

# Identifying and managing the risks of medical ionizing radiation in endourology

Todd Yecies, MD, Timothy D. Averch, MD, Michelle J. Semins, MD

Department of Urology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA

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**Introduction:** *The risks of exposure to medical ionizing radiation is of increasing concern both among medical professionals and the general public. Patients with nephrolithiasis are exposed to high levels of ionizing radiation through both diagnostic and therapeutic modalities. Endourologists who perform a high-volume of fluoroscopy guided procedures are also exposed to significant quantities of ionizing radiation. The combination of judicious use of radiation-based imaging modalities, application of new imaging techniques such as ultra-low dose computed tomography (CT) scan, and modifying use of current technology such as increasing ultrasound and pulsed fluoroscopy utilization offers the possibility of significantly reducing radiation exposure. We present a review of the literature regarding the risks of medical ionizing radiation to patients and surgeons as it pertains to the field of endourology and interventions that can be performed to limit this exposure.*

**Materials and methods:** *A review of the current state of the literature was performed using MEDLINE and PubMed. Interventions designed to limit patient and surgeon radiation exposure were identified and analyzed. Summaries of the data were compiled and synthesized in the body of the text.*

**Results:** *While no level 1 evidence exists demonstrating the risk of secondary malignancy with radiation exposure, the preponderance of evidence suggests a dose and age dependent increase in malignancy risk from ionizing radiation. Patients with nephrolithiasis were exposed to an average effective dose of 37mSv over a 2 year period. Multiple evidence-based interventions to limit patient and surgeon radiation exposure and associated risk were identified.*

**Conclusion:** *Current evidence suggest an age and dose dependent risk of secondary malignancy from ionizing radiation. Urologists must act in accordance with ALARA principles to safely manage nephrolithiasis while minimizing radiation exposure.*

**Key Words:** radiation safety, ALARA, fluoroscopy, nephrolithiasis

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## Introduction

The risks of exposure to medical ionizing radiation is of increasing concern both among medical professionals and the general public. Publications involving the MESH terms “radiation safety” have increased from 196 in 1996 to 1,640 in 2016. Despite the widespread concern regarding medical radiation exposure, less

is understood about the evidence regarding risks to patients and providers. In this paper we aim to summarize the current evidence regarding the risks of medical ionizing radiation. We also outline the scope of radiation exposure within the specialized field of endourology and the risks it poses to patients and providers. Lastly, we identify evidence-based interventions that have been demonstrated to limit this exposure.

A variety of terminology is used when discussing radiation safety and understanding the meaning of the terms used is important. There are two principle methods of discussing quantities of radiation, either by expressing the absolute quantity of ionizing radiation delivered to a specific point, or by expressing the

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Address correspondence to Dr. Michelle J. Semins, UPMC Department of Urology, 1350 Locust Street, Suite G100a, Building C, Pittsburgh, PA 15219 USA

relative effect of a given quantity of radiation on the target tissue or individual. Absorbed dose is a measure used to express radiation delivery to a specific location or tissue, and is denoted by the units rad or the SI equivalent of gray (Gy). Effective dose is a calculated value measured in either joules/Kg or the SI equivalent of sievert (Sv) that takes into account the absorbed dose and the radiation sensitivity of the target tissue to assess the potential for damage from the radiation source. This can be calculated by the equation effective dose (Sv) = absorbed dose (Gy) x tissue weighting factor. The tissue weighting factor describes the sensitivity of the target tissue to radiation injury. When describing radiation delivered to the whole body, this value is 1 and the effective dose is equal to the absorbed dose. To provide context, the average annual background radiation exposure in the United States is estimated at 3 mSv.<sup>1</sup>

### Evidence for risk from medical ionizing radiation

The risks of ionizing radiation are divided into two principal categories: deterministic and stochastic effects. Deterministic effects are characterized by having a threshold dose below which there is no measurable effect, as occurs in skin injury, hair loss, and cataract formation. These effects have been well studied, with cataract formation, skin injury, and hair loss estimated to occur above doses of 0.5 Gy, 2 Gy, and 3 Gy, respectively.<sup>2</sup> These thresholds are seldom encountered by patients during urologic imaging or intervention. Stochastic effects are those in which there is no threshold dose for injury. The risk of radiation induced malignancy follows a stochastic model. It is precisely because there is no known safe threshold of radiation exposure that the overarching principle of medical radiation management is to keep levels as low as reasonably achievable (ALARA).

