Modeling the Incidence of Secondary Malignancy Related to Ionizing Radiation Use in the Management of Nephrolithiasis

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OBJECTIVE To model the risk of secondary malignancy and associated mortality due to ionizing radiation from the evaluation and management of nephrolithiasis.

METHODS A PUBMED-based literature search was performed to identify model inputs, specifically annual incidence of nephrolithiasis sub-stratified by age and gender and radiation exposure associated with nephrolithiasis episodes. Estimates of age and gender specific radiation-induced malignancy and mortality rates were obtained from the BEIR VII Phase 2 report with dose extrapolation using the linear no-threshold model.

RESULTS Incidence of new diagnoses of nephrolithiasis ranged from 42/100,000 in males 20-30 years old to 248/100,000 in males 60-70 years old. Radiation exposure per nephrolithiasis episode was 37.3 mSv over a 2-year period. Data regarding average stone episodes per patient with nephrolithiasis was limited and conservatively estimated at 1.5. Modeled lifetime attributable risk of secondary malignancy and subsequent mortality in individual stone patients ranged from 0.096% and 0.085%, respectively, in males over the age of 70 to 0.59% and 0.39% in females 20-30 years old. In the USA, overall incidence of secondary malignancy and associated mortality related to nephrolithiasis management was calculated to be 862.7 and 545.3 cases/year, respectively.

CONCLUSION This model suggests that ionizing radiation from the management of nephrolithiasis carries a small but significant risk of causing secondary malignancy. This knowledge must be considered when using modalities that involve radiation in the diagnosis and therapeutic management of nephrolithiasis. UROLOGY 130: 48−53, 2019. © 2019 Elsevier Inc.

The risks of exposure to ionizing radiation are of increasing concern among medical professionals. Patients with nephrolithiasis are exposed to significant quantities of ionizing radiation through diagnostic imaging and fluoroscopy-guided interventions. Though the risk of radiation-induced malignancy for any individual patient is likely small, due to the high incidence and recurrence rate of nephrolithiasis, even small risks could translate into a significant quantity of future malignancies. To accurately assess the long-term secondary malignancy risk would require lifelong follow-up of an extremely large patient cohort. A more practical and readily available method of risk assessment is to use consensus-based risk-projection models.

The Committee on Biological Effects of Ionizing Radiation (BEIR) is a committee of the National Research Council that is tasked with evaluating current evidence regarding the risks of ionizing radiation. Their most recent report, BEIR VII phase 2, provides a framework for estimating the lifetime attributable risk of radiation-induced malignancy based on patient age, gender, and radiation dose. The risk of radiation-induced malignancy in patients with nephrolithiasis has never been assessed.

In this study we performed a literature search to identify the radiation dose from evaluation and management of nephrolithiasis and nephrolithiasis incidence sub-stratified by patient age and gender. We combined this data with the risk models from the BEIR VII to estimate the annual rate of radiation-induced malignancy from nephrolithiasis management. In addition to quantifying the health impact of current management strategies, we aimed to identify cohorts that are at higher risk of secondary malignancy to which interventions to reduce radiation exposure could be targeted.

MATERIALS AND METHODS

The current incidence of nephrolithiasis sub-stratified by age and gender was obtained from the prospective database of all medical

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care in Olmsted County, MN, from the Rochester Epidemiology Project.[1] Data from the year 2000 was used as this was the most recent available. Only new diagnoses of symptomatic nephrolithiasis were included. PUBMED-based literature review was used to identify the radiation dose associated with a nephrolithiasis episode and rates of stone recurrence. No specific data regarding the average number of lifetime stone episodes per patient could be identified. However, because nephrolithiasis recurrence is estimated at 50% over a 5-year period and up to 75% over a 20-year period, and many patients will have multiple recurrences, the mean number of stone episodes per patient was conservatively estimated at 1.5. Due to lack of available data, pediatric patients were excluded.

United States population data was obtained from the 2000 US Census. The risk of secondary malignancy and associated mortality was obtained from the BIER VII phase 2 report with dose extrapolation using the linear no-threshold model. Due to disparities in age grouping between the stone incidence study, which used 10-year age ranges, and the BEIR VII report, which reports secondary malignancy risk for a specific age, the value at the upper end of the age ranges was selected. For example, when evaluating stone formers aged 20-30, the radiation-induced malignancy risk of a 30 year-old patient was used to create a conservative estimate.

