

A novel dosimeter for measuring the amount of radiation exposure of surgeons during percutaneous nephrolithotomy: Instadose™

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Introduction The aim of this study was to demonstrate the efficacy of Instadose™, a novel dosimeter designed for radiation workers to provide a measurement of the radiation dose at any time from any computer; to determine the amount of radiation exposure during percutaneous nephrolithotomy (PNL); and to evaluate the factors that affect the amount of radiation exposed.

Material and methods Two experienced surgeons wore Instadose™ on the outer part of their lead aprons during the PNL procedures performed between December 2013 and July 2014. Patient demographics and stone characteristics were noted. Factors affecting radiation dose were determined. Fluoroscopic screening time was compared with the amount of radiation in order to validate the measurements of Instadose™.

Results Overall, 51 patients with a mean age of 43.41 ± 18.58 (range 1–75) years were enrolled. Male to female ratio was 35/16. The amount of radiation was greater than 0.01mSv in only 19 (37.25%) cases. Stone location complexity ($p = 0.380$), dilation type ($p = 0.584$), stone size ($p = 0.565$), dilation size ($p = 0.891$) and access number ($p = 0.268$) were not associated with increased radiation exposure. Instadose™ measurements were correlated with fluoroscopic screening time ($r = 0.519$, $p = 0.001$).

Conclusions Instadose™ is a useful tool for the measurement of radiation exposure during PNL. The advantage of measuring the amount of radiation exposure after each PNL operation is that it may aid urologists in taking appropriate precautions to minimize the risk of radiation related complications.

Key Words: exposure ↔ fluoroscopy ↔ kidney stone ↔ percutaneous nephrolithotomy ↔ radiation ↔ urinary stone disease

INTRODUCTION

Ionizing radiation exposure of the population in the United States has almost doubled during the past two decades, and medical procedures are considered to be the main source of radiation [1]. This radiation exposure comes from diagnostic imaging studies as well as fluoroscopic visualization utilized during therapeutic interventions. The estimated personal radiation exposure in 2006 was 3.0mSv and computed tomography contributed to almost 50% of the total amount whereas radia-

tion from interventions utilizing fluoroscopy, accounts for 14% [2].

With its increased prevalence all over the world during recent years, urinary stone disease is becoming an important health problem and patients with urinary stone disease are at a higher risk for increased radiation exposure [3, 4, 5]. It has been shown that after an acute stone event, the median total effective radiation dose received per patient is 29.7mSv during the first year of follow-up [5]. Moreover, recently developed minimally invasive treatment modalities for urinary stone disease further increase the amount

of radiation exposure as extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PNL) and retrograde intrarenal surgery (RIRS) are usually performed under fluoroscopic guidance. Despite vigorous preventative measures, both the patients and the operating staff are under risk of radiation exposure during these procedures. In addition to numerous radiation safety protocols developed to minimize the risk of exposure, a recent study demonstrated that real-time dose reporting may be beneficial in reducing the radiation exposure by increasing the awareness of the physicians [6].

Instadose™ is a novel dosimeter designed to provide a precise measurement of the radiation dose at any time from any computer with accurate long-term exposure tracking. This study was designed to demonstrate the efficacy of Instadose™ for the measurement of radiation exposure during PNL and define the factors that affect the amount of radiation exposure.

MATERIAL AND METHODS

Study design

After obtaining institution review board approval, all patients who underwent PNL for kidney stones between December 2013 and July 2014 were consecutively enrolled. The attending surgeons placed Instadose™ on the right chest of the outer part of their lead aprons during PNL procedures. Patient demographics, stone characteristics and operative findings were recorded. Stone size was calculated as the largest diameter of the stone while stone locations were classified as either calyceal or pelvic/upper ureteral. Stones were accepted as simple if they were located in a single calyx and complex if they occupied more than one location (partial and complete staghorn stones). The radiation dose experienced at the end of each case was noted and analyzed to define factors affecting the radiation dose.

Radiation measurements

The Instadose™ dosimeter utilizes Direct Ion Storage (DIS) technology for its radiation detection. DIS is a non-volatile analog memory cell surrounded by a gas filled ion chamber. For photon radiation, initial interactions take place in the wall of the chamber and secondary electrons ionize the gas inside the chamber. Dose is determined by taking the differences in charge from one read event to the next. The dosimeter is composed of two ion storage chambers. The first chamber measures the dose from 0.01mSv to approximately 120mSv cumulative dose

and the doses exceeding 120mSv are calculated using the second chamber.

