

Pulsed versus continuous mode fluoroscopy during PCNL: safety and effectiveness comparison in a case series study

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Abstract To compare the total fluoroscopy time (FT) based on the fluoroscopy mode used—continuous vs. pulsed—in patients who underwent percutaneous nephrolithotomy (PCNL). The study cohort evaluated 111 patients who underwent PCNL by a single surgeon. Standard (continuous) fluoroscopy of 30 frames per second (fps) was used in the first 56 cases (SF group), while the next 55 consecutive cases were performed under pulsed fluoroscopy of two fps (PF group). The presence of surgeon's previous experience decreased the possible impact of the learning curve on the outcome. In both groups, using ultrasound in combination to fluoroscopy performed the renal access. The stone complexity was determined using Guy's stone score (GSS). Complications were evaluated using Clavien-Dindo classification. Median FT was significantly lower in PF group (76.8 s) compared to SF group (155.4 s) ($p < 0.001$). Stone-free rate was related to the Guy's stone score (GSS) classification reaching 100 % in GSS 1 cases in both groups. In GSS 2 cases the stone free rate was 87.5 % in SF group, while in PF group it was 92.3 %. Stone free rate in GSS 3 cases was 73.3 and 85.7 % in SF and PF groups, respectively. In cases of GSS 4 stone free rate was 52 % in SF group and 55.6 % in PF group, respectively.

Presence of residual fragments and complications were comparable in both groups. Following ultrasound-guided puncture during PCNL, the use of pulsed fluoroscopy leads to significantly lower radiation exposure comparing to the use of continuous fluoroscopy. This advantage does not compromise the safety and efficacy of the procedure.

Keywords Fluoroscopy time · Percutaneous nephrolithotomy · Pulsed fluoroscopy · Radiation exposure · Ultrasound guidance

Introduction

Evaluation and management of urolithiasis is associated with repeated exposure to radiation [1, 2]. As all modern techniques of stone fragmentation are performed under fluoroscopy there is rising concern over the radiation exposure for both the patients and the surgical team. Radiation exposure is linearly correlated to the exposure time and is a risk factor for the development of secondary malignancies [3]. The concern arises even more when cumulative exposure is taken into consideration.

Since its introduction percutaneous nephrolithotomy (PCNL) has underwent significant improvements in terms of efficacy, and is recognized today as the treatment of choice for kidney stones larger than 2 cm [4]. Obtaining the precise, planed and desired access to a specific part of the pyelocaliceal system is the first and crucial step for a successful and safe PCNL. Fluoroscopy is mandatory for puncturing the kidney, confirming the correct position of the needle and the guidewires into the desired calix, evaluating the progress of the procedure and confirming the final result. PCNL is associated with the highest radiation exposure compared to other techniques used for the treatment

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of renal stones [5–7]. As a consequence, the surgeon and the patient receive the highest amount of radiation during PCNL [8].

Following the already established principle of ALARA one of the most important fields of improvement in modern treatment of urolithiasis is the decrease of radiation exposure [9].

Fluoroscopy time (FT) is one of the few controllable variables that impact radiation exposure, and that is why the FT is mostly used as a surrogate marker for estimating radiation doses [10]. Pulsed fluoroscopy was introduced to reduce the fluoroscopy radiation dose by limiting the number of exposures per second and the total time of exposure to X-ray beams [11]. There are not many studies that have investigated a decrease in total fluoroscopy time by use of pulsed fluoroscopy during PCNL [5, 10].

The aim of the present study was to compare the effectiveness and safety of the PCNL procedure when pulsed fluoroscopy was used instead of continuous mode fluoroscopy.

Materials and methods

After the approval of the Scientific Ethical Committee of our institution, the study cohort gained prospectively collected data from 111 consecutive patients who underwent PCNL by a single surgeon (O.D.), between August 2010 and December 2014.

The first 56 cases were performed under continuous, standard fluoroscopy (SF group), while in the next 55 consecutive cases pulsed fluoroscopy (PF group) was used. Digital fluoroscopy unit was used. (Dornier Compact Delta II ‘UIMS’, Germany) The unit uses refresh mode of 30 frames per second (fps) in continuous, standard fluoroscopy mode (SF), while in pulsed mode it is adjusted to two fps (PF).

The inclusion criterion for a patient to undergo PCNL in our study was to have a renal stone larger than 2 cm in diameter. All patients which were classified as ASA four were excluded, as were patients with chronic renal failure and active urinary tract infection.