To calculate the number of stone episodes within a specific age and gender cohort, the incidence rate within that cohort was multiplied by the population size. The number of cases of secondary malignancy and mortality within each cohort was obtained by multiplying the number of stone episodes within said cohort by the age and gender specific individual risk of secondary malignancy and mortality. The primary outcome measure was the annual number of cases of secondary malignancy and associated mortality from radiation exposure in the management of nephrolithiasis.

Sensitivity analysis was performed using TreeAge Pro 2017 R2 software to identify the sensitivity of our primary outcome measurements to less certain or modifiable inputs, most notably the number of stone episodes per patient and radiation dose per stone episode.

RESULTS

Model inputs and associated sources are summarized in Table 1. Incidence rates of symptomatic nephrolithiasis ranged from 42/100,000 to 248/100,000 in males aged 20-30 and 60-70, respectively, and from 62/1000 to 125/100,000 in females aged over 70 and 20-30, respectively. The 2-year radiation dose associated with a single stone episode was 37.3 mSv as identified by Fahmy et al and Ferrandino et al.[2,3]

Table 1. Model inputs and associated sources

Model Input				Source
Incidence of Nephrolithiasis (New Cases Per 100,000)	Age	Male	Female	Lieske et al, 2006
	20-30	42	125	
	30-40	91	113	
	40-50	165	235	
	50-60	235	68	
	60-70	248	70	
	70+	153	62	
United States population	Age	Male	Female	US Census Bureau, 2000
	20-30	21649695	21038081	
	30-40	20038522	20103219	
	40-50	21603062	21996493	
	50-60	20456922	21506008	
	60-70	13930047	15323140	
	70+	11510413	16322308	
Radiation dose per nephrolithiasis episode	1 year	29.3 mSv	29.7 mSv	Fahmy et al, 2012 Ferrandino et al, 2008
	2 year	37.3 mSv		Fahmy et al, 2012
Lifetime attributable risk of radiation induced malignancy from 37.3 mSv	Age	Male	Female	BEIR VII phase 2 report
	20-30	0.256%	0.397%	
	30-40	0.242%	0.330%	
	40-50	0.220%	0.276%	
	50-60	0.182%	0.219%	
	60-70	0.128%	0.153%	
	70+	0.065%	0.080%	
Lifetime attributable risk of mortality from radiation induced malignancy from 37.3 mSv	Age	Male	Female	BEIR VII phase 2 report
	20-30	0.142%	0.265%	
	30-40	0.141%	0.183%	
	40-50	0.134%	0.170%	
	50-60	0.119%	0.132%	
	60-70	0.093%	0.099%	
	70+	0.057%	0.057%	

mSv, millisievert; BEIR, biological effects of ionizing radiation.

The lifetime attributable risk of malignancy and associated mortality for an individual nephrolithiasis episode declined as age of exposure increased. Malignancy risk was lower for males than females due to greater increase in risk of radiation-induced ovarian and uterine cancer in females compared to prostate cancer in males. Radiation-induced malignancy and subsequent mortality risk for a single exposure to 37.3 mSv ranged from 0.064% and 0.093%, respectively in males over age 70 to 0.39% and 0.26%, respectively, in females aged 20-30.

Table 2 summarizes calculations extrapolating individual risk to the United States population. Each year, 267,485 new diagnoses of symptomatic nephrolithiasis were calculated to occur. Using an estimate of 1.5 stone episodes per patient, we calculate that there are 862.7 cases of radiation induced secondary malignancy with 545.3 associated fatalities annually in the United States. The number of cases of radiation-induced malignancy increases to 1150.3 and 1725.4 when the number of lifetime nephrolithiasis episodes is modeled at 2 and 3 episodes, respectively. The number of patients needed to harm, with harm defined as a radiation-induced malignancy, was 310 for all patients and ranged from 168 for females aged 20-30 to 1026 for males over the age of 70.

Sensitivity analysis demonstrated that our findings were robust to a wide range of model inputs (Fig. 1). Because the risk of radiation-induced malignancy is purported to follow the linear no-threshold model, the number of cases of radiation-induced malignancy varies linearly with radiation dose and number of nephrolithiasis episodes.

DISCUSSION

This study demonstrates that though the absolute risk of radiation-induced malignancy to an individual patient is relatively small, the national burden of secondary malignancy and mortality is significant. This risk is disproportionately placed on young and female patients, with a number needed to harm of as low as 168 in females aged 20-30, and thus special care should be taken to limit radiation exposure in these populations. In the United States, radiation associated with nephrolithiasis management is estimated to cause 862 cases of malignancy annually.