The Instadose™ in conjunction with the web-based software performs the calculations of dosage and only the dose accumulated between two reads is reported (Figure 1). The overall cumulative dose is also maintained but not shown.

PNL technique

After biochemical and hematological evaluation, all the procedures were performed by two specialized endourologists (EY and MT). Each patient underwent PNL in prone position, beginning with transurethral insertion of a ureteral catheter for the delivery of contrast material to delineate the renal collecting system. Percutaneous access was achieved in the operating room by the attending urologist under the guidance of a C-arm (Sire Mobil Compact L, Siemens AG, Erlangen, Germany) fluoroscopic examination. The tract was dilated either with a high-pressure Nephro Max® (Boston Scientific, Natick, MA, USA) balloon dilator, or Amplatz Type Renal Dilators® (Boston Scientific Natick, MA, USA). Finally an 18, 24 or 30-F Amplatz sheath was placed. Nephroscopy was performed with a rigid 26-F nephroscope (Karl Storz Gmb H&Co, Tuttlingen, Germany). Fragmentation of the stone burden was accomplished using an ultrasonic lithotripter (Swiss Litho Clast Master, Switzerland). Large fragments were removed using tri-pod forceps. Additional tracts were created when indicated during the same session. In short, non-bleeding cases without any preoperative complications, the sheath was removed without a tube. Otherwise, a 14-F nephrostomy tube was placed inside the renal pelvis or the involved calyx at the end of each case. To check the stone free status and the anatomy of the collecting system, a final nephrostography was performed at the conclusion of the case.

X-ray of the kidneys, ureters and bladder was obtained on the first postoperative day to assess the initial results of the procedure and the nephrostomy tube was removed on the second postoperative day, if the patient was rendered stone free. In tubeless cases, the ureteral catheter was removed on postoperative day one and asymptomatic patients were discharged. All cases were evaluated with non-contrast CT on postoperative third month follow-up visits. PNL was considered successful if the patient was stone free.

Statistical analysis

Statistical analyses were performed by Number Cruncher Statistical System 2007 statistical soft-

