Prospective Assessment of Radiation in Pediatric Urology: The Pediatric Urology Radiation Safety Evaluation Study

A. G. Dudley,* M. E. Dwyer, J. A. Fox, J. T. Dwyer, P. Dangle, B. T. Ristau, H. A. Stephany, F. X. Schneck, G. M. Cannon and M. C. Ost

From the Department of Urology, Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania, and de la Torre Research, New York, New York (JTD)

Abbreviations and Acronyms

BMI = body mass index

CT = computerized tomography

FPS = frames per second

PCNL = percutaneous nephrolithotomy

Accepted for publication January 24, 2016.

No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

Study received institutional review board approval (No. PRO10040374).

* Correspondence: Department of Urologic Surgery, Vanderbilt University Medical Center, AA-1302 Medical Center North, 1161 21st Ave. South, Nashville, Tennessee 37232 (e-mail: annedudleymd@gmail.com).

Purpose: Pediatric tissues are exquisitely sensitive to ionizing radiation from diagnostic studies and therapies involving fluoroscopy. We prospectively monitored radiation exposure in our pediatric urology patients during fluoroscopy guided operative procedures with single point dosimeters to quantify radiation dose.

Materials and Methods: Children undergoing fluoroscopy guided urological procedures were prospectively enrolled in the study from 2013 to 2015. Single point dosimeters were affixed to skin overlying the procedural site for the durations of the procedures to record dosimetry data. Patient demographics, procedural variables and fluoroscopic settings were recorded.

Results: A total of 78 patients underwent 96 procedures, including retrograde pyelography, ureteral stent insertion, ureteroscopy and percutaneous nephrolithotomy. Median patient age was 12 years (range 0.3 to 17) and median body mass index percentile for age was 70.7 (1.0 to 99.1). Median skin entrance radiation dose for all procedures performed was 0.56 mGy. Median dosages associated with the 29 diagnostic procedures and 49 definitive interventions were 0.6 mGy (mean 0.8, range 0.1 to 2.2) and 0.7 mGy (1.1, 0.0 to 5.5), respectively. The dose associated with the 18 procedures of temporization was significantly higher by comparison (median 1.0 mGy, mean 2.6, range 0.1 to 10.7, $p = 0.02$).

Conclusions: Pediatric radiation exposure is not insignificant during urological procedures. Further multi-institutional work would provide context for our findings. Protocols to optimize fluoroscopic settings and minimize patient exposure, and guidelines for radiation based imaging should have a key role in all pediatric radiation safety initiatives.

Key Words: diagnostic techniques, urological; endoscopy; nephrolithiasis; pediatrics; radiation exposure

UROLOGICAL operative procedures often use fluoroscopy for diagnosis and treatment of stone disease and structural anomalies, and to determine the etiology of hematuria. Pediatric tissues are uniquely sensitive to the effects of ionizing radiation with infants and young children, particularly those with genetic instability syndromes, at the greatest risk.[1] Stochastic effects of radiation such as malignancy are thought to be cumulative and dose dependent.[2] Congenital anomalies and metabolic conditions predispose pediatric urology patients to repeated radiation

0022-5347/16/1961-0202/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2016.01.109
Vol. 196, 202-206, July 2016
Printed in U.S.A.

exposure during diagnosis, treatment and followup. We prospectively documented radiation exposure in a cohort of patients undergoing procedures with fluoroscopic guidance.

METHODS

Eligible patients 0 to 18 years old undergoing fluoroscopy guided urological procedures at our institution between 2013 and 2015 were invited to enroll in this prospective institutional review board approved study (No. PRO10040374). The procedures could be unilateral or bilateral and included PCNL; cystoscopy with retrograde pyelography; intraoperative cystography; ureteral stent placement, removal or exchange; ureteroscopy, and any combination thereof. The only exclusion criterion was parent unwillingness to enroll the patient.

The urological surgeons were not blinded. After induction of anesthesia a member of the surgical team affixed a nanoDot™ thermal leak detector using a standardized clear adhesive patch (fig. 1). All dosimeters were calibrated by a radiation safety officer before use. If the procedure included imaging of the renal pelvis, the dosimeter was applied to the tip of the ipsilateral twelfth rib. If the procedure did not include imaging of the renal pelvis, the dosimeter was applied posteriorly to the ipsilateral sacroiliac joint. For a bladder procedure dosimeters were placed posteriorly at the level of the sacroiliac joints in the midline. A clarification in our methods midway through the study resulted in 16 patients who underwent bilateral procedures with a single dosimeter in place (16 dosimeters) and 5 patients who underwent bilateral procedures with 2 dosimeters in place (10 dosimeters).

Figure 1. nanoDot thermal leak detector (ie dosimeter for measurement of skin entrance radiation doses).

All fluoroscopy was performed with a C-arm fluoroscopy machine (OEC® 9910 Elite) that uses an integral device to compare emitted radiation dose with the returned dose, thereby calculating the air kerma (mGy). Fluoroscopy FPS and dose mode were recorded. Skin to source distance was measured with a designated laser distance tool. After procedure completion dosimeters were transferred to a blinded radiation safety officer for analysis.

Patient charts were reviewed retrospectively to assess radiation based imaging performed during the study period. CTs and x-rays were each counted as 1 imaging study.

Statistical analyses were performed using R statistical programming software, version 3.0.2-1 (R Project for Statistical Computing, http://www.R-project.org). Akaike information criterion backward stepwise feature selection pruning of 50 variables was performed to create a simpler model for assessment of linear regression dependence. Confidence intervals were based on 1,000 bootstrap replicates using seed 2116113. The Grubb test was used to identify outliers ($p < 0.05$) and the Student t-test was used to compare independent means. A p value of 0.05 or less was considered significant.

RESULTS

A total of 96 dosimeters were collected from 78 patients who underwent 34 right-sided procedures, 34 left-sided procedures, 21 bilateral procedures and 2 bladder procedures. Median patient age was 12 years and male-to-female ratio was 0.85:1. Median BMI percentile was 70.7 (range 1.0 to 99.1). Additional patient characteristics are outlined in table 1. There were 17 types of procedures performed. Only 1 case included PCNL, 36 cases included ureteroscopy and 59 cases involved neither. There were 19 specific indications for surgery. Cases were categorized as definitive intervention in 49 instances, diagnostic study in 29 and temporizing measure in 18. Frame rate (FPS) was 15 (continuous) for 57 procedures and 8 (pulsed) for 33. The mode was set to low dose for all but 2 procedures.

Type of Procedure

The skin entrance dose for procedures including unilateral ureteroscopy (median 0.82 mGy, mean 1.21, range 0.04 to 4.45) was significantly higher

Table 1. *Patient characteristics*

Mean yrs age at procedure (range)	10.7 (0.3—17)
Mean ± SD BMI (kg/m^2) at procedure	21.3 ± 6.0
Mean ± SD BMI percentile for age	61.2 ± 32.5
Mean ± SD urological operations at single institution during lifetime	1.9 ± 1.7
Mean ± SD abdominal/pelvic fluoroscopies/radiograms	2.1 ± 4.3
Mean ± SD abdominal/pelvic CTs	0.4 ± 1.1