Low-Dose Fluoroscopy Technique Drastically Decreases Patient Radiation Exposure during Percutaneous Nephrolithotomy

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Abstract

Introduction

Fluoroscopy is essential in percutaneous nephrolithotomy (PCNL) but exposes patients and operating room staff to radiation. We investigated whether a low-dose (LD) protocol could reduce radiation exposure during fluoroscopy-guided access without compromising clinical outcomes.

Methods

Patients undergoing PCNL with fluoroscopy-guided access at a tertiary care stone center between January 2019 to July 2021 were identified. Prior to September 3, 2020, the Philips Veradius C-arm's default settings were used: standard per-frame dose, 15 pulses per second (PPS) frame rate. After this date, a low-dose protocol was used: reduced per-frame dose, reduced frame rate of 8 PPS for needle puncture and 4 PPS for all other steps. Clinical and radiographical data were retrospectively collected. The primary outcome was cumulative radiation dose. Secondary outcomes were stone-free status (SFS; defined as no fragments ³2mm) and complications. Multivariate regression analysis was performed.

Results

100 patients were identified; 31 were in the LD group. The LD cohort was exposed to a significantly lower mean cumulative radiation dose of 11.68 mGy compared to 48.88 mGy ($p<0.0001$). There were no differences in operative time, fluoroscopy time, stone burden, SFS or complications. In a multivariable regression model adjusting for several variables, LD protocol was associated with lower radiation dose while skin-to-calyx-distance (STCD) was positively associated with cumulative radiation dose. Higher preoperative stone burden was associated with longer operative time ($p=0.0001$) and lower odds of postoperative SFS (odds ratio=0.959, $p=0.0007$).

Conclusions

Low-dose fluoroscopy and decreased frame rate during PCNL decreased radiation exposure four-fold without affecting SFS or complication rates.

Introduction

Urolithiasis affects nearly 9% of the population in the United States[1]. Symptomatic patients who are surgical candidates that have either failed intervention (shock wave lithotripsy or ureteroscopy) or who have a total renal stone burden > 20 mm should be offered percutaneous nephrolithotomy (PCNL)[2]. Fluoroscopy is commonly used to achieve access and is almost always used in other portions of the procedure. This exposes the patient and operating room staff to ionizing radiation, increasing the risk of future malignancy [3, 4]. The International Commission for Radiological Protection and corresponding international safety standards recommend annual dose limits and actions to keep exposure as low as reasonably achievable (ALARA)[3]. Recent efforts to decrease radiation exposure by using ultrasound still require the use of fluoroscopy in the confirmation of nephrostomy tube placement[5]. Further, the use of intraoperative ultrasound for access and dilation requires specialized equipment, training and practice. This can impact patient outcomes as well as surgical training during the learning curve. With the low-dose (LD) fluoroscopy technique, the surgeon can specifically control fluoroscopy settings on the C-arm screen in the operating room to decrease radiation exposure by lowering the per-frame dose and frame rate. We sought to investigate whether a novel low-dose fluoroscopy protocol could be used to significantly reduce radiation exposure without compromising clinical outcomes.