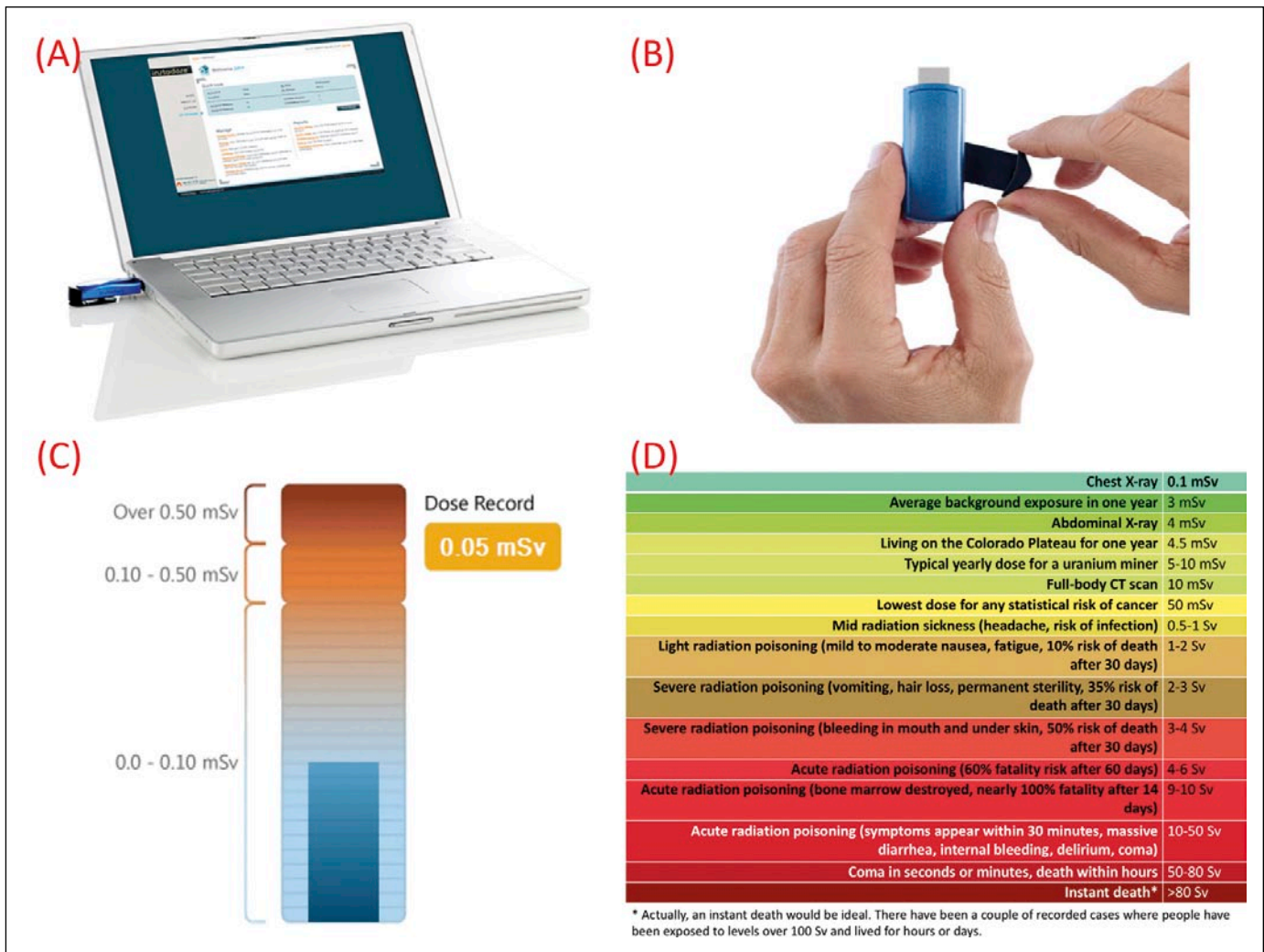


Figure 1. (A) The physician can easily connect the device to personnel computers and manage all the elements of radiation monitoring program online from anywhere. (B) The device is USB compatible and can be connected to any computer. (C) The graphical representation of the dose is loaded on the screen. (D) The known tissue effects of radiation is provided together with the exposed dose after each reading.

ware package program (NCSS, LLC, Kaysville, UT). In addition to descriptive statistics (mean, standard deviation, median, interquartile range), data were evaluated by the Mann-Whitney U test for comparison of paired groups and Spearman's correlation test for the detection of correlations between variables. Statistical significance was set as $p < 0.05$.

RESULTS

Patient demographics and stone characteristics

Overall, 51 patients with a mean age of 43.41 ± 18.58 (range 1–75) years were enrolled. Patient characteristics can be seen in Table 1. Mean stone size was 36.58 ± 15.47 (range = 12–80) mm. Of the patients,

10 (19.60%) had calyceal and 14 (27.45%) had pelvic or upper ureteral stones. Partial and complete staghorn stones were detected in 17 (33.33%) and 10 (19.60%) patients, respectively (Table 1).

Operative findings

The dilation of the tract was performed up to 18Fr in 1 (1.9%), 24Fr in 11 (21.6%) and 30Fr in 39 (76.4%) patients. Balloon dilators and Amplatz renal dilators were used in 39 (76.4%) and 12 (23.6%) patients, respectively. Subcostal access was necessary in 44 (86.27%) patients whereas 7 (13.72%) patients required intercostal access. Multiple accesses were performed in 7 (13.72%) patients to achieve stone-free status. Fourteen (27.45%) patients underwent

tubeless PNL. Operative findings are summarized in Table 2. At the third month control, stone free rate was 80.39% while 13.72% patients were referred to auxiliary treatments.

Radiation exposure

The amount of radiation was detectable ($>0.01\text{mSv}$) in 19 (37.25%) of the cases. The mean radiation dose was 0.02 ± 0.03 (range: 0–0.11) mSv. Instadose™ measurements were correlated with fluoroscopy time ($r = 0.519$, $p = 0.001$) (Table 3). However, there was no significant difference in the amount of radiation exposure between patients with simple and complex stone location (0.029 ± 0.036 mSv *vs.* 0.021 ± 0.033 , $p = 0.380$) as well as between PNL operations performed with balloon dilators and Amplatz renal dilators (0.021 ± 0.031 *vs.* 0.055 ± 0.077 , $p = 0.584$). Moreover stone size ($p = 0.565$), dilation size ($p = 0.891$), access number ($p = 0.268$) and operation time ($p = 0.201$) were not associated with increased radiation exposure (Table 3).

