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

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Abstract

Purpose—After prospective measurement of radiation exposure during pediatric ureteroscopy (URS) for urolithiasis, we identified targets for intervention. Our objective was to systematically reduce radiation exposure during pediatric URS.

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

Results—Direct observation was performed on 32 consecutive URS procedures using the safety checklist, 27 of whom were pediatric patients meeting inclusion criterion. Outcomes were compared to 37 patients from the pre-checklist phase. Pre- and post-checklist groups were similar with regard to patient age, total surgical time, or patient thickness. Mean ESD was reduced by 88% ($p < 0.01$) and mean MLD by 87% ($p < 0.01$). Significant improvements were noted among the major determinants of radiation dose including the total fluoroscopy time (reduced by 67%, $p < 0.01$), dose rate setting (appropriate reduced dose setting in 93% vs 51%, $p < 0.01$), and excess skin to intensifier distance (reduced by 78%, $p < 0.01$).

Conclusions—After systematic evaluation of our practices and implementation of a fluoroscopy quality checklist, there were dramatic reductions in the radiation doses to children during URS procedures.

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Keywords

Nephrolithiasis; Pediatrics; Urolithiasis; Radiation

Introduction

Medical radiation exposure is a major concern in the United States and represents the most rapidly increasing source of radiation exposure.¹ Children have a longer remaining lifespan 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 (NCRP) advocates the “as low as reasonably achievable” (ALARA) principle when using ionizing radiation for medical purposes, and the Alliance for Radiation Safety in Pediatric Imaging recently released their “Image Gently” campaign to bring attention to the need for judicious use of radiation in pediatric patients.^{3, 4}

We recently published a systematic investigation into the radiation exposure levels for pediatric patients undergoing ureteroscopy at our institution.⁵ Among 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 radiation reduction without prohibiting the safe and effective completion of the procedure.

The aim of this current project was to design and implement a pre-fluoroscopy surgical checklist aimed at reducing radiation exposure during ureteroscopy in pediatric stone patients.

Methods

After IRB approval, we prospectively monitored all URS procedures by pediatric urologists (n=6 surgeons) at our institution from September 2009 to December 2010. The specifics of data collection methods have been described in detail previously.⁵ In short, a trained research assistant was present for each ureteroscopic procedure in its entirety, and collected data on patient characteristics, operative factors, fluoroscopy settings and radiation exposure.

Based on the findings from this project, a pre-fluoroscopy checklist was designed with collaborative input from multiple stakeholders and 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. (Figure 1) 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 time period.

After incorporation of the checklist in regular clinical use, we again performed prospective data collection from June 2011 to June 2012 using the same surgeons, collected variables,

personnel (a Radiation Technologist activated the imaging as per standard practice at this center) and equipment (Phillips® BV Pulsera mobile units) as the initial study period with additional information regarding checklist use. The same criterion were used for inclusion/exclusion as in the prior report (limiting to patients <21 years old undergoing unilateral ureteroscopy for urolithiasis).⁵ Distinct from the pre-checklist procedures, surgeons and operating room staff were informed about the checklist components and the primary project aims.

Our primary outcome measure was patient radiation dose, calculated as both entrance skin dose (ESD) and midline dose (MLD). ESD estimates radiation dose to the skin, 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 fluoroscopy unit's dosimeter: (air kerma) at 70 cm from the radiation source. To calculate ESD, the air kerma is adjusted for back scatter (factor of 1.2), bed/pad attenuation (measured as 0.40 at 70kV), and observed source-to-skin distance (SSD) (using the inverse square law). MLD at the midpoint of the patient's umbilical AP diameter (measured with calipers by surgeon, researcher or staff) was estimated from the calculated ESD by applying appropriate tissue attenuation factors for a 70kV beam from a mobile fluoroscope. SSD was calculated from direct measurements of the patient, table height and fluoroscopy unit. In this report we added the dose area product (DAP) as an additional dose index, corrected for table attenuation. The DAP (mGy²) takes into account the use of 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's body that is exposed to the direct beam and can significantly reduce the total radiation delivered. All dose calculations were performed under the supervision of a radiation physicist (KS).