Evidence that ionizing radiation increases risk of malignancy comes from three predominant sources. The first is an analysis of the rates of malignancy developed by survivors of the atomic explosions in Hiroshima and Nagasaki. Based on the distance from the explosions, the radiation dose among survivors was estimated, and rates of malignancy were compared to those of the general population. It was found that there was an excess relative risk of solid malignancy of 0.00035 for every mGy of radiation exposure, and this was true across almost all primary malignancy sites.<sup>3,4</sup> The effect was dose-dependent without an apparent threshold of effect. It was also age dependent, with excess relative risk of malignancy increasing by 29% for every decline in age of exposure of 10 years.

Additional evidence of the risk of ionizing radiation stems from monitoring of workers in nuclear power plants. Based on analysis of the radiation exposure patterns of over 407,000 workers it was found that there was an excess relative risk of 0.00097/mSv for non-leukemia malignancies, and 0.0020/mSv for leukemia.<sup>5</sup> Approximately 1%-2% of cancer deaths in this cohort were estimated to be due to radiation exposure. Both of the prior study designs are limited by their retrospective nature and the different mechanisms of radiation exposure. While the radiation dose in many of the patients in the aforementioned studies were similar to what one might encounter in medical imaging, it is unclear to what extent the effects of nuclear fallout or occupational exposure can accurately be extrapolated to patients undergoing medical imaging or procedures.<sup>6</sup>

More recently, epidemiological evidence has emerged demonstrating increased risk of secondary malignancy with increasing medical radiation exposure. Pearce et al retrospectively analyzed all pediatric patients receiving CT scans under the National Health Service in England and then identified patients who subsequently developed malignancy and found that prior CT scan exposure was a significant risk factor. They estimated that there was approximately two excess cases of malignancy for every 10,000 CT scans performed.<sup>7</sup> Mathews et al performed a similar study using pediatric patients within the national health database in Australia, and identified an excess relative risk of cancer diagnosis of 0.16 for every CT performed in a dose dependent relationship.<sup>8</sup> Both of these studies are limited by the low incidence of pediatric malignancy, limited follow up duration, their retrospective nature, and the high risk for selection bias, namely that patients undergoing CT scans may be for reasons related to their subsequent development of malignancy. The authors of both studies attempted to account for this factor by excluding all CT scans performed within a certain time frame of cancer diagnosis, but the potential for bias remains.

Based on the data presented above, modeling studies have been performed by Gonzalez et al and by Brenner et al that have estimated that approximately 2% of malignancies in the US may be attributable to the use of medical imaging.<sup>9,10</sup> In summary, while there is no level 1 evidence demonstrating the risk of secondary malignancy with radiation exposure, the preponderance of evidence at this juncture suggests a dose and age dependent increase in malignancy risk from ionizing radiation, and medical providers should act accordingly.

## Radiation exposure and risks to patients and physicians within endourology

Patients with nephrolithiasis are exposed to high levels of ionizing radiation through both diagnostic and therapeutic modalities. Ferrandino et al found that over a 1 year period, patients with a urolithiasis episode underwent an average of 1.7 CT scans, 1 abdominal x-ray, and 1 excretory urogram. The overall median dose was 29.7 mSv, with 20% of patients receiving > 50 mSv, exclusive of treatment-related radiation.<sup>11</sup> These results were confirmed by Fahmy et al, who found a median 1 year dose of 29.3 mSv and 37.3 mSv at 2 years.<sup>12</sup> Given that recurrence rates of nephrolithiasis are high, estimated at up to 50% at 5 years, this patient population is at high risk for repeated high levels of radiation exposure. Additionally, the mainstay of minimally invasive treatment of nephrolithiasis are fluoroscopy guided interventions, including, percutaneous nephrolithotomy (PCNL), extra-corporeal shock wave lithotripsy (SWL), and ureteroscopy (URS). Mancini et al found on review of 96 cases with prospective use of patient dosimeters that PCNL was estimated to carry a mean effective dose of 8.66 mSv, while Lipkin et al and Sandilos et al used similar methods to estimate median effective doses of 1.13 mSv and 1.63 mSv during URS and SWL, respectively.<sup>13-15</sup> For both URS and PCNL, obesity and increased stone burden were associated with increased effective dose. Obesity in particular is noted to increase effective dose even if fluoroscopy time does not increase due to higher dose rates required to obtain adequate images.<sup>16</sup>

