

Prospective Systematic Intervention to Reduce Patient Exposure to Radiation During Pediatric Ureteroscopy

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Abbreviations and Acronyms

ALARA = as low as reasonably achievable

AP = anterior to posterior

DAP = dose area product

ESD = entrance skin dose

MLD = midline absorbed dose

SSD = source-to-skin distance

URS = ureteroscopy

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Study received institutional review board approval.

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Purpose: After prospective measurement of radiation exposure during pediatric ureteroscopy for urolithiasis, we identified targets for intervention. We sought to systematically reduce radiation exposure during pediatric ureteroscopy.

Materials and Methods: We designed and implemented a pre-fluoroscopy quality checklist for patients undergoing ureteroscopy at our institution as part of a quality improvement initiative. Preoperative patient characteristics, operative factors, fluoroscopy settings and radiation exposure were recorded. Primary outcomes were the entrance skin dose in mGy and midline dose in mGy before and after checklist implementation.

Results: We directly observed 32 consecutive ureteroscopy procedures using the safety checklist, of which 27 were done in pediatric patients who met study inclusion criteria. Outcomes were compared to those in 37 patients from the pre-checklist phase. Pre-checklist and postchecklist groups were similar in patient age, total operative time or patient thickness. The mean entrance skin dose and midline dose were decreased by 88% and 87%, respectively ($p < 0.01$). Significant improvements were noted among the major radiation dose determinants, total fluoroscopy time (reduced by 67%), dose rate setting (appropriately reduced dose setting in 93% vs 51%) and excess skin-to-intensifier distance (reduced by 78%, each $p < 0.01$).

Conclusions: After systematic evaluation of our practices and implementation of a fluoroscopy quality checklist, there were dramatic decreases in radiation doses to children during ureteroscopy.

Key Words: kidney, nephrolithiasis, ureteroscopy, radiation dosage, checklist

MEDICAL radiation exposure is a major concern in the United States and it represents the most rapidly increasing source of radiation exposure.¹ Children have a longer remaining life span and more radiosensitive tissues, making them particularly vulnerable to the long-term effects of ionizing radiation.² The United States National Council on Radiation Protection and

Measurements advocates the ALARA principle when using ionizing radiation for medical purposes and the Alliance for Radiation Safety in Pediatric Imaging recently released the "Image Gently" campaign to bring attention to the need for judicious use of radiation in pediatric patients.^{3,4}

We recently reported a systematic investigation of radiation exposure

levels in pediatric patients undergoing URS at our institution.⁵ Of the major determinants of radiation exposure total fluoroscopy time was most important, followed by dose rate setting, patient thickness and skin-to-source distance. Data obtained from direct observation of procedures as part of a quality improvement project were used to identify opportunities for reducing radiation without prohibiting safe, effective completion of the procedure.

We designed and implemented a pre-fluoroscopy surgical checklist meant to decrease radiation exposure during URS in pediatric patients with stones.

METHODS

After receiving institutional review board approval, we prospectively monitored all URS procedures done by 6 pediatric urologists (surgeons) at our institution from September 2009 to December 2010. Specific data collection methods were previously described in detail.⁵ Briefly, a trained research assistant was present for each URS procedure in its entirety who collected data on patient characteristics, operative factors, fluoroscopy settings and radiation exposure.

Based on the findings of this project, we designed a pre-fluoroscopy checklist with collaborative input from multiple stakeholders. This was tested during several procedures before undergoing subsequent revisions. The final checklist included 6 items and was pilot tested on several additional procedures before laminated copies were fixed to the fluoroscopy machines (see Appendix). In addition, a radiation physicist gave a 50-minute didactic session to the urology department. No other protocol changes were made by the department during this period.

After incorporating the checklist in regular clinical use, we again prospectively obtained data from June 2011 to June 2012 on the same surgeons, collected variables, personnel (a radiation technologist activated imaging according to standard practice at this center) and equipment (BV Pulsera mobile units, Phillips, Best, The Netherlands) as during the initial study period with additional information on checklist use. The same criteria were used for inclusion/exclusion as in the prior report, limiting patients to those younger than 21 years undergoing unilateral URS for urolithiasis.⁵ Distinct from the pre-checklist procedures, surgeons and operating room staff were informed about checklist components and primary project aims.

Our primary outcome measure was the patient radiation dose, calculated as ESD and MLD. ESD estimates radiation dose to the skin, which is the organ that receives the maximum dose, while MLD is a better approximation of the average dose received by all irradiated tissue. Doses were indirectly measured from the dosimeter of the fluoroscopy unit (air kerma) at 70 cm from the radiation source. To calculate ESD, air kerma is adjusted for backscatter by a factor of 1.2, bed/pad attenuation measured as 0.40 at 70 kV and observed SSD using the inverse square law. MLD at the midpoint of the patient umbilical AP diameter, measured with calipers by the

surgeon, researcher or staff, was estimated from the calculated ESD by applying appropriate tissue attenuation factors for a 70 kV beam from a mobile fluoroscope. SSD was calculated from direct measurement of the patient, table height and fluoroscopy unit. In this study we added DAP as an additional dose index, corrected for table attenuation. The DAP in mGy m² considers collimation, a process by which peripheral or iris-type radiation barriers are used to block radiation delivery to the periphery of the field of view. This results in a smaller portion of the patient body exposed to the direct beam and can significantly decrease the total radiation delivered. All dose calculations were performed under the supervision of a radiation physicist (KJS).

Known determinants primarily responsible for radiation exposure in the setting of fluoroscopy include patient AP diameter, total fluoroscopy time, SSD and the dose rate setting of the fluoroscope, eg voltage and tube current. Differences in these determinants between the pre-checklist and postchecklist cohorts were compared by univariate tests of association, including the t or Wilcoxon rank sum, chi-square or Fisher exact test based on data characteristics. Multivariate linear regression was used to control for potential confounding when sufficient data points per outcome group were available. For the fluoroscopy time outcome items identified as potential predictors at $p \leq 0.1$ in our prior study⁵ were included on multivariate analysis. Log transformation was performed on skin entrance dose and DAP outcomes to allow for parametric analysis. All analyses were performed using SAS®, version 9.2. All tests were 2-sided with $p \leq 0.05$ considered statistically significant.

RESULTS

We observed 32 URS procedures using the fluoroscopy checklist, of which 5 were excluded from study due to patient age greater than 21 years, leaving 27 patients. We compared the characteristics of this group to those of the pre-checklist cohort of 37 patients (table 1). The groups were similar in age, AP diameter, preoperative stent in place, post-lithotripsy stenting, ureteral access sheath and safety wire use, retrograde pyelograms and trainee role. Time required to complete the checklist was anecdotally noted to be less than a minute.

Table 2 lists radiation dose outcomes in the pre-checklist and postchecklist groups. Compared to the pre-checklist group, mean ESD was decreased in the postchecklist group by 88% from 46.4 to 5.7 mGy ($p < 0.01$). Similarly, mean MLD was reduced by 87% from 6.2 to 0.8 mGy ($p < 0.01$). DAP was decreased by 88% from 0.82 to 0.10 mGy m² ($p < 0.01$). After adjusting for the effect of small differences in patient thickness, reductions in primary dose outcomes remained significant (changes in ESD, MLD and DAP after vs before checklist each $p < 0.01$).

Significant improvements were noted among the major radiation dose determinants. Total fluoroscopy time was decreased by 67% from 2.68 to

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