The increase in CT scan utilization has significantly increased the radiation dose associated with a stone episode, however there is no evidence demonstrating that this improves clinical outcomes. In fact, multiple studies have demonstrated that increasing CT utilization is not associated with any change in hospital admissions, diagnosis of nephrolithiasis, or diagnosis of significant alternative pathology.[4,5,6] Stone disease causes a significant health burden in terms of hospitalizations and quality of life, but the risk of mortality from nephrolithiasis is low. While the mortality rate of nephrolithiasis in the USA has not been assessed, an estimate of stone related mortality in England identified an average of 130.1 cases per year.[7] Adjusting for population size, this would correspond to 792.2 cases per year in the USA. Given that our estimated mortality from the radiation involved in the management of stone disease approaches the estimated mortality from the disease itself, this suggests a need for re-evaluation of approaches to radiation stewardship.

The results of this model are relevant to urologic practice because the radiation dose associated with a nephrolithiasis episode can be drastically reduced using existing and widely

Table 2. Projections of radiation-induced secondary malignancy and mortality from management of nephrolithiasis in the United States Population

Estimated Annual Cases of Symptomatic Nephrolithiasis	Age	Male	Female	Total
	20-30	9092.9	26,297.6	35390.5
	30-40	18,235.1	22,716.6	40951.7
	40-50	35,645.1	19,796.8	55441.9
	50-60	48,073.8	14,624.1	62697.9
	60-70	34,546.5	10,726.2	45272.7
	70+	17,610.9	10,119.8	27730.8
	Total	163,204.2	10,4281.2	**267485.4**
Estimated Annual Cases of Radiation Induced Secondary Malignancy	Age	Male	Female	Total
	20-30	34.6	155.4	190.2
	30-40	65.6	111.7	177.3
	40-50	116.9	81.3	198.2
	50-60	130.5	47.6	178.0
	60-70	65.8	24.3	90.1
	70+	17.0	12.0	29.0
	Total	430.4	432.4	**862.7**
Estimated annual fatalities due to radiation induced secondary malignancy	Age	Male	Female	Total
	20-30	19.2	103.8	123.0
	30-40	38.2	61.9	100.1
	40-50	71.2	50.0	121.2
	50-60	85.1	28.7	113.8
	60-70	47.9	15.8	63.7
	70+	15.0	8.5	23.5
	Total	276.6	268.7	**545.3**

