Dysphagia (2019) 34:922–929
https://doi.org/10.1007/s00455-019-09993-w

ORIGINAL ARTICLE

Radiation Risks to Adult Patients Undergoing Modified Barium Swallow Studies

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Received: 17 November 2018 / Accepted: 23 February 2019 / Published online: 4 March 2019

Abstract

Modified Barium Swallow Studies (MBSSs) are a fluoroscopic exam that exposes patients to ionizing radiation. Even though radiation exposure from MBSSs is relatively small, it is necessary to understand the excess cancer risk to the patient, in order to ensure a high benefit-to-risk ratio from the exam. This investigation was aimed at estimating the excess radiation risks during MBSSs. We examined 53 adult MBSSs performed using the full Modified Barium Swallow Impairment Profile (MBSImP) protocol. For each exam, the radiation dose (in terms of dose area product), patient age, and sex was recorded. Using published methodology, we determined the effective dose and organ specific dose then used BEIR VII data to calculate the excess cancer incidence related to radiation exposure from MBSSs in adults. Excess cancer incidence risks due to MBSSs were 11 per million exposed patients for 20-year-old males, 32 per million exposed patients for 20-year-old females, 4.9 per million exposed patients for 60-year-old males, and 7.2 per million exposed patients for 60-year-old females. Radiation exposure to the thyroid, lung, and red bone marrow contributed over 90% of the total cancer incidence risk. For the 20-year-old males, the excess cancer incidence risk is 4.7%/Sv, which is reduced to 1.0%/Sv in the 80-year-olds. For the 20-year-old females, the excess cancer incidence risk is 14%/Sv, which is reduced to 1.3%/Sv for 80-year-olds. Overall, the risk per unit effective dose from MBSSs is lower than the risk estimates for uniform whole-body irradiation. Patient age is the most important determinant of patient cancer risk from MBSSs.

Keywords Deglutition disorders · Fluoroscopy · Radiation exposure · Cancer risks

Introduction

Dysphagia, swallowing impairment, affects approximately one in every 25 adults per year [2] and, if untreated, can lead to aspiration pneumonia and increased mortality rates [1]. Modified Barium Swallow Studies (MBSSs) are fluoroscopy studies that allow clinicians to visualize a patient's swallow, from the oral cavity to the esophagus, to determine the presence and nature of a swallowing impairment, and trial therapeutic interventions [14, 15]. While MBSSs are critical to the assessment and treatment of a patient with swallowing impairment, they are a fluoroscopy examination which exposes patients to ionizing radiation.

When any patient is exposed to ionizing radiation in a MBSS, it is the responsibility of the operator to ensure that the patient is adequately protected. Radiation protection philosophy has evolved over the last 100 years with a well-defined approach that can be applied to patients undergoing procedures that expose them to ionizing radiation. Any examination must be "Justified", which means that there

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must be a net benefit to a patient. What this means is that the perceived benefit to the patient must exceed any corresponding risks, including those associated with ionizing radiation [8]; ICRP [11, 12].

To ensure that only clinically indicated examinations are being performed, account must always be taken of the benefits to the patients of the diagnostic information being generated. This gross benefit can be weighed against any possible downsides, including those associated with exposure to radiation. However, to do this requires that the operator understands the magnitude of the patient risk. If the radiation risk is unknown, it would simply be impossible to deem that the benefits of the radiological examination exceed an unknown radiation risk. Armed with a quantitative estimate of the exam risk, the responsible clinician can make an informed judgement as to whether the examination is appropriate.

Although the radiation doses associated with MBSSs are relatively modest [6, 13, 21, 22], it remains important to quantitate these risks for practitioners who need to make informed risk/benefit decisions. In addition, because the thyroid is the radiosensitive organ that receives the highest doses in MBSSs [5], and given the very large variations in thyroid cancer risk with patient demographics [11], studying how MBSS risks vary with age and sex can potentially be useful for exam optimization. In this study, we obtained an estimate of organ doses (including thyroid doses), and the corresponding carcinogenic radiation risks, for an average patient undergoing a full protocol MBSS.