Materials And Methods

The retrospective study design was reviewed and approved by the institutional review board. Patients aged ≥ 18 years old undergoing PCNL with fluoroscopy-guided percutaneous access at a tertiary care stone center by a single surgeon between January 2019 to July 2021 were identified. The procedure was performed in the prone split-leg position. Initially, cystoscopy is done, and two guide wires are passed up to the kidney, followed by a ureteral access sheath. Flexible ureteroscopy is then performed to identify the ideal calyx for access. In this series, upper pole access was attempted when possible. Needle puncture is performed with bi-planar angulation of the C-arm and bullseye technique. Nephrolithotomy is then carried out with an ultrasonic lithotripter or holmium laser. Once stone clearance is confirmed, a double-J stent is placed retrograde for drainage. Exclusion criteria included an additional, concomitant primary procedure not involving the kidney (i.e. cystolitholopaxy), missing data (demographic, clinical, or imaging), more than one percutaneous access in the same case, post-op nephrostomy tube placement, or concurrent contralateral procedure. A Philips Veradius C-arm, flat detector type 718 130 (Philips Medical Systems NL B.V. Amsterdam, The Netherlands) was used. Prior to September 3, 2020, machine default settings were used: the per-frame dose was set at the default setting, and a pulse frequency or frame rate of 15 pulses per second (PPS) was used. After this date, a low-dose protocol was used which reduced the per-frame dose and reduced the frame rate to 4 PPS for the whole case, except for the needle puncture, where 8 PPS was used. Demographic, clinical and imaging data (operative and fluoroscopy time, pre- and post-operative stone burden, skin-to-calyceal distance (STCD), stone density, and location of access) were recorded. The Student's t-test was used to compare continuous variables while Chi Square and Fisher's exact test were used to compare discrete variables. The primary outcome was cumulative radiation dose while secondary outcomes were stone-free status (SFS; defined as no fragments ≥2mm) and complications. Stone burden was assessed with a pre-operative computed tomography scan by recording the sum of the longest linear measurement of all stones. Stone free status was evaluated with post-operative day 1 computed tomography scan. Subjects without residual fragments greater than 2mm were considered stone-free. Multivariate regression analysis was performed to assess how STCD, stone burden, density, and location of access would affect cumulative radiation dose and post-operative SFS.

Results

One hundred subjects were identified. Thirty-one who underwent PCNL after September 3, 2020 were in the LD group, while sixty-nine were in the standard dose group. There was no significant difference in the age, BMI, pre-operative stone burden, and pre-operative stone density between the LD and standard groups (Table 1). The LD cohort had a significantly lower mean cumulative radiation dose of 11.68 mGy compared to 48.88 mGy ($p < 0.0001$) with no statistically significant differences in operative time ($p = 0.4723$), fluoroscopy time ($p = 0.1133$), stone burden ($p = 0.5029$), SFS ($p = 0.4559$) or complications ($p = 0.7394$) (Table 2). Complications from PCNL included lung injury, hematoma, and urinary tract infections. In a regression model including STCD, stone burden, density, and location of access, being in the standard fluoroscopy protocol group and a higher STCD were associated with higher cumulative radiation dose ($p < 0.0001$, $p = 0.0124$, respectively; Table 3). Higher preoperative stone burden was associated with longer operative time ($p = 0.0001$) and lower odds of postoperative SFS (odds ratio = 0.959, $p = 0.0007$) (Tables 4 and 5).

Table 1
Demographic and pre-operative clinical factors. Results are reported in mean ± standard deviation.

	Standard (n = 69)	**Low Dose (n = 31)**	**P value**
Age	57.07 ± 13.80	61.13 ± 13.01	0.1624
BMI (kg/m^2)	32.5 ± 7.94	30.9 ± 7.28	0.3185
Pre-op Stone Burden (mm)	40.56 ± 24.25	45.41 ± 36.39	0.5029
Pre-op Stone Density (HU)	963.82 ± 378.29	892.82 ± 365.42	0.5029
Skin to Calyceal Distance (mm)	101.11 ± 22.69	94.55 ± 28.56	0.2713

Table 2
Comparison of clinical outcomes between patients receiving either the standard or low-dose protocol. Results are reported in mean ± standard deviation (minimum-maximum) and percentages.

	Standard (n = 69)	**Low Dose (n = 31)**	**P value**
Fluoroscopy Time (sec)	147.62 ± 73.94 (30–508)	123.59 ± 67.02 (1.17–342)	0.1133
Operative Time (min)	136.45 ± 40.86 (73–245)	129.29 ± 47.75 (60–240)	0.4723
Cumulative Radiation Dose (mGy)	48.88 ± 36.84 (5.87–221.20)	11.68 ± 7.01 (0.21-29)	< 0.0001*
Stone Free Status	75.41%	67.86%	0.4559
Post-operative Complications	21.74%	12.90%	0.7394
* Denotes statistical significance, p < 0.05			

Table 3

Results of multivariable regression analysis using STCD, stone burden, stone density, and access location as variables to predict radiation exposure.