At this time, no study estimating the lifetime radiation exposure of stone formers or the subsequent risk of secondary malignancy has been performed. Currently available models suggest that for the average patient in the Ferrandino et al study with a mean age of 48, the radiation dose associated with a single stone episode would increase lifetime malignancy rate by an absolute level of 0.15%.

Urologists are also exposed to ionizing radiation through performing fluoroscopy guided procedures. At this time there are no studies assessing the risk of radiation induced malignancies in urologists, however, studies from other disciplines do give significant cause for concern. A survey of a prospectively gathered cohort of over 90,000 radiation technologists found significant increases in the incidence of melanoma, breast cancer, and brain cancer among technologists who helped perform fluoroscopy guided interventions compared to those who did not work with fluoroscopy.<sup>17</sup> A series of 31 cases of brain and neck tumors in interventional

radiologists and cardiologists has been reported and demonstrated that 85% of cases were localized to the left side, where radiation exposure is known to be highest.<sup>18</sup> Additionally, interventional cardiologists and catheterization lab staff have also been shown to be at a threefold higher risk of developing radiation induced posterior cataracts relative to controls.<sup>19</sup>

Radiation exposure to endourologists has been measured in multiple studies. Wenzler et al and Kumari et al used case-specific dosimeters to measure a surgeon effective dose during PCNL of 0.04 mSv and 0.1 mSv, respectively.<sup>20,21</sup> Similar methods were used to estimate effective surgeon dose during URS to be 0.033 mSv.<sup>22</sup> A busy endourologist who performs 100 ureteroscopies and 40 PCNLs annually could thus be estimated to have an annual effective dose of approximately 7.3 mSv. This roughly corresponds to the estimated annual endourologist exposure as measured from vest-worn dosimeters, which range from deep dose equivalent of 8.13 mSv/yr to as high as 32 mSv/yr for resident urologists.<sup>23,24</sup> While these levels remain below the International Commission on Radiological Protection (ICRP) recommended maximum annual occupational exposure of 50 mSv, when extrapolated over the length of a urologists career it remains highly concerning.<sup>25</sup> With respect to cataract formation, urologist lens exposure has been estimated at 5.64 µGy per case.<sup>26</sup> A review of our dosimeter records estimated a higher lens exposure of approximately 43 µGy per case.<sup>27</sup> Based on either level, a urologist could not feasibly reach the threshold for cataract formation during a typical career length. However, given the identified increased cataract risk in interventional cardiologists and the fact that wearing protective glasses has no associated risk, it is still recommended to wear appropriate lens protection.

## Interventions to reduce radiation exposure

A wide variety of interventions have been studied to reduce patient and physician radiation exposure. The first and most important intervention is to limit studies or interventions involving radiation exposure to those that are strictly medically necessary. While this is a common-sense principle, a review of 459 CT and MRI scans at a single academic medical center found that 26% did not meet evidence-based appropriateness criteria.<sup>28</sup> Implementation of electronic record based imaging clinical decision support tools have been shown to significantly reduce medical imaging utilization, partially via reducing the impact of duplicated imaging studies.<sup>29,30</sup>