Methods

PCXMC

We used PCXMC 2.0.1 [20], a commercial software program to calculate organ doses to patients undergoing MBSSs. Doses are obtained for all organs and tissues of interest to the medical radiation protection community. Patient anatomy is modeled as mathematical hermaphrodite phantom models. Monte Carlo techniques are used to obtain organ doses with X-ray photons randomly directed toward the mathematical phantom, and all X-ray interactions simulated in a random manner. After many such interactions, with the energy deposited in each voxel tracked, the complete pattern of energy deposition in the mathematical phantom permits the average radiation dose to be determined.

PCXMC allows the operator to vary the X-ray beam penetrating power (quality) by changing the X-ray tube voltages over the range generally encountered in clinical practice. The operator can also select Al and/or Cu as added filter materials, and the appropriate filter thickness. The X-ray beam intensity incident on a patient is expressed as air Kerma (K_{air}) measured in mGy. The Kerma–Area Product (KAP) is obtained by multiplying the K_{air} by the corresponding X-ray beam area, which is measured in Gy-cm^2. KAP is directly related to the patient stochastic (carcinogenic) radiation risk.

PCXMC permits the operator to define the X-ray irradiation geometry, which includes image receptor dimensions, as well as the source to image receptor distance (SID) and the corresponding air gap. Based on the actual filtration typically used in MBSSs, we modeled the X-ray beam with a filtration of 2.5 mm Aluminum (Al) (inherent) and 0.3 mm Copper (Cu).

Patients and MBSS Examinations

Inclusion criteria were (1) all patients underwent a clinically indicated MBSS, (2) the MBSS was completed under continuous fluoroscopy (30fps), (3) the full protocol of the MBSImP was completed, and (4) the exam was completely recorded. Full protocol MBSSs were defined as patients who completed all 13 swallows of the Modified Barium Swallow Impairment Profile (MBSImP) [16]. Patients with various medical diagnoses and levels of swallowing impairment were included.

Doses and Risk

The radiation risk to any exposed organ and tissue depends on three factors: average radiation absorbed dose (mGy), individual sex, and age at exposure. Organ doses were generated using PCXMC as described above. PCXMC also generates effective doses using ICRP 60 as well as ICRP 103 [11] tissue weighting factors, and these were also included. Radiation risk was estimated using data in BEIR VII (Biological Effects of Ionizing Radiation report VII), and accounted for age and sex in exposed organs [18]. The BEIR VII report, which was published in 2006 by the National Academy of Sciences, provides data on cancer incidence risks and cancer death risks from exposure to low levels of ionizing radiation. In particular, the report lists the number of cases of cancer incidence in various organs per 100,000 persons exposed to a single dose of 100 mGy. These data, which are reported separately for males and females of various ages in BEIR VII, were used to estimate the organ risk, based on the organ doses received by patients undergoing MBSS exams, and then summed to obtain the total excess cancer risk.

Results

Patients and Radiation Techniques

Table 1 shows the distribution of heights and weights of 53 successive patients undergoing full protocol MBSSs at

Table 1 Patient characteristics, for the study cohort ($n = 53$), showing height and weight, and exam characteristics, tube voltage (kV), kerma area product (KAP), and effective dose (ED) for the 4 views: Lateral, posterior–anterior (PA)—upper (U-GI), PA—middle (M-GI), and PA—lower (L-GI)

	Height (m)	Weight (kg)	kV				KAP (Gy-cm^2)				ED (mSv)			
			Lat	U-GI	M-GI	L-GI	Lat	U-GI	M-GI	L-GI	Lat	U-GI	M-GI	L-GI
Mean	1.68	77	61	75	77	94	0.517	0.269	0.116	0.397	0.12	0.04	0.02	0.17
Median	1.70	73	61	75	79	90	0.428	0.211	0.084	0.310	0.10	0.03	0.02	0.12
SD	0.10	18	2	6	8	11	0.278	0.199	0.131	0.328	0.06	0.03	0.03	0.15
Min	1.50	51	60	64	65	78	0.205	0.067	0.014	0.057	0.05	0.01	0.00	0.02
Max	1.94	122	72	91	98	120	1.506	0.857	0.686	1.358	0.35	0.12	0.13	0.66

Table 2 Organ doses for each of the four projections for the radiosensitive organs and tissues that are explicitly listed in BEIR VII