DISCUSSION

The aim of this study was to demonstrate the efficacy of Instadose™ for the measurement of radiation exposure during PNL and to define the factors that affect the amount of radiation exposure. Instadose™ is a novel dosimeter that is designed to provide the opportunity of performing precise and instant measurements of exposed radiation dose and its utility in urological procedures has not been evaluated before. The device records doses over 0.01mSv and this amount of dose was reached in only 37.25% of our cases. Contrary to the previously published series which evaluated radiation exposure in terms of fluoroscopy screening time [7, 8, 9], our results showed that stone location complexity ($p = 0.380$), stone size ($p = 0.565$), dilation type ($p = 0.584$), dilation size ($p = 0.891$) and access number ($p = 0.268$) were not associated with increased radiation exposure. The small number of cases in which the amount of radiation was detectable may be responsible for these conflicting findings. Moreover, assessing the amount of radiation exposure instead of calculating the fluoroscopic screening time may play a role in this phenomenon. The settings and maintenance status of the device used, the angle of the camera, the distance between the source and the intensifier, level of magnification, and collimation, together with the patient position and size all affects the dose of radiation [6].

In the National Council on Radiation Protection and Measurements (NCRP) reports, it is recorded

Table 1. Patient characteristics

Characteristics	
Mean age (years \pm SD)	43.41 \pm 18.58 (range: 1–75)
Gender (male/female)	35/16
Mean BMI (kg/m ² \pm SD)	24.93 \pm 4.97 (range: 13–38.6)
Stone location	
Calyceal	10 (19.60%)
Pelvic/Upper ureteral	14 (27.45%)
Partial Staghorn	17 (33.33%)
Complete Staghorn	10 (19.60%)
Preoperative mean serum creatinine (mg/dl \pm SD)	1.01 \pm 0.43 (range: 0.46–2.68)

BMI – Body Mass Index

Table 2. Operative findings

Mean operation time (minute \pm SD)	82.84 \pm 39.23 (range: 20–180)
Mean fluoroscopy time (minute \pm SD)	4.51 \pm 2.58 (range: 1.2–10)
Mean radiation exposure (mSv \pm SD)	0.02 \pm 0.03 (range: 0–0.11)
Overall Complications (Clavien Grade 2)	
Blood transfusion	2 (3.92%)
Postoperative fever	3 (5.88%)
Mean hospitalization time (days \pm SD)	3.76 \pm 3.41 (range: 1–21)
Mean nephrostomy time (days \pm SD)	2.56 \pm 2.75 (range: 0–14)

Table 3. Operative findings

Variable	Instadose™ (mSv)
Stone size (mm)	
r	0.082
p	0.565
Operation time (min)	
r	0.182
p	0.201
Fluoroscopy time (min)	
r	0.519
p	0.001
Dilation size (Fr)	
r	0.021
p	0.891
Access number	
r	0.158
p	0.268

that radiation protection must be based on the guiding principles of justification, dose limitation and the reduction of dose to levels as low as reasonably achievable (ALARA) [10, 11]. The Council set specific upper limits of acceptable dose for occupationally exposed individuals to 50 mSv per year for the whole body. On the other hand, the International

Commission on Radiation Protection recommends an effective dose of 20 mSv per year over a defined period of 5 years on average as the occupational dose limit [12]. Fortunately, the amount of radiation one is exposed to during PNL was undetectable in the majority of our cases and it has never exceeded 0.2 mSv.

Several studies searched for factors which may have an impact on the total amount of radiation. Tepeler et al. [9] evaluated the data of 282 patients who underwent PNL and demonstrated that having a large stone necessitating multiple renal accesses was the only factor that significantly increased the fluoroscopic screening time. Mancini et al. [13] also determined the risk factors for increased radiation exposure in 96 PNL cases. Instead of fluoroscopic screening time, they calculated the effective dose exposure (multiplication of the dose area product provided by the fluoroscopy unit with a conversion number) for reporting the amount of radiation. The mean effective dose was 8.66 mSv and was significantly associated with stone burden, increased number of accesses and BMI. However, it has been shown that calculating the effective dose is not a reliable method either and it underestimates the radiation exposure [14].