Another intervention is to substitute the use of imaging studies with lower radiation doses, such as

kidney-ureter-bladder (KUB) x-ray or ultrasound (US) for detection of nephrolithiasis instead of CT scan. KUB is significantly less expensive than CT or US and carries an effective radiation dose of 0.6-1.1 mSv.<sup>31</sup> However, sensitivity and specificity for detection of nephrolithiasis with KUB are poor with pooled sensitivity of 45%-59%, and specificity of 71%-77%.<sup>32</sup> The use of US has many advantages, including that it does not emit ionizing radiation, is non-invasive, and costs less than CT. However, the use of ultrasound for diagnosis of urolithiasis carries significant limitations. A systematic review of the literature demonstrated a pooled sensitivity of only 45% and specificity of 88% for diagnosis of renal calculi, compared to 95% and 98% respectively on non-contrast CT scan.<sup>33</sup> Additionally, US tends to overestimate stone size, with a mean discordance of 1mm for stones < 5 mm in size.<sup>34</sup> Despite these limitations, a recent randomized controlled trial published in the *New England Journal of Medicine* demonstrated that initial use of US over CT for suspected nephrolithiasis was associated with significantly lower radiation exposure over a 6 month period without increased complication or readmission rate, although up to 40% of patients receiving ultrasound required a subsequent CT scan during the same ER admission.<sup>35</sup> Based on these findings, many now advocate for US being the initial test of choice for suspected nephrolithiasis.

A promising innovation to reduce patient radiation exposure has been the development of low dose CT (LDCT) and ultra-low dose CT (ULDCT) scan technology. The efficacy of LDCT for diagnosis of nephrolithiasis has been well studied, with a meta-analysis demonstrating pooled sensitivity and specificity of 96% and 95% respectively.<sup>36</sup> The estimated radiation dose ranges from 1.4-2.0 mSv in comparison to 11.2 mSv for standard single-phase CT.<sup>37</sup> ULDCT protocols are defined as those that deliver an effective dose of less than 1 mSv, which is comparable to the radiation dose of a KUB. In a prospective trial comparing ULDCT and LDCT, Pooler et al found a sensitivity of ULDCT of 91% and specificity of 96% for stones larger than 4 mm.<sup>38</sup> When looking at stones of all sizes, however, sensitivity drops to 72%. For both LDCT and ULDCT, sensitivity is significantly impacted by patient body mass index (BMI), with sensitivity as low as 50% for BMI > 30 kg/m<sup>2</sup> if dose adjustment is not performed.<sup>39</sup> Comparison of the relative efficacy and cost of LDCT or ULDCT in comparison to renal ultrasound as a first line study for suspected nephrolithiasis has not been studied.

In addition to reducing patient radiation exposure from diagnostic imaging, multiple interventions have

been studied to reduce the radiation dose associated with endourologic interventions. The simple act of measuring and reporting fluoroscopy time to the operating surgeon was shown to reduce mean fluoroscopy time by 24%.<sup>40</sup> Implementation of a physician radiation safety training curriculum has also been demonstrated to reduce fluoroscopy usage by up to 56%.<sup>41</sup> C-arm lasers used to target device without image exposure and last image hold technology to avoid duplicate exposures have been shown to reduce fluoroscopy use as part of a multi-modal radiation reduction protocol.<sup>42</sup> C-arm settings can also be modified by reducing the fluoroscopy pulse rate or using the low dose setting. The pulse rate can be set from a continuous rate of 30 pulses per second (pps) to as low as a single pps. Settings of 12, 4, and 1 pps have been studied, with identified decreases in fluoroscopy time during URS of 34%, 55%, and 79%, respectively without any changes in perioperative outcomes.<sup>27,43,44</sup> During PCNL, use of a multi-modal protocol including a dedicated fluoroscopy technician, low dose and 1 pps fluoroscopy reduced fluoroscopy time by 81%.<sup>45</sup> Furthermore, a blinded panel of radiologists found pulsed fluoroscopy images to be clinically equivalent to continuous fluoroscopy for a variety of interventional procedures.<sup>46</sup> Use of the low dose setting has been shown to reduce absorbed radiation dose by 57%.<sup>47</sup> In our experience, the combined use of reduced fluoroscopy pulse rates and low dose fluoroscopy is a simple measure that allows for significant reduction in radiation dose without any alteration of surgical technique or clinically significant compromise of image quality.

Alternative surgical techniques have been developed to drastically reduce or completely eliminate fluoroscopy usage during URS, ESWL, and PCNL. URS with extremely limited fluoroscopy or without image guidance has been demonstrated to be safe and technically feasible through standardization of technique with increased use of tactile feedback, external visual cues, and direct visualization.<sup>48,49</sup> Multiple small randomized trials have been performed comparing US guided URS without the use of fluoroscopy to fluoroscopy guided intervention and found it to be a safe and technically feasible alternative.<sup>50,51</sup> While these results are promising, it should be noted that these trials have generally been limited to non-complex cases and due to the rare nature of complications associated with URS, they were not sufficiently powered to show non-inferiority.