Organ	Lateral		Upper GI		Middle GI		Lower GI		Total
	µGy	%	µGy	%	µGy	%	µGy	%	µGy
Stomach	0.1	0.1	0.2	0.2	1.3	1.4	92.9	98.3	94.5
Colon	0	0.0	< 0.1	0.0	0.1	1.3	8.6	98.7	8.7
Breasts	1.8	4.2	1.6	3.7	6.5	14.8	33.7	77.3	43.6
Lungs	8.6	3.6	8.2	3.4	43.5	17.9	183	75.2	243
RBM	46.1	17.0	32.1	11.8	37.9	14.0	155	57.2	271
Bladder	0	0.0	0	0.0	< 0.1		< 0.1		< 0.1
Liver	0.3	0.2	0.3	0.2	2.7	1.9	140.1	97.7	143
Thyroid	1400	84.5	234	14.1	18	1.1	4	0.2	1660
Prostate	0	0.0	0	0.0	0	0.0	0.3	100.0	0.3
Ovaries	0	0.0	0	0.0	0	0.0	4.5	100.0	4.5
Uterus	0	0.0	0	0.0	< 0.1	0.7	1.9	99.3	1.9

These doses pertain to a patient of median height and weight, exposed to the median techniques listed in Table 1. Organ doses are all expressed in µGy, and the percentages pertain to contribution of each projection to the total organ dose

our institution. The table also includes the X-ray tube voltages (kV) used in each of the four projections as well as the KAP (Gy-cm^2). The mean height was 1.68 m, and the mean weight was 77 kg, which were used in the dosimetry computations described below. The median X-ray tube voltage increased from 61 kV in the lateral projection to 90 kV in the lower GI (posterior–anterior, PA) view. The median KAP was the highest in the lateral projection at 0.428 Gy-cm^2, and the lowest in the middle GI projections at 0.084 Gy-cm^2.

Table 3 Median effective dose and contribution to total dose by projection

Projection	Effective dose (mSv)	Percentage contribution to total (%)
Lateral	0.10	37
Upper	0.03	11
Middle	0.02	7
Lower	0.12	45
Total	0.27	100

Radiation Doses

Table 2 shows the organ doses of organs and tissues with the highest radiosensitivity obtained for each of the four projections, as well as the corresponding total organ dose for the full protocol MBSS. The highest organ dose was to the thyroid (1.7 mGy), with the lateral projection accounting for 85% of this total, and the upper GI projection accounting for another 14%. Only four other organs received organ doses exceeding 0.1 mGy, namely the lung (0.24 mGy), the red bone marrow (RBM) (0.27 mGy), the liver (0.14 mGy), and the esophagus (0.43 mGy).

Table 3 provides a summary of the effective patient doses for the four projections, as well as for the total MBSS. The median total effective dose is 0.27 mSv, with the lower GI projection accounting for about half, and the lateral projection accounting for a third of this total.

Excess Cancer Incidence Risks

Figure 1 shows how the excess carcinogenic risk from the full protocol MBSS exams varies in adult males and females over the range of 20 to 80 years. 20-year-old male risks from MBSSs were 11 per million exposed patients and 20-year-old female risks were almost three times higher at 32 per million exposed patients. In sharp contrast, 60-year-old male from MBSS examinations were 4.9 per million exposed patients and 60-year-old female risks were only about 1.5 times higher at 7.2 per million exposed patients.

Figure 2 shows how the three principle organs (thyroid, lung, and RBM) contribute to the total patient risks, and how these contributions vary with age. In all cases, these three organs contributed over 90% of the total excess cancer incidence risk. In 20-year-old males, the thyroid accounted for 33% of the total carcinogenic risk, the RBM (leukemia) accounted for 24% of the risk, and the lung for 34%. In 20-year-old females, the thyroid accounted for 59% of the risk, the RBM (leukemia) for 6%, and the lung for 26%. As age increases in both males and females, the thyroid risk falls to zero, and the risk contributions of both leukemia and lung cancer increase. In the oldest males, leukemia is the largest contributor to the carcinogenic risks, whereas in the oldest females, it is lung cancer that contributes most to the total carcinogenic risk.