Parameter	**Estimate of Covariate Coefficients**	**Standard Error**	**Wald 95% Confidence Limits**		**P-value**
Group Comparison (Standard vs LD)	-34.845	6.987	-48.538	-21.151	< .0001*
STCD	0.346	0.139	0.075	0.618	0.0124*
Stone Burden	0.051	0.113	-0.171	0.272	0.6543
Stone Density	0.007	0.009	-0.010	0.025	0.4174
Middle Pole Access	15.734	11.927	-7.643	39.111	0.1871
Lower Pole Access	1.774	7.083	-12.108	15.655	0.8023
*Denotes statistical significance, p < 0.05					

Table 4

Results of multivariable regression analysis using skin-calyceal distance, stone burden, stone density, and access location as variables to predict operative time.

Parameter	**Estimate of Covariate Coefficients**	**Standard Error**	**Wald 95% Confidence Limits**		**P-value**
Group Comparison (Standard vs. LD)	-11.912	8.805	-29.170	5.347	0.1761
STCD	-0.199	0.175	-0.541	0.144	0.2556
Stone Burden	0.544	0.142	0.265	0.822	0.0001*
Stone Density	0.009	0.011	-0.013	0.032	0.4056
Middle Pole Access	5.038	15.032	-24.425	34.500	0.7375
Lower Pole Access	15.675	8.926	-1.821	33.170	0.0791
*Denotes statistical significance, p < 0.05					

Table 5
Results of multivariable regression analysis using skin-calyceal distance, stone burden, stone density, and access location as variables to predict the odds of post-op SFS.

Odds Ratio Estimates				
Effect	Point Estimate	95% Wald Confidence interval		P-value
Group	0.831	0.233	2.962	0.7749
STCD	1.008	0.984	1.033	0.5083
Stone Burden	0.959	0.936	0.982	0.0007*
Stone Density	1	0.999	1.002	0.5563
Middle Pole vs. Upper Pole Access	0.116	0.013	1.006	0.2857
Lower Pole vs Upper Pole Access	0.114	0.029	0.446	0.1056
*Denotes statistical significance, p < 0.05				

Discussion

In this study, we demonstrate that a low-dose fluoroscopy protocol significantly reduced patient radiation exposure without affecting clinical outcomes such as operative time, fluoroscopy time, stone-free rate or complications suggesting that the LD protocol can provide safe and efficient fluoroscopy guidance during PCNL without compromising patient outcomes. These results were obtained and remain significant without any selection bias with regards to BMI. From the multivariable regression models, these data support the known association between higher STCD and higher operative times. Additionally, a higher preoperative stone burden was associated with longer operative time and lower odds of postoperative SFS.

Impetus for change came from anecdotal observation that PCNL cases resulted in significant radiation exposure to the patient. From the surgeon’s experience, applying the low-dose fluoroscopy technique caused a slight readjustment to the workflow. However, by the end of the first case, the surgeon and assistants were comfortable with using the technique. Residents had difficulty using 4PPS during needle access, and thus 8PPS was used, which was felt to be adequate.

Vassileva et al. described radiation exposure associated with endourologic procedures with data from several centers. In this analysis, four centers reported average radiation exposure during PCNL of ranging from 27.0 mGy to 58.4 mGy [4]. This is comparable to the standard dose protocol used in our study. Implementation of the LD protocol led to a four-fold decrease in total radiation exposure in our study.