Preoperative evaluation consisted of basic laboratory tests, such as complete blood count, biochemistry, creatinine, renogram/scintigraphy with glomerular filtration rate estimation, urinalysis, urine culture and coagulation profile. In all patients, excretory urography was performed to clarify the renal stone size and location, the anatomy of pyelocaliceal system as well as to detect the most appropriate calix for optimal access. The renal stone complexity was graded according to Guy’s stone score [12]. One week postoperatively, the stone free rate was calculated based on plain abdominal radiography of the kidney, ureters and

bladder and ultrasound. Postoperative success was defined as stone free, if no residual fragments 4 mm or bigger were found.

Operative technique

Under general anesthesia a cystoscopy was performed with the patient in a lithotomy position, to insert a 6 F ureteral catheter (Rüsch, Germany) to the renal pelvis. The ureteral catheter was fixed to an indwelling 16 F Foley catheter. The patient was then turned into a prone position. The renal access was performed under US-guidance, with concomitant fluoroscopy control. The puncture through the fornix of the desired calix was performed with an 18-gauge Chiba needle (Rüsch, Germany), using a 5 MHz ultrasound (BK Medical, Denmark) probe with a metal needle holder by side. Success of the puncture axis was estimated by fluoroscopy. Fluoroscopy was self-controlled by the surgeon, by a foot pedal. Contrast medium was injected through the ureteral catheter to check the appropriateness of the access. After urine was emitted, the procedure was maintained with the placement of 0.035-in J-tipped guidewire. The nephrostomy tract was developed with the use of the metallic dilators. The tract was progressively enlarged with the use of the coaxial stainless dilators up to 28 Fr, over which an Amplatz (Olympus, Japan) sheath was placed. During tract dilation a second guide wire was placed through the guiding tube. All steps of tract formation were controlled by fluoroscopy. In the moment of indwelling of the nephroscope (Olympus, Japan) and visualization of the stone, the consumed tract formation time and fluoroscopy to tract formation were recorded. Lithotripsy was performed by an ultrasonic lithotripter. (Olympus LUS-2, Japan) At the end of the procedure, an 18 F nephrostomy catheter (Synergy, Protos Medical, USA) was placed. Appropriate position of nephrostomy tube was confirmed by contrast medium and catheter was fixed with a suture to the skin. Fluoroscopy time (FT) was calculated as the fluoroscopy consumed from the beginning to the end of the operation, including the nephrostomogram. Operative time was recorded at the same moment.

Puncture was US-guided, with continuous fluoroscopy control in group SF, while in group PF access was controlled by pulsed fluoroscopy. Last image-hold mode was used in both groups.

Data are presented as counts (%), mean \pm SD or median (25th–75th percentile). T test was used to assess statistical difference between two groups comparing numerical data with normal distribution while Mann–Whitney U test was used for ordinal data or interval data with non-normal distribution. Chi square test was used for group comparison with nominal data. Correlation between variables was examined using Spearman correlation. All data were

analyzed using SPSS 20.0 (IBM corp.) statistical software. All *p* values less than 0.05 were considered significant.

Results

There were no significant differences between the two groups regarding age, laterality and gender. In both groups mostly one tract was established (83.9 % in SF group and 85.5 % in PF group (*p* = 0.823). The biggest proportion of patients showed a Guy score 4–25(44.6 %) in SF group and 18 (32.7 %) in PF group. Guy 3 classified cases were the second most common group with 15 (26.8 %) in SF group and 14 (25.5 %) in PF group, respectively. Guy 2 and 1 were present in 8 (14.3 %) and 8 (14.3 %) in SF group and 13(32.7 %) and 10 (18.2 %) in PF group, respectively (*p* = 0.152). Significant difference considering

stone diameter between the two groups was not detected (*p* = 0.430) (Table 1). Successful access to the pyelocaliceal system was achieved in all cases.

Data for the two groups are shown in Table 1.

Median fluoroscopy time (FT) was significantly lower in PF group (76.8 s) compared to SF group (155.4 s; *p* < 0.001), as was also a fluoroscopy to tract formation (45.0 vs. 85.2 s; *p* < 0.001) (Table 1).

Stone-free rate was related to the Guy's stone score (GSS) classification reaching 100 % in GSS 1 cases in both groups. In GSS 2 cases the stone free rate was 87.5 % in SF group, while in PF group it was 92.3 %. Stone free rate in GSS 3 cases was 73.3 and 85.7 % in SF and PF groups, respectively. In cases of GSS 4 stone free rate was 52 % in SF group and 55.6 % in PF group, respectively (*p* = 0.621).