Excess cancer incidence risks can be divided by the corresponding patient's effective dose to obtain a risk per unit effective dose value that is normally expressed in terms of the percentage cancer risk per unit effective dose (i.e., %/Sv). Figure 3 shows how the excess cancer risk per Sv varies for males and females undergoing a representative MBSS with an effective dose of 0.27 mSv (open circles, dotted line). For 20-year-old males, the excess cancer incidence risk is 4.7% per Sv, which is reduced to 1.0% per Sv in 80 year olds. For 20-year-old females, the excess cancer incidence risk is 14% per Sv, which is reduced to 1.3% per Sv for 80 year olds. These values may be compared with the cancer risks for uniform whole-body irradiation using the BEIR VII risk estimates which are also shown in Fig. 3 (solid circles, dashed line). As seen in the figure, the excess cancer risks due to MBSS (% per Sv) are lower than those obtained for uniform whole-body irradiation for both males and females.

Discussion

MBSSs are a critical examination in the assessment and treatment of patients with swallowing disorders (also termed deglutition disorders). Since MBSSs use ionizing radiation, and clinicians are trained to minimize ionizing radiation, often MBSSs are shortened or otherwise modified to reduce radiation exposure presumably to reduce cancer risks. These modifications frequently diminish the diagnostic accuracy of the exam [3]. While reducing radiation exposure does reduce stochastic risks, this is not a well-considered decision without the additional knowledge of what the excess cancer risks are for a full protocol MBSS [16]. This study provides the crucial information of the level of radiation associated with a full protocol MBSS and the related excess cancer risks.