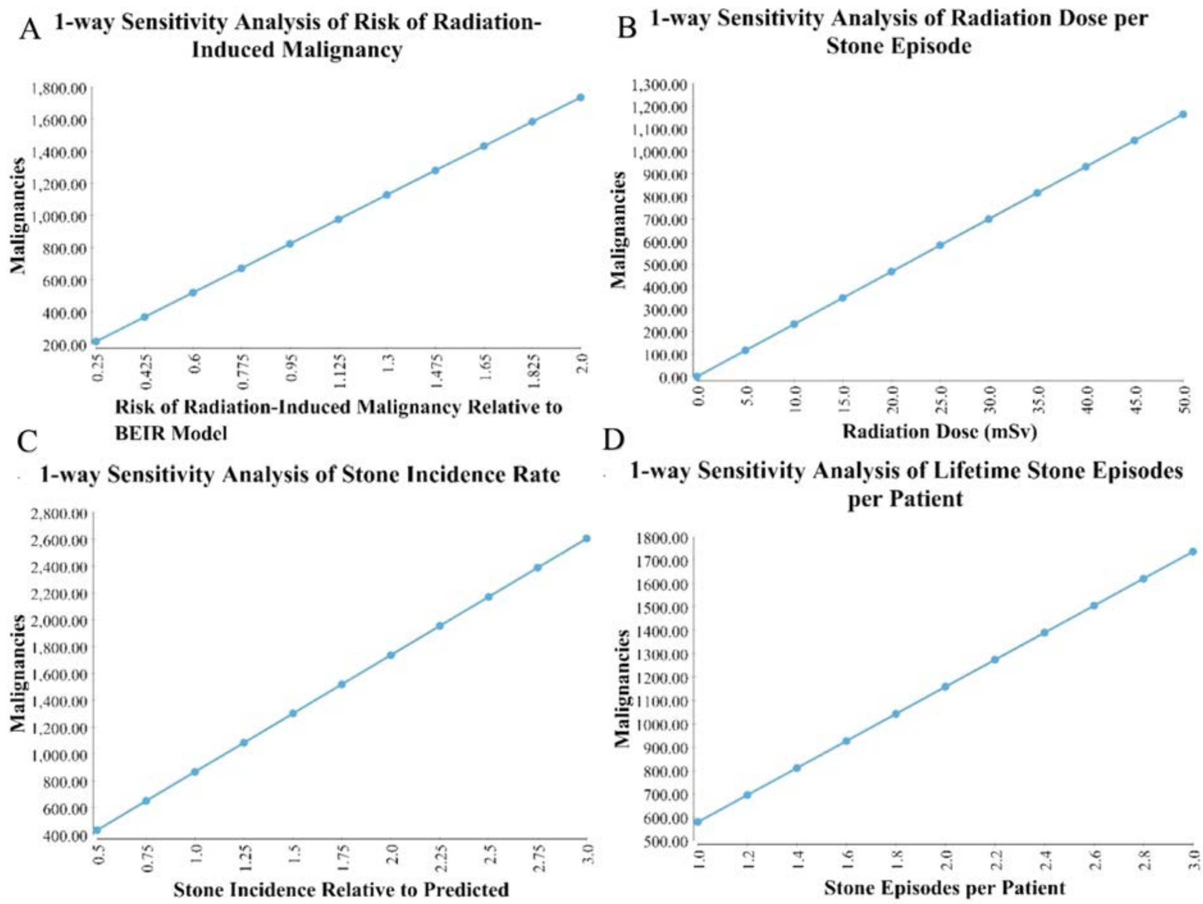

Figure 1. One-way sensitivity analyses of model inputs performed to identify the robustness of model output to variable inputs. Assessed variables included; (**A**) the risk of radiation-induced malignancy relative to the predicted risk in the BEIR mode, (**B**) the radiation dose associated with a nephrolithiasis episode, (**C**) the stone incidence rate relative to modeled rate, and (**D**) the lifetime number of stone episodes per patient. (Color version available online.)

available technology. Initial use of renal ultrasound for evaluation of renal colic has been demonstrated to reduce average patient radiation dose without adversely effecting outcomes, despite the fact that 33% of patients will require a subsequent CT scan.[8] In patients for whom additional anatomic information is desired, low-dose, and ultra-low-dose CT scan technology has excellent sensitivity for stones ≥4 mm while reducing radiation dose significantly.[9,10] In performing fluoroscopy-guided interventions, use of low-dose and pulsed fluoroscopy can reduce radiation dose by up to 97.7% for a given exposure time.[11] Ultrasound is also effective for follow-up of known stones or to assess for silent obstruction postoperatively.[12]

Through utilization of these techniques, the potential exists to significantly reduce the radiation dose associated with a stone episode. For example, a hypothetical patient who receives a preoperative low-dose CT scan (1.54 mSv), followed by an ureteroscopy using low-dose and pulsed fluoroscopy (0.05 mSv), and subsequently followed with renal ultrasound could receive a radiation dose of approximately 1.6 mSv. Thus, the risk of radiation-induced malignancy could be reduced by a factor of 23 compared to what was modeled in this study using readily-available interventions.

There is no level one evidence demonstrating that medical ionizing radiation causes secondary malignancy and it is thus reasonable to question whether radiation stewardship concerns should significantly alter patient care. Evidence regarding the risks of low dose radiation stems from 3 primary sources. First is evaluation of the survivors of atomic explosions, which demonstrated that doses as low as 10 mSv were associated with significant increases in malignancy risk.[13] Second is evaluation of nuclear power workers, which also demonstrated a dose-dependent increase in malignancy risk.[14] Third are epidemiological studies of the national health services in England and Australia, which demonstrated that patients who underwent CT scanning have higher rates of subsequent malignancy.[15,16] All of these approaches have methodologic limitations, however, given that the preponderance of evidence suggests a dose and age dependent risk of radiation-induced malignancy, it is our opinion, shared by the authors of the BEIR VII report that interventions should be performed to limit radiation exposure.