The known determinants primarily responsible for radiation exposure in the setting of fluoroscopy include the patient AP diameter, total fluoroscopy time, SSD, and the fluoroscope's dose rate setting (e.g. voltage and tube current). Differences in these determinants between the pre- and post-checklist cohorts were compared with univariate tests of association (t-tests or Wilcoxon rank sum, chi-square or Fisher's exact tests based on data characteristics). Multivariable linear regression was used to control for potential confounding when sufficient data points per outcome group were available. For the outcome of fluoroscopy time, items that were identified as potential predictors (p < 0.1) in our prior publication⁵ were included in multivariable analyses. 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 (SAS Institute Inc., Cary, NC). All tests were two-sided and p-values of 0.05 or less were considered statistically significant.

Results

We observed 32 URS procedures using the fluoroscopy checklist, 5 of which were excluded (due to patient age > 21 years) leaving 27 patients. Characteristics of this group compared to the pre-checklist cohort of 37 patients. (Table 1) Groups were similar in terms of age, anterior-posterior diameter, pre-operative stent in place, post-lithotripsy stenting, ureteral

access sheath use, safety wire use, retrograde pyelograms, and trainee role. Time taken to complete the checklist was anecdotally noted to be less than a minute.

Radiation dose outcomes in the pre- and post-checklist groups are presented in Table 2. Mean ESD was reduced in the post-checklist group by 88% from 46.4 to 5.7 mGy ($p<0.01$) as compared to the pre-checklist group. Similarly, mean MLD was reduced by 87% from 6.2 mGy to 0.8 mGy ($p<0.01$). The DAP was reduced by 88% from 0.82 mGym² to 0.10 mGym² ($p<0.01$). After adjusting for the effect of small differences in patient thickness, reductions in primary dose outcomes remained significant ($p<0.01$ for changes in ESD, MLD, and DAP in post compared to pre-checklist groups).

Significant improvements were noted among the major determinants of radiation dose. The total fluoroscopy time was reduced by 67% (from 2.68 to 0.88 mins, $p<0.01$). Mean reduction by individual surgeon was 69% (range 45%–89% decrease). The total stone volume (assuming spherical shape, $p=0.13$) and type of ureteroscope (semi-rigid ($n=13$) vs flexible ($n=51$), $p=0.20$) were not significantly associated with fluoroscopy time. Cases with complications did have higher average fluoroscopy times ($p=0.01$), however they accounted for only 8% of the reduced fluoroscopy time in the post intervention group and did not alter the results when added to the multivariable model. After adjusting for access sheath use, retrograde pyelography, and post-lithotripsy stent placement in a multivariable model, significant reductions (-2 min 95% CI -1.3 to -2.7 , $p<0.01$) in total fluoroscopy time were still seen in the post- as compared to pre-checklist groups.

An appropriate or reduced dose rate setting was used in 93% in the post- as compared to only 51% in the pre-checklist group ($p<0.01$). In 12/27 (44%) instances a lower than maximum allowable setting was used in the post-checklist group as compared to only 1/37 (3%) cases in the pre-checklist group. The average excess skin to intensifier distance was reduced by 78% (from 12.3 cm to 2.7 cm $p<0.01$). The effect of this was an increase in the average source to skin distance (from 67 cm to 76 cm) and lowering of the radiation dose by 22% on average. Collimation was used in only one case (3%) in the pre-checklist cohort and in 6/27 (22%) in the post-checklist cohort (the reduction in the exposure field secondary to collimation was not directly measured).

Discussion

The use of medical radiation is an especially important issue in the pediatric population. Children are up to 3–10 times more radiation-sensitive than adults because of a longer life span and relatively higher radiosensitivity.⁶ Collaborative efforts of clinicians, radiation physicists, public health officials and industry have promoted the ALARA principle,⁷ and there is widespread agreement that reducing radiation exposure is a public health priority.^{4, 8} The Pause and Pulse initiative from the Image Gently Campaign of the Alliance for Radiation Safety in Pediatric Imaging specifically addresses the use of fluoroscopy in young patients.³ With respect to genitourinary related procedures, there are reports of significant variations in the number of images, fluoroscopy times, and total radiation doses for the same type of procedure.⁹ This variation suggests that a common protocol may assist in reducing radiation doses in keeping with the ALARA principle.