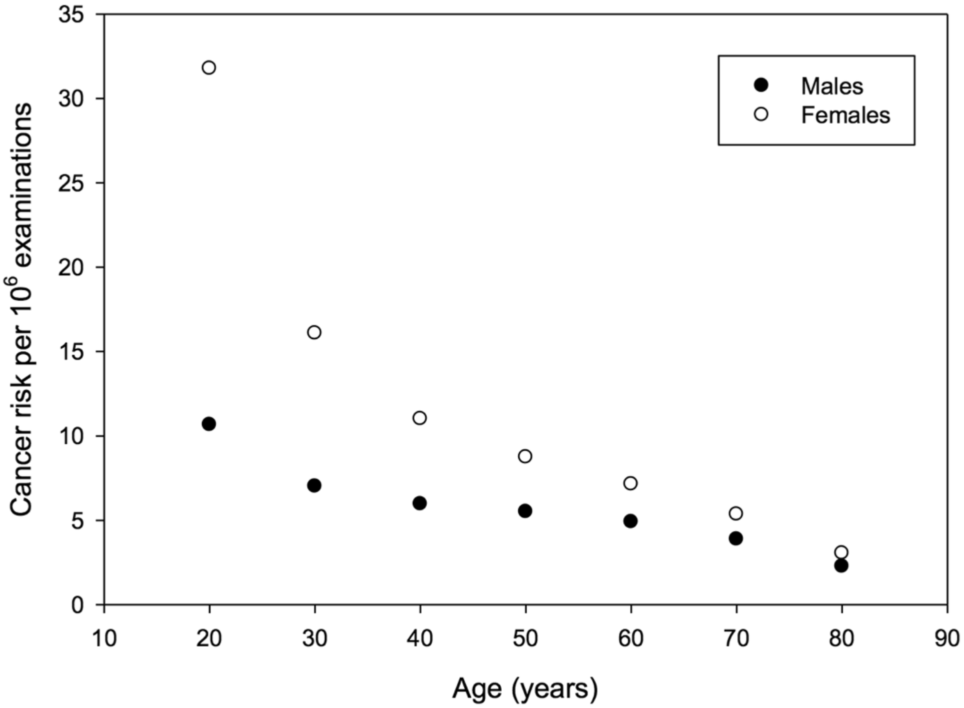

Fig. 1 Excess risks for full protocol MBSSs

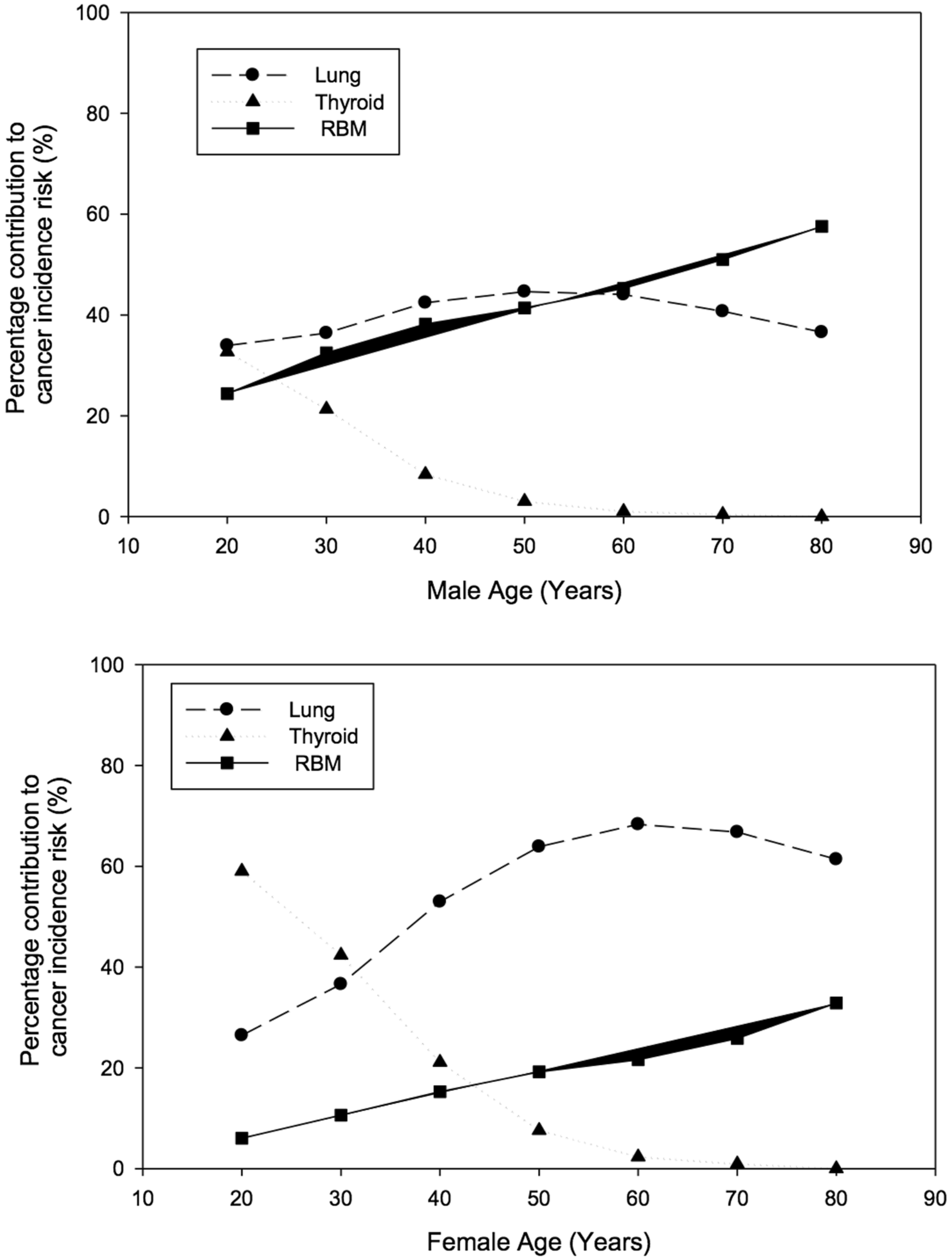

Fig. 2 Contribution of three organs (lung, thyroid, and red bone marrow) to total excess cancer incidence risk

Table 1 shows that the median X-ray tube voltage increases from 61 kV for the lateral projection to 90 kV for the lower GI projection. This increase in X-ray tube voltage shows how the system responds to increasing attenuation (X-ray absorption) by the patient. As the patient attenuation increases, the X-ray tube voltage is driven up to ensure that the radiation incident at the image receptor is kept constant without substantially increasing the patient dose. If the voltage was kept constant, the patient dose would increase exponentially which is not optimal.

According to the data depicted in Table 1, the total KAP used in an average examination may be taken to be approximately 1.0 Gy-cm^2. This value may be compared to 0.1 Gy-cm^2 for a typical PA chest X-ray examination, and 2.5 Gy-cm^2 for an anterior–posterior (AP) abdominal X-ray radiograph [7]. The KAP in MBSSs is close to the median value encountered in radiographic examinations, and like that of a complete skull X-ray examination (AP + lateral view). It is worthy of note that KAP values for MBSSs are much lower than those encountered in fluoroscopy-guided studies. Gastrointestinal and genitourinary tract fluoroscopy-guided examinations have average KAP values of 20 Gy-cm^2, whereas the median KAP in an interventional radiology examination would likely be 200 Gy-cm^2 [7].