Clavien 0 and 1 complications were recorded in 62.5 and 19.6 % in SF group, and 70.9 and 16.4 % in PF

Table 1 Demographic, clinical and operative characteristics

	Group		<i>p</i> value
	SF (<i>n</i> = 56)	PF (<i>n</i> = 55)	
Age	49.6 ± 12.7	46.4 ± 14.2	0.216 ^c
Gender male	22 (39.3 %)	25 (45.5 %)	0.511 ^a
Side left	32 (57.1 %)	29 (52.7 %)	0.640 ^a
Stone diameter (mm)	53.9 (48.6–59.4)	51.2 (46.5–55.8)	0.430 ^b
Guy's stone score			
1	8 (14.3 %)	10 (18.2 %)	0.152 ^b
2	8 (14.3 %)	13 (23.6 %)	
3	15 (26.8 %)	14 (25.5 %)	
4	25 (44.6 %)	18 (32.7 %)	
Number of tracts			
1	47 (83.9 %)	47 (85.5 %)	0.823 ^a
2	9 (16.1 %)	8 (14.5 %)	
Residual fragments	17 (30.4 %)	11 (20 %)	0.293 ^a
Stone free by Guy's stone score distribution (GSS) ^d			
1	8/8 (100 %)	10/10 (100 %)	0.621 ^b
2	7/8 (87.5 %)	12/13 (92.3 %)	
3	11/15 (73.3 %)	12/14 (85.7 %)	
4	13/25 (52.0 %)	10/18 (55.6 %)	
Clavien			
0	35 (62.5 %)	39 (70.9 %)	0.331 ^b
1	11 (19.6 %)	9 (16.4 %)	
2	7 (12.5 %)	5 (9.1 %)	
3a	2 (3.6 %)	2 (3.6 %)	
4a	1 (1.8 %)	0	
Operative time (min)	81.5 (74.8–88.1)	82.4 (75.7–89.1)	0.839 ^b
Tract formation time (min)	15 (11–18.5)	13 (10–16)	0.146 ^b
Fluoroscopy to tract formation (median, s)	85.2 (60–124.2)	45.0 (28.8–74.4)	<0.001 ^b
Fluoroscopy time (median, s)	155.4 (109.8–202.2)	76.8 (66.0–143.4)	<0.001 ^b

Results are presented as N (%), mean ± SD or median (25th–75th percentile)

^a Chi square test, ^b Mann–Whitney U test, ^c *t* test, ^d percent of Guy's stone score

group, respectively. Clavien 2 complications were present in 12.5 % of cases in SF group and 9.1 % of cases in PF group. Clavien 3a was recorded in 3.6 % of patients in both groups. Clavien 4a was present in 1.8 % in SF group. There was no difference among the incidence and the severity of the complications between the two groups, even when the cases were adjusted for the GSS ($p = 0.331$) (Table 1).

Discussion

During the last decade PCNL technique was improved significantly, in terms of safety and efficacy, and is currently considered as a treatment of choice for kidney stones larger than 2 cm [4]. During its development some new challenges arose, such as the significant exposure to ionizing radiation and its detrimental effects [1, 2, 13]. Fluoroscopy leads to radiation exposure which is associated with possible carcinogenesis [3]. We have shown that using pulsed instead of continuous fluoroscopy we can significantly decrease the radiation exposure time without compromising the effectiveness and the surgical safety of the procedure.

The appropriate access to the pyelocaliceal system is fundamental to obtain a high stone-free rate during percutaneous surgery. Despite the fact that zero radiation exposure is the ultimate goal, the majority of urologists still prefer to control the renal access with fluoroscopy. Data from the CROES study showed that percutaneous access was obtained using ultrasound guidance only in 13.7 %, while fluoroscopic guidance was used in 86.3 % of cases [14]. Undoubtedly, the use of ultrasound to puncture the desired calyx diminishes the radiation exposure both to the patient and the surgical team [15]. Although strong advocates of ultrasound-guided puncture have published data supporting the completeness of a safe and efficacious procedure under just ultrasound control [16, 17], fluoroscopy should always be available in the operating theater. The last holds true especially when large stones, impacted stones, staghorn stones, or stones located in undilated collecting systems or within renal anatomical malformations are being treated. In these cases, the precise control of the renal access, the position of the working and safety guidewires as well as the intraoperative follow-up of the proper advancement of the surgical procedure are all critical factors related to the stone-free status of the patient. Fluoroscopy is considered absolutely necessary to achieve a high stone-free rate on such cases [5, 18].

Apart from US implementation several other measures have been proposed to reduce the radiation exposure during PCNL. Along with the surgeon's experience radiation less demanding techniques of tract formation, such as balloon dilatation or single shot dilators, may additionally decrease radiation exposure [19, 20]. Endoscopic combined

intrarenal surgery (ECIRS) may also contribute to decrease of radiation exposure [21]. Two randomized controlled trials have been performed recently, comparing the combination of US and fluoroscopy to fluoroscopy guidance alone [15, 22]. Basiri et al. concluded that access for PCNL using US-guidance with fluoroscopy control is an acceptable alternative to fluoroscopy and decreases radiation hazards [22]. Duration of radiation exposure for renal access decreased significantly from 0.95 to 0.69 min. Our results are quite similar; the fluoroscopy time to tract formation was 45 s. In contrast to Basiri, who used a single step technique, in our study the tract was established by the use of Alken bougies.

