinical Trial

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Article info

Article history:
Accepted February 2, 2017

Associate Editor:
James Catto

Keywords:
Percutaneous nephrolithotomy
Ultrasonic
Pneumatic

Abstract

Background: Percutaneous nephrolitotomy (PCNL) is the preferred treatment for large renal stones. There is a need for more comparative data for different lithotripters used in PCNL.
Objective: To evaluate the comparative safety and efficacy of ultrasonic and pneumatic lithotripsy in patients undergoing PCNL.
Design, setting, and participants: This randomized clinical trial was conducted at Labbafinejad University Hospital, Tehran, Iran. A total of 180 patients were selected and divided randomly into two groups: 88 patients to pneumatic and 92 to ultrasonic lithotripsy.
Intervention: Standard fluoroscopy-guided PCNL was performed using pneumatic or ultrasonic lithotripsy.
Outcome measurements and statistical analysis: The primary outcome was the procedure success rate. We also evaluated other outcome measures including operation time, stone fragmentation and removal time (SFRT), length of hospital stay, and postoperative complications. We used SPSS software version 18.0 for data analysis.
Results and limitations: The two groups were similar in baseline characteristics. There were no significant differences between the groups in stone fragmentation and removal time ($p = 0.63$), stone free rate ($p = 0.44$), and hospital stay ($p = 0.66$). SFRT for hard stones was shorter using pneumatic lithotripsy ($p < 0.001$). By contrast, ultrasonic lithotripsy was associated with a shorter SFRT for soft stones ($p < 0.001$). Postoperative complications were similar in the two groups. A limitation of this study might be the 3-mo follow-up period.
Conclusions: In general, there were no significant differences in the success rate and complications between pneumatic and ultrasonic lithotripsy. SFRT was significantly shorter using pneumatic lithotripsy for hard stones, and ultrasonic lithotripsy for soft stones.
Patient summary: We found no significant differences in the success rate and complications of percutaneous nephrolitotomy using pneumatic and ultrasonic lithotripsy. Ultrasonic and pneumatic lithotripsy differed in the time for stone fragmentation and removal for hard and soft stones.

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http://dx.doi.org/10.1016/j.euf.2017.02.003
2405-4569/

1. Introduction

It is estimated that nephrolithiasis results in annual medical cost of $2.1 billion [1]. In light of the considerable recurrence rate for urolithiasis, the goal of treatment is to achieve the highest stone-free rate with the least invasion [1]. Percutaneous nephrolithotomy (PCNL) is the treatment of choice for large kidney stones [2,3]. Pneumatic and ultrasonic lithotripters are commonly used to disintegrate stones in PCNL [4]. Ultrasonic lithotripters can break the stones into small fragments that can then be removed via suction through the central lumen of the ultrasonic probe. However, the process can be tedious, especially for large or dense stones. In addition, without continuous irrigation, the device can overheat during use, causing the system to malfunction and interrupt the lithotripsy [5]. Pneumatic devices can break up large or hard renal calculi, but the broken pieces must be removed via the cumbersome process of grasper use. In addition, repeatedly passing the nephroscope through the working sheath risks inadvertently dislodging safety wires, working wires, or even the sheath itself [5]. While the stones can be fragmented successfully, some of the fragments can be propelled, with the potential for adverse results. To the best of our knowledge, this is the first randomized clinical trial comparing ultrasonic and pneumatic lithotripsy in PCNL in a pure mode (not a combination of different lithotripters in one arm).

2. Patients and methods

2.1. Patients and setting

This was a randomized clinical trial conducted for 1 yr, from December 2014 to December 2015, in the Department of Urology at Labbafinejad University Hospital (Shahid Beheshti University of Medical Sciences, Tehran, Iran). All patients with kidney stones larger than 2 cm scheduled for PCNL were included in the study. The exclusion criteria were age <18 yr, coagulopathy disorders, pregnancy, and patients with scattered stones that required multiple access tracts. The study was approved by the Ethics Committee at Shahid Beheshty University of Medical Sciences, and each patient provided informed consent before inclusion in the study. The study was registered at www.clinicaltrials.gov (NCT02751281).

Initially, 203 patients were enrolled in the study, but 23 of them were excluded from the final analysis. Of those 23 patients, 15 did not meet the inclusion criteria (6 were aged <18 yr, 2 had coagulopathy disorders, and 7 had multiple stones that required several access tracts). The remaining 188 patients in the final sample were randomly divided into two groups of 94 patients. However, the final number of patients in the study was 180, because two patients in the ultrasonic group and six in pneumatic group were lost to follow-up and were not included in the final analysis. Randomization was performed using a table of random numbers generated by random allocation software [6]. All of the surgeries were performed by senior fellows under the supervision of an expert endourologist. Table 1 summarizes the preoperative baseline characteristics for the patients in the two groups.

2.2. Surgical procedure

A standard PCNL procedure was performed in all patients, as previously described [7]. In brief, with the patient under general or spinal

Table 1 – Demographic data for patients undergoing percutaneous nephrolithotomy using a pneumatic or ultrasonic lithotripter.

	Pneumatic (n = 88)	Ultrasonic (n = 92)	p value
Age (yr)	48.02 ± 11.99	49.19 ± 13.56	0.54
Sex (female/male)	21/71	23/65	0.60
Body mass index (kg/m^2)	27.13 ± 2.71	25.73 ± 1.78	0.71
Side (left/right)	47/41	50/42	0.89
Stone burden (mm)	35.86 ± 16.92	37.26 ± 15.56	0.56
Stone type, n (%)			0.57
Calcium oxalate monohydrate	29 (16)	27 (15)	
Calcium oxalate dihydrate	34 (19)	38 (21)	
Calcium phosphate	2 (1)	3 (2)	
Struvite	6 (3)	11 (6)	
Uric acid	15 (8)	11 (6)	
Cystine	2 (1)	2 (1)	
Stone position, n (%)			0.91
Complete staghorn	13 (7)	17 (10)	
Partial staghorn	27 (15)	29 (16)	
Calyceal	14 (7)	15 (9)	
Pelvis	27 (15)	23 (13)	
Calyceal + pelvis	7 (4)	8 (4)	
Opacity, n (%)			0.73
Opaque	62 (34)	68 (38)	
Semi-opaque	13 (7)	14 (8)	
Lucent	13 (7)	10 (6)	
Risk factors, n (%)			
Diabetes mellitus	11 (6)	12 (7)	0.91
Ischemic heart disease	5 (3)	7 (4)	0.62
History of kidney surgery	12 (7)	9 (5)	0.39
Preoperative creatinine (mg/dl)	1.16 ± 0.41	1.18 ± 0.51	0.81
Preoperative hemoglobin (g/dl)	14.83 ± 1.78	14.70 ± 1.72	0.63

Data for continuous variables are presented as mean ± standard deviation.

Please cite this article in press as: Radfar MH, et al. Comparing the Efficacy and Safety of Ultrasonic Versus Pneumatic Lithotripsy in Percutaneous Nephrolithotomy: A Randomized Clinical Trial. Eur Urol Focus (2017), http://dx.doi.org/10.1016/j.euf.2017.02.003