Table 1 shows that the total median effective dose was 0.27 mSv which may be taken to indicate a low dose

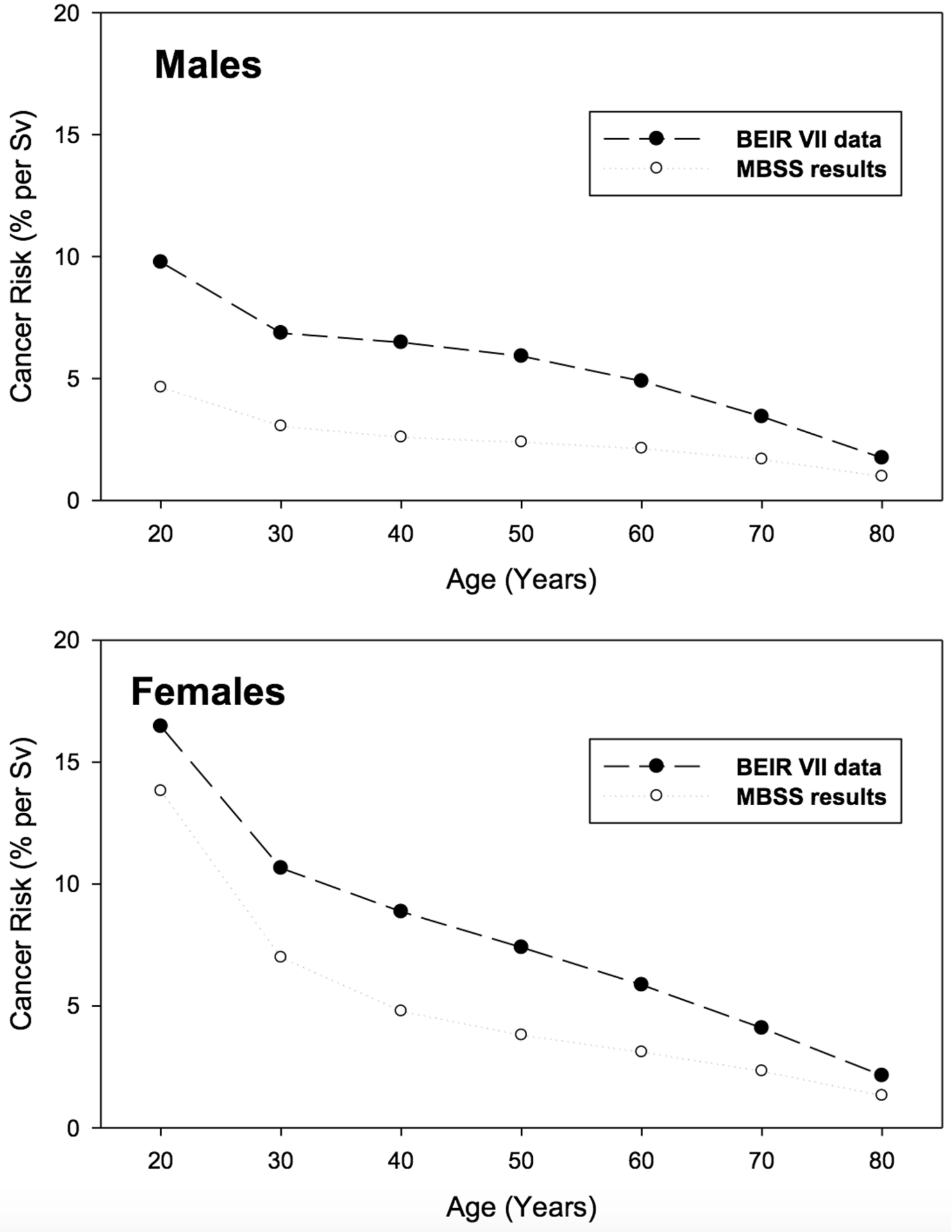

Fig. 3 Excess cancer induction risks per Sv for uniform whole-body irradiation (BEIR VII data) and for MBSSs

examination (0.1 to 1 mSv), whereas examinations with effective doses below 0.1 mSv are very low dose examinations [11]. Examinations with effective doses between 1 and 10 mSv are moderate dose studies, whereas those in excess of 10 mSv would be considered to be high dose studies [11]. For comparison purposes, average effective doses in the US from natural background radiation are 3 mSv per annum (Radiological Society of North America (RSNA) & American College of Radiology) [19]. Regulatory occupational effective dose limits in the US are currently 50 mSv/year [11], with the most highly exposed workers such as Fellows working in Interventional Radiology receiving typically 5 mSv during their formal fellowship training 17].