Modification of the radiation-emitting mode was shown to reduce radiation exposure during extracorporeal shock wave lithotripsy (ESWL) without influencing the quality of the images and the success of the procedure [23]. Having used a pulsed radiation mode in our PCNL cases we have ended with a similar outcome. The results of our study are in accordance with those of other PCNL studies that evaluated radiation exposure during the procedure [5, 10].

In our knowledge, the study of Elkoushy et al. is the only one that was focused on the comparison of FT, dependent on the settings of the fluoroscopy, comparing pulsed fluoroscopy to the continuous, during PCNL [10].

When compared to the study of Elkoushy et al. our study group had bigger stone diameter and proportion of complex stones (staghorn/partial) (Table 2). The discrepancy in stone complexity could explain the stone free rate difference. Despite the presence of more complicated cases, in our study FT was shorter (76.8 vs. 121.5 s). This improvement may be a result of US-guidance used for access, but also setting used for pulsed fluoroscopy, as we used 2 fps, compared to 4 fps. This improvement could be even better if some of less radiation consuming dilation techniques were used [19, 20].

Blaire et al. [5] have presented the study of pulsed fluoroscopy used during PCNL with single pulse per second adjustment. Using this setting the mean FT was decreased from 175.6 to 33.7 s. The comparison to this study becomes difficult when we take into consideration the fact that percutaneous access was performed by interventional radiology before PCNL, with no recording of FT used during nephrostomy tube placement. In both studies, Elkoushy et al. and Blaire et al., the balloon technique of tract dilatation was used. This could be a possible field of improvement of our technique, to decrease radiation exposure time.

Our study confirmed previous data [10] showing that as the complexity of the cases treated increases with increasing GSS the FT and the complication rate and severity also increase. Having used the pulsed fluoroscopy we managed to reduce the FT both in low and high GSS score patients. More importantly this has been achieved without affecting

Table 2 Comparison of our study to study of Elkoushy et al. (groups with use of pulsed fluoroscopy)

	Study	
	Elkoushy et al. (n = 50)	Our study (n = 55)
Age	55.7 (49.6–59.6)	46.4 ± 14.2
Gender male	23 (46 %)	25 (45.5 %)
Side left	20 (40 %)	29 (52.7 %)
Stone diameter (mean; median, mm)	33.2 (29.8–39.4)	51.2 (46.5–55.8)
Multiplicity of stones		
Single	16 (32 %)	10 (18.2 %)
Multiple	18 (36 %)	13 (23.6 %)
Staghorn/partial	16 (32 %)	32 (58.2 %)
Number of tracts		
Used previous	10 (20 %)	0 (0 %)
1	35 (70 %)	47 (85.5 %)
2	5 (10 %)	8 (14.5 %)
Tract development	Balloon	Alken
Stone free	47 (94 %)	44 (80 %)
Operation time (min)	100.4 (88–111)	82.4 (75.7–89.1)
Fluoroscopy time (mean; median, s)	121.5 (108.3–144.2)	76.8 (66.0–143.4)

Results are presented as *N* (%), mean (95 % CI) or median (25th–75th percentile)

the stone-free rate or the rate and the severity of the complications encountered in the two groups. No deviation from the normal postoperative course (Clavien 0), or without need for intervention (Clavien 1) were observed in 82.1 % in SF group and 87.3 % in PF group. These results were similar to those presented in the review of Seitz et al. and CROES Global study [24, 25]. Stone free rate was neither affected by lowering the pulse rate in PF group, as there was no difference in stone free rate between groups. High percentage of complete staghorn stones (44.6 % of GSS 4 in SF group and 32.7 % in PF group) may influence the overall efficacy.

Our study has several limitations. Although the data are prospectively collected depicting no major differences in the demographic parameters between the two groups, no randomization was performed. In addition, the cases were consecutive in the experience of one surgeon, fact that may have led to selection bias as the second group may have benefitted from the surgeon's higher experience. In addition, fluoroscopy time does not necessarily accurately reflect radiation dose received by either the surgeon or the patient. In our study, dosimeters were not used to actually measure the radiation exposure of the involved parts.

In conclusion, even with pulsed fluoroscopy refresh rate of 2 fps, PCNL can be controlled and performed without impact on its safety and efficacy. Significant decrease of FT

when US-guidance and PF are used together is offering the new window of opportunities for further decrease of radiation exposure during PCNL, especially for the access.

Compliance with ethical standards

Conflict of interest Authors declare no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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