In addition to the aforementioned risk factors, the surgeon's knowledge regarding the best practice guidelines during fluoroscopy may have an impact on the amount of radiation exposure. Reducing the fluoroscopy time, limiting high dose digital acquisition runs, collimation to the area of interest and using pulsed fluoroscopy can decrease the exposed dose [15]. As it is not possible to manipulate the stone and patient related factors, several protocols and techniques are described to decrease the radiation exposure [16–19]. Sheyn et al. [20] demonstrated the efficacy of the radiation safety education initiative in reducing the radiation exposure. After giving a lecture and an article regarding ALARA principles for optimizing radiation dose to the radiology staff, they recorded that dose-area product, fluoroscopy time and the use of shield equipment before and after the education program and concluded that radiation safety education improved the practice of the staff and decreased the exposure to radiation. Patel et al. [6] retrospectively analyzed the data of 291 pediatric patients to determine the efficacy of a radiation safety protocol to reduce radiation exposure. Their protocol consisted of low pulse rate fluoroscopy settings, low dose cine frame setting, operator notification of skin entrance dose at every 1,000 mGy, adjusting cameras by >5 degree at every 1,000 mGy and appropriate collimation. After implementation of this protocol, they reported significant reduc-

tions in all measures of radiation exposure including fluoroscopy time, skin entry dose, dose area product and effective dose. The authors concluded that radiation safety protocols, which increase physician awareness by using real-time radiation monitoring, may be effective. We believe that measuring the amount of radiation exposure after each PNL operation may also increase the physician's awareness and motivate them to apply appropriate radiation safety protocols more strictly.

Several studies measured the amount of radiation exposure during PNL [21–27]. Although the overall exposed radiation dose was as high as 20 to 40 μ Sv in older studies, a recent paper reported that it is less than 2 μ Sv per case [25]. This downward trend can be explained by better understanding of the hazardous effects of radiation, advancements in technology, increase in urologists' experience and improved operating and disposable instruments. In this study, the Instadose™ recorded radiation of 0.01mSV in only 19 (37.35%) procedures despite wearing it on the outer surface of the lead aprons. Our findings also confirmed that with proper precautions, the exposed radiation dose is minimal.

Our study has several limitations. First of all the operators wore the dosimeter on the outer surface of their lead apron instead of the inner surface and hence overestimated the exposed total dose. Also, dosimeter was worn only on the torso and the hands and the eyes were excluded. Future studies may be designed to measure the amount of radiation exposure in different parts of the body of both surgeons and patients. Finally, measuring the radiation exposure in every stage of the operation (i.e. access, dilation, stone removal, drain placement) would be of benefit.

CONCLUSIONS

Instadose™ is a useful tool for the measurement of radiation exposure during PNL. The advantage of measuring the amount of radiation exposure after each PNL operation may aid urologists take appropriate precautions to minimize the risk of radiation related complications. Further prospective studies are required to demonstrate the beneficial effects of instant dose measurement at the end of each case.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

COMPLIANCE WITH ETHICAL STANDARDS

Funding: The Instadose™ devices were provided by the manufacturer. No other funding has been obtained.

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.