As concerning as these findings are, we believe that this model is likely to underestimate the radiation exposure in stone-formers. The analysis of 2-year radiation exposure by Fahmy et al excluded the radiation dose of fluoroscopy-guided interventions, which average 1.13 mSv for ureteroscopy, 1.63 mSv for ESWL, and 8.66 mSv for PCNL.[17,18,19] Furthermore, studies assessing radiation dose associated with nephrolithiasis have been performed at academic centers; evidence exists that nonteaching hospitals have higher utilization of CT scanning for suspected renal colic.[20] Using the Olmsted county experience to identify stone incidence may underestimate the national incidence of nephrolithiasis, as there is a greater prevalence of nephrolithiasis in warmer climates.[21] Finally, the most recent data regarding stone incidence modeled in this study was from the year 2000, and nephrolithiasis incidence has been known to increase since that time.[22]

This study should be interpreted while considering several limitations. Like any modeling study, this study is limited by the quality of input data. The Olmsted county experience was used because it provides the most comprehensive data of nephrolithiasis incidence, however focusing on a specific county fails to account for geographical variation. Data regarding the recurrence rate of nephrolithiasis and median recurrences per patient is of limited quality and disparate between studies. Additionally, the average time to stone recurrence, which would affect the risk of radiation from subsequent stone episodes was not known and thus not modeled, which we aimed to correct for by using a conservative estimate for the age-based risk of ionizing radiation as detailed in the methods section. Finally, it is unknown whether the radiation dose associated with recurrent nephrolithiasis episodes is equivalent to the dose of the incident episode. While pediatric patients were not included in this study, they also represent a population at high risk from radiation exposure.

CONCLUSIONS

This model suggests that ionizing radiation from the management of nephrolithiasis carries a small but significant risk of causing secondary malignancy. This knowledge, as well as awareness of the disproportionate risk burden of radiation on younger and/or female patients must be considered when using modalities that involve radiation in the evaluation and management of nephrolithiasis.

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EDITORIAL COMMENT

The authors present important information about the potential risk of secondary malignancy related to imaging for patients with nephrolithiasis. It is important to note that the authors found the absolute risk for any given patient to be low, but given the prevalence of nephrolithiasis, the overall risk for the population is significant. Whenever deciding on an imaging modality, the relative risks and benefits to the individual patient must be considered. For imaging ureteral stones, the American Urological Association does have a best practice paper which takes radiation exposure into consideration.[1] These recommendations suggest using plain abdominal radiography and ultrasound when clinically appropriate to reduce radiation exposure to patients. However, the reduced sensitivity of these modalities, particularly with ureteral stones, need to be balanced with the increased radiation from computed tomography (CT) scans.

One critical thing to note regarding the findings of the present paper is that the radiation exposure per stone episode used in this paper to model risk was from papers published prior to the wide spread use of low dose CT.[2,3] In the paper by Ferrandino et al, the dose of radiation from a single CT was reported to be 20 mSv per CT. In contrast, low dose CT, which is commonly performed, has a dose of 3 mSv or less[4] Therefore, the current study may significantly overestimate the actual risk.

Regardless, every effort should be made to reduce radiation exposure to our stone patients who are at high risk for recurrent exposure to ionizing radiation. In any clinical decision, the relative risks and benefits need to be weighed on a case by case basis. This paper helps inform patients of the potential risks of imaging during their stone episode.

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AUTHOR REPLY

We thank the authors of this editorial for their very thoughtful comments. They are correct that the use of low dose CT (LDCT) scan can significantly reduce the radiation dose associated with kidney stone management. The sensitivity of LDCT for nephrolithiasis is well-established and comparable to that of standard dose CT scan (SDCT), especially in nonobese patients.[1] Unfortunately, while the technology is available, limited evidence exists that widespread adoption of LDCT has occurred, especially in the emergency department setting where a significant percentage of imaging for nephrolithiasis is performed. In fact, an analysis of the American College of Radiology's dose registry identified that of CT scans performed for kidney stone evaluation, only 7.6% were considered "reduced-dose" scans in 2015-2016.[2] While this did represent an improvement from 2% in 2011-2012, the low rate of LDCT utilization suggests that our model, which was intentionally constructed to be a conservative estimate, is unlikely to overestimate the effects of the current impact of radiation use in kidney stone management. These data also demonstrate a clear target for change. Increasing substitution of standard dose CT with LDCT in the evaluation of renal colic and increasing the use of nonradiation based imaging such as ultrasound for follow-up of kidney stone patients, can drastically lower radiation doses in this high-risk population.

Ultimately the goal of any urologist treating kidney stone patients should be to provide optimal care while limiting radiation exposure. Unfortunately, the current data show we still have a long way to go in achieving this goal.

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