There are a number of published reports describing efforts to reduce radiation exposure for patients with genitourinary conditions. Some have focused on diagnostic procedures such as voiding cystourethrography^{10, 11} for congenital abnormalities or CT scanning for identification of urolithiasis.^{12, 13} Others have looked at ways to reduce radiation exposure during endourological procedures with specific protocols and technical modifications.¹⁴ An example of such a protocol was designed to standardize how many images and which types were to be typically performed during urodynamic studies, yielding 71% reduction in fluoroscopy times (40.9 to 11.7 seconds per procedure), 73% reductions in mean air kerma (15.48 to 4.25 mGy), and 71% reduction in mean dose area product (518.90 to 150.28 mGym²).¹⁵ Another investigation of cystogram protocols found that adjusting machine settings has the potential to reduce radiation without compromising study quality.¹⁶

Taking a cue from the aerospace and other high-risk industries, checklists have been introduced into the operating room environment and evidence suggests that their use can significantly improve outcomes and reduce the incidence of errors.¹⁷⁻¹⁹ Video monitored investigations of operating room personnel have shown that critically important steps are 6 times as likely to be performed when a checklist is available.²⁰ In addition to the performance of key process measures, checklists are associated with fewer complications and improvement in clinician perceptions of teamwork and safety climate.¹⁷

Simply constructing and mandating a thorough safety checklist, however, is not sufficient for achieving successful long-term radiation reduction goals. It is clear that a more holistic, systems based approach is needed to achieve maximal levels of effectiveness, safety, and quality.²¹ Efforts to explain the rationale behind the checklist, “buy-in” from surgical staff, and training in the proper use of the checklist are all critical to success.²² Our own anecdotal experience confirms the need for training; the checklist had to be initiated at first by the research assistant, and specific steps, such as patient and fluoroscope positioning, had to be demonstrated. We also solicited input from surgeons, radiation physicists, radiologists, radiation technologists and nursing staff when designing the checklist and determining logistics for the timing of key steps and the location of equipment.

While a checklist does help to achieve the lowest reasonably achievable doses, other strategies may be important as well. Lower total exposure times have been found when there is routine documentation of fluoroscopy times in official reports (40%) or when feedback is provided (24%).^{10, 23} In addition, specialized equipment such as laser-guided c-arms and a dedicated radiologic technologist familiar with the nuances of pediatric ureteroscopy may also be important components of an overall dose reduction program.¹⁴ Finally, the introduction of new technologies may be able to reduce doses in the future as demonstrated by the success of pulsed fluoroscopy and digital imaging.

Fluoroscopy machines allow various exposure settings including continuous and pulsed modes as well as reduced dose rate settings that allow for maintained image quality with lowered radiation exposure. The final checklist allowed for the lowest dose rate setting to be used at the start of the procedure as a default when patient thickness measurements were not available; in cases where the initial positioning images were of insufficient quality, the dose rate setting could then be increased. Interestingly, surgeons were content with the image

quality at the lowest setting in almost every instance, and typically completed the case with the lower setting.

The results of our analyses should be interpreted in light of their limitations. This study involves patients treated at a single tertiary center and patient characteristics, surgical practices and other factors in this setting may not apply to other settings. Although we did compare procedures with and without the checklist, this study was not a randomized trial, and therefore differences in outcomes between the pre- and post-checklist groups may be due to factors other than the initiation of the checklist, such as changes in procedure techniques or equipment, or greater general awareness of radiation safety issues. However, we believe that the magnitude of reductions in observed exposure is such that it is highly unlikely that such ancillary factors would have had such an impact. Furthermore, it is possible that the findings were due in part to the Hawthorne effect (surgeons and OR staff were aware that they were being observed and altered their behavior as a consequence).²⁴ However, it should be pointed out that surgeons and staff were aware that they were being monitored during both the pre- and post-checklist periods. Therefore, while the overall exposure levels measured during the course of the study may have been reduced by the Hawthorne effect, this would do little to explain the differences between study periods. We also cannot comment on the long-term effectiveness of the checklist to maintain these reduced exposure levels. Finally, as with our prior report, indirect methods were used to calculate patient dose outcomes from measured exposure levels. Despite strong correlation between indirect and direct methods, estimated patient doses always contain some error.