References

- Schauer DA, Linton OW. NCRP Report No. 160, Ionizing Radiation Exposure of the Population of the United States, medical exposure--are we doing less with more, and is there a role for health physicists? *Health Phys.* 2009; 97: 1-5.
- Mettler FA Jr, Thomadsen BR, Bhargavan M, et al. Medical radiation exposure in the U.S. in 2006: preliminary results. *Health Phys.* 2008; 95: 502-507.
- Stamatelou KK, Francis ME, Jones CA, Nyberg LM, Curhan GC. Time trends in reported prevalence of kidney stones in the United States: 1976-1994. *Kidney Int.* 2003; 63: 1817-1823.
- Musulmanoglu AY, Binbay M, Yuruk E, et al. Updated epidemiologic study of urolithiasis in Turkey. I: Changing characteristics of urolithiasis. *Urol Res.* 2011; 39: 309-314.
- Ferrandino MN, Bagrodia A, Pierre SA, et al. Radiation exposure in the acute and short-term management of urolithiasis at 2 academic centers. *J Urol.* 2009; 181: 668-672.
- Patel AR, Ganley J, Zhu X, Rome JJ, Shah M, Glatz AC. Radiation safety protocol using real-time dose reporting reduces patient exposure in pediatric electrophysiology procedures. *Pediatr Cardiol.* 2014; 35: 1116-1123.
- Zeng G, Zhao Z, Zhong W, et al. Evaluation of a novel fascial dilator modified with scale marker in percutaneous nephrolithotomy for reducing the X-ray exposure: a randomized clinical study. *J Endourol.* 2013; 27: 1335-1340.
- Agarwal M, Agrawal MS, Jaiswal A, Kumar D, Yadav H, Lavania P. Safety and efficacy of ultrasonography as an adjunct to fluoroscopy for renal access in percutaneous nephrolithotomy (PCNL). *BJU Int.* 2011; 108: 1346-1349.
- Tepeler A, Binbay M, Yuruk E, et al. Factors affecting the fluoroscopic screening time during percutaneous nephrolithotomy. *J Endourol.* 2009; 23: 1825-1829.
- Limitation of Exposure to Ionizing Radiation. In: *Measurements NCoRPa*, ed. Report No. 116. Bethesda, Maryland: NCRP; 1993.
- Operational Radiation Safety Program. In: *Measurements NCoRPa*, ed. Report No. 127. Bethesda, Maryland: NCRP; 1998.
- Wrixon AD. New ICRP recommendations. *J Radiol Prot.* 2008; 28: 161-168.
- Mancini JG, Raymundo EM, Lipkin M, et al. Factors affecting patient radiation exposure during percutaneous nephrolithotomy. *J Urol.* 2010; 184: 2373-2377.
- Le Heron JC. Estimation of effective dose to the patient during medical x-ray examinations from measurements of the dose-area product. *Phys Med Biol.* 1992; 37: 2117-2126.
- Mitchell EL, Furey P. Prevention of radiation injury from medical imaging. *J Vasc Surg.* 2011; suppl 1: 22-27S.
- Park S, Pearle MS. Imaging for percutaneous renal access and management of renal calculi. *Urol Clin North Am.* 2006; 33: 353-364.
- Lipkin ME, Mancini JG, Zilberman DE, et al. Reduced radiation exposure with the use of an air retrograde pyelogram during fluoroscopic access for percutaneous nephrolithotomy. *J Endourol.* 2011; 25: 563-567.
- Hosseini MM, Hassanpour A, Farzan R, Yousefi A, Afrasiabi MA. Ultrasonography-guided percutaneous nephrolithotomy. *J Endourol.* 2009; 23: 603-607.
- Osman M, Wendt-Nordahl G, Heger K, Michel MS, Alken P, Knoll T. Percutaneous nephrolithotomy with ultrasonography-guided renal access: experience from over 300 cases. *BJU Int.* 2005; 96: 875-878.
- Sheyn DD, Racadio JM, Ying J, Patel MN, Racadio JM, Johnson ND. Efficacy of a radiation safety education initiative in reducing radiation exposure in the pediatric IR suite. *Pediatr Radiol.* 2008; 38: 669-674.
- Bush WH, Jones D, Brannen GE. Radiation dose to personnel during percutaneous renal calculus removal. *AJR Am J Roentgenol.* 1985; 145: 1261-1264.
- Lowe FC, Auster M, Beck TJ, Chang R, Marshall FF. Monitoring radiation exposure to medical personnel during percutaneous nephrolithotomy. *Urology.* 1986; 28: 221-226.
- Baldock C, Greener AG, Batchelor S. Radiation dose to patients and staff from Storz Modulith SL20 lithotripter. *J Stone Dis.* 1992; 4: 216-219.
- Tse V, Lising J, Khadra M, et al. Radiation exposure during fluoroscopy: should we be protecting our thyroids? *Aust N Z J Surg.* 1999; 69: 847-848.
- Hellawell GO, Mutch SJ, Thevendran G, Wells E, Morgan RJ. Radiation exposure and the urologist: what are the risks? *J Urol.* 2005; 174: 948-952.
- Kumari G, Kumar P, Wadhwa P, Aron M, Gupta NP, Dogra PN. Radiation exposure to the patient and operating room personnel during percutaneous nephrolithotomy. *Int Urol Nephrol.* 2006; 38: 207-210.
- Majidpour HS. Risk of radiation exposure during PCNL. *Urol J.* 2010; 7: 87-89. ■