Alternative percutaneous renal access methods have also been assessed to reduce radiation exposure. Use of retrograde air pyelogram instead of iodinated contrast pyelogram has been demonstrated to reduce effective dose without change in fluoroscopy time,

likely due to reduced photon energy required to penetrate air rather than contrast material.<sup>52</sup> Use of ureteroscopic guidance has been associated with fewer puncture attempts and subsequently reduced radiation exposure in small series.<sup>53</sup> US guided percutaneous access has also been demonstrated to be technically feasible, safe, and significantly lowers radiation exposure without an associated increase in complications.<sup>54,55</sup> Similar to the studies regarding ureteroscopy, these results are promising but do not prove superiority to fluoroscopy guided access and in the case of US guidance requires technical expertise that is not always available.

US guided SWL has been described since the development of second generation lithotripter units in 1990. In addition to reducing radiation exposure, US guidance carries the potential benefit of visualization of radiolucent stones. The comparative efficacy of US versus fluoroscopy guided SWL has never been studied. The largest identified series of US guided SWL demonstrated a successful fragmentation rate of 86%, comparable to series of fluoroscopy guided SWL. However, other studies have noted lower success rates due to difficulty with stone localization.<sup>56,57</sup>

Additional interventions have been identified to reduce surgeon radiation exposure. The first and simplest measure is to use readily available radiation protection instruments. A 2011 survey of endourologists found that compliance with chest and pelvic shields was 97%, however compliance with use of thyroid shields, dosimeters, leaded glasses, and leaded gloves was only 68%, 34%, 17%, and 10% respectively.<sup>58</sup> The effectiveness of leaded shielding in clinical practice, however, may be less than expected. A standard 0.5 mm lead apron has been cited to block between 90% and 99% of x-ray dose at commonly used kVp.<sup>59</sup> Leaded glasses and gloves reduce estimated dose by 50%-66% and 15%-30%, respectively.<sup>60</sup> In practice, however, studies that placed dosimeters above and below lead aprons during fluoroscopic procedures found dose reductions of 37%-82%, with variation likely stemming from the degree of scatter radiation and the specific equipment used.<sup>61,62</sup> These findings again emphasize that leaded protective equipment should be considered an adjunct to radiation safety practices, not an alternative. Given the significant dose reduction from leaded equipment and lack of associated risk, use of this equipment should be standard for all urologists. Measures to reduce patient radiation exposure also carry the additional benefit of reducing exposure to the urologist and operating room staff. For example, use of single pulse per second fluoroscopy was shown to reduce surgeon

effective dose by 60%.<sup>27</sup> Finally, proper surgeon and operating room table setup can have a significant effect on surgeon radiation dose. Using a phantom model, increasing x-ray source to skin distance, placing lead protection under the OR table between the x-ray source and the surgeon, and operating in the standing rather than the seated position were all associated with significant reductions in surgeon effective dose.<sup>63</sup>

With all of these described measures, it is important to interpret their benefits within the context of the individual patient. While radiation reduction is important, saving the patient the effective dose equivalent of a KUB x-ray during URS is likely not worth exposing the patient to additional surgical risk or prolonging anesthetic exposure. Surgeons will have varying comfort levels with different fluoroscopy settings and surgical techniques. It is thus incumbent on each individual provider to identify the optimal approach that provides the best balance between minimizing radiation exposure, surgical duration, and operative risk in keeping with ALARA principles.

## Conclusion

While there is no level one evidence demonstrating the risk of radiation associated malignancy in patients or surgeons, the preponderance of data suggests that there is a linear, no-threshold effect of medical ionizing radiation on secondary malignancy risk. Multiple interventions have been described to reduce patient and surgeon radiation exposure from both diagnostic and therapeutic modalities. Urologists must apply these techniques appropriately and in accordance with ALARA principles to safely manage nephrolithiasis while minimizing radiation exposure. □

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