In the era of ALARA and increased awareness of the potential dangers of ionizing radiation, fluoroscopy guidance in PCNL has come under scrutiny as a target for improvement and optimization. To this end, several groups have reported the use of ultrasound-guided access and dilation. In general, fluoroscopy is still used for the dilation and drainage tube placement portions. Zampini et al. reported a mean radiation dose of 14.21 and 14.67 mGy with ultrasound-guided percutaneous access with prone and supine positions, respectively, while Chi et al. reporting a mean radiation dose of 3.1 ± 3.2 mGy with fluoroscopy only used for nephrostomy tube placement[5, 6]. In Zampini's study, on average patients had a BMI of 27.28 and 29.60 for the prone and supine positions respectively. They also reported a STCD of 91.3 mm and 83.7 mm for the prone and supine groups respectively. In this study, we demonstrate that using the low dose protocol in an initial cohort of 31 patients brought the cumulative radiation exposure to 11.68 ± 7.01 mGy. We also saw that the last fifteen of these had only approximately 9 mGy of radiation exposure, suggesting that the low dose protocol can be further optimized. Despite a mildly higher BMI and STCD in our study, we were able to achieve a lower cumulative radiation dose. The results of our study may be especially relevant to practice settings where acquisition of additional and oftentimes expensive ultrasound equipment represents a significant potential investment.

Bayne et al showed that higher BMI was associated with a more challenging learning curve for ultrasound guided PCNL[7]. Of note, the mean BMI was 32 ± 7.7 (standard 30; LD 32) in our cohort, with the average patient meeting the "obese" definition. In the Chi et al. study, the average BMI was 26, possibly decreasing ability to generalize conclusions to a more obese population[5]. Furthermore, the lack of hydronephrosis and presence of staghorn calculi have been associated with less successful ultrasound PCNL access[8, 9]. Our data support the utility of a low-dose fluoroscopy protocol, which does not require training in use of a separate technology and is equally effective in obese and morbidly obese patients. Clinical outcomes and rate of success of percutaneous access were unchanged when using the LD protocol.

In a study from Elkoushy et al, using pulsed fluoroscopy with a pulsed frequency of 4 frames per second on PCNL was associated with a decrease in *fluoroscopy time* compared to continuous fluoroscopy of 30 frames per second (341.1 vs 121.5 sec, $p < 0.001$)[10]. Fluoroscopy time was used in this study as a surrogate for radiation dose. The data presented here support the conclusion that decreased fluoroscopy frame rate can reduce intraoperative radiation exposure.

The limitations of this study include its single institution, single surgeon, and unblinded nature. Other potential bias that may have occurred from the study include the Hawthorne effect since the protocol change was made outside of a controlled experiment. An overall cohort of 100 subjects may limit the power of the statistical analysis. Surgeon preference at this institution is to pursue upper pole access when safe to do so. As such, there were few observations for the middle and lower pole accesses (6 in the standard treatment protocol, and 3 in the LD). These data suggest the feasibility of low-dose radiation protocols reducing radiation without compromising clinical outcomes or requiring use of a separate imaging modality.

Future investigations should test this protocol in a prospective, randomized fashion to ensure consistency of results. Expanding the study design to include additional surgeons and multiple institutions would further corroborate the results. A more aggressive reduction of the frame rate to 2 PPS for most of the case would further reduce radiation exposure[10, 11]. In the experience of the surgeon, while 4 PPS is feasible for most straightforward needle punctures in experienced hands, there is an anecdotally higher risk of requiring more than one puncture (and therefore higher radiation exposure) when residents or fellows are being trained. Based on previous literature, comprehensive preoperative review of imaging and the use of end-expiration timed fluoroscopy in combination with the low-dose fluoroscopy protocol should yield great reductions in cumulative radiation exposure[12].

Conclusion

In this study, we demonstrate that a low-dose fluoroscopy protocol that decreases per-frame radiation and frame rate during PCNL led to a four-fold decrease in patient radiation exposure without affecting stone-free rates and complication rates. Combining this protocol with diligent preoperative planning promises to minimize radiation exposure in traditional fluoroscopy-guided PCNL without compromising clinical outcomes.

Statements And Declarations

Competing Interests: The authors disclose no financial or non-financial interests that are directly or indirectly related to the work submitted for publication.

Ethics Approval: Ethical approval was waived by the local Ethics Committee of University of Rochester Medical Center in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.

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