Conclusion

The use of a pre-fluoroscopy checklist resulted in significant reductions in overall radiation doses and fluoroscopy times delivered to pediatric patients undergoing ureteroscopy for urolithiasis. Additional systems changes may provide further reductions, and efforts need to be made to ensure the durability of these effects.

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Abbreviations

ALARA	As Low As Reasonably Achievable
ESD	Entrance skin dose
MLD	Midline absorbed dose
SSD	Source to skin distance
URS	Ureteroscopy

AP	Anterior to posterior
CT	Computed tomography
DAP	Dose Area Product

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Fluoroscopy Checklist

1. Are the patient's arms to the side?
2. Is the table height OK?
3. Has intensifier been brought to within one fist of patient?
4. What is the patient thickness? Has the dose rate setting been adjusted for patient size?
 - a. Toddler: A-P diameter <12 cm
 - b. Child: A-P diameter 12-20 cm
 - c. Adult: A-P diameter >20 cm

**If patient thickness hasn't been measured, set to "toddler" for first image

5. Is the exposure mode set to digital?
6. Is everyone wearing lead?

Notes:

<p>Standard Accepted Terminology:</p> <ul style="list-style-type: none"> • "Live Fluoro" • "Spot Fluoro" or "Single X-ray" • "Off" or "Stop" • "Save" • "High Resolution" or "High Dose" • <i>Repeat Back to surgeon</i>
<p>Collimate when deemed appropriate</p> <ul style="list-style-type: none"> • i.e. if only working on Right side, collimation on the left
<p>Feedback at the end of case</p> <ul style="list-style-type: none"> • i.e. fluoroscopy time and radiation dose

Figure 1.

Pre-fluoroscopy Checklist. The included portions represent key factors identified using data from the initial data collection period and input from stakeholders. The primary goal was simplicity and attention to safe performance of the procedure first (eg surgeon comfort for item #2) followed by important radiation reduction maneuvers.

Table 1

Descriptive Information.

Child Factors	Pre-Intervention (n=37)	Post-Checklist (n=27)
Age		
Mean (yrs)	14.8± 4.0	16.0± 4.0
Less than 6 years	0 (0%)	2 (7%)
6–10 years	7 (19%)	2 (7%)
10–12 years	2 (5%)	4 (15%)
>12 years	28 (76%)	19 (70%)
Anterior Posterior Thickness (at Umbilicus in cm)	18.6± 4.3	17.8± 3.7
Technical Related Factors		
Total Surgery Time (min)	73± 45	76± 39
Pre-op stent in place (n)		
Yes	41% (15)	44% (12)
No	59% (22)	56% (15)
Post-op stent (n)		
Yes	84% (31)	89% (24)
No	16% (6)	11% (3)
Ureteral Access Sheath (n)		
Yes	70% (26)	70% (19)
No	30% (11)	30% (8)
Retrograde Pyelogram (n)		
Yes	86% (32)	93% (25)
No	14% (5)	7% (2)
Safety Wire Used (n)		
Yes	84% (31)	100% (27)
No	16% (6)	0% (0)
Complications (n)		
Yes	11% (4)	0% (0)
No	89% (33)	100% (27)
Surgeon		
Trainee Role (n)		
<50%	8% (3)	7.5% (2)
50%	81% (30)	81.5% (22)
>50%	11% (4)	11% (3)

Table 2

Primary dose outcomes for pediatric ureteroscopy before and after implementation of the fluoroscopy checklist.

Primary Outcomes	Pre-Intervention	Post-Checklist	% Change	p-value
Entrance Skin Dose (mGy)	46.4 (range 2.7–223)	5.7 (range 0.4–34.4)	88%	<0.01
Midline Dose (mGy)	6.2 (range 0.7–17.1)	0.8 (range 0.07–3.1)	87%	<0.01
Dose Area Product (mGy ²)	0.82 (range 0.01–8.88)	0.10 (range 0.01–0.57)	88%	<0.01
Modifiable Determinants of Dose				
Total Fluoroscopy time (min)	2.68 ± 1.8	0.88 ± 0.8	67%	<0.01
Proportion Using Higher than Recommended Dose Rate Setting	49% (18/37)	7.4% (2/27)	85%	<0.01
Skin Exit to Intensifier (cm)	12.3 ± 6.7	2.7 ± 4.9	78%	<0.01