It is interesting to note that the lower GI examination accounts for half of the patient effective dose, but accounts for only a third of the total KAP incident on the patient. There are two reasons why effective dose is not expected to correlate with the KAP incident on the patient. The first reason relates to the fact that as the X-ray tube voltage increases, the X-ray beam becomes more penetrating and will thereby deposit more energy into a given patient [9, 10]. The second factor relates to the organs and tissues that are irradiated where body examinations irradiate more radiosensitive organs and tissues than neck irradiations, which will increase the effective dose even when organ doses are similar [9, 10].

Figure 1 shows the relative importance of age and sex on patient radiation risks. The average female-to-male patient risk ratio over the age range of 20–80 was 1.84. This ratio is also age dependent, which was 3.0 for a 20 year old, but only 1.3 in an 80 year old. For males, the risk for a 20 year old was 4.72 higher than that in an 80 year old, and for females, the risk for a 20 year old was 10.4 times higher than that in an 80 year old. These data clearly indicate that patient age is the most important determinant of patient radiation risk, and much higher than that of sex.

Data in Fig. 2 show the risk of thyroid cancer is relatively high in young patients but falls off dramatically as patient age increases. By age 50, the excess thyroid carcinogenic risk contribution is below 9% in females and 3% in males. In older patients, the excess thyroid carcinogenic risk is essentially negligible. These findings are important for practitioners interested in optimizing radiological studies to minimize risks without adversely impacting diagnostic performance. For younger patients, it is more important to reduce thyroid doses for the lateral projections. For older patients, it is more important to reduce the lung and RBM doses in the lower GI portion of this radiological examination.

In this study, we only considered organs and tissues that are explicitly listed in BEIR VII, and did not consider "other" organs and tissues. For adult males, the other organ category would account for 23% of the total carcinogenic risk for uniform whole-body irradiation, and for adult females, this other category would account for 18% of the total carcinogenic risk. These data suggest that radiation risks estimates might be up to 20% or so higher if account were taken of this other category. Given the relatively small size of the X-ray beams used in MBSS examinations, it is more likely that any underestimates in excess carcinogenic risk due to MBSS will be markedly less than 20%, which is much lower than the current uncertainties in radiation risk estimates. Any assessment of radiation risks at the levels associated with radiographic imaging should always consider that current risks' estimates are believed to carry uncertainties of factors of two to three, in both directions.

Figure 3 shows how the risk per unit effective dose (%/Sv) varies with age and sex for patients undergoing MBSSs. These values are generally lower than the risk estimates for uniform whole-body irradiation. One reason why MBSS risks per unit effective dose are lower than the risk estimates for uniform whole-body irradiation is that the "other category" has not been included in our calculations, although this is likely a minor factor. Of greater importance is the use of age- and sex-averaged weighting factors for thyroid, lung, and RBM in computing patient effective doses. The effective dose is a very crude measure of patient detriment, and the risk per mSv will always be exam specific [4]. Given that effective dose can be readily obtained in MBSS examinations, the data shown in Fig. 3 can be used to estimate excess patient cancer risk for a given effective MBSS dose.

It is interesting to consider how patient size will impact on the resultant radiation risk for patients undergoing MBSSs. As the patient size increases, both the X-ray tube voltage (beam penetrating power) and the total amount of radiation incident on the patient (KAP) increase. However, when the patient size increases, the effective dose per unit KAP will be reduced because the deposited energy will be diluted over a larger patient mass [4]. Given that two of the factors (kV and KAP) would increase patient doses, and one of the factors (kg weight) would reduce patient doses, the overall effect on patient dose is clearly indeterminate. This is an issue that has received no attention in the scientific literature so far and is thus currently being investigated in our research laboratory.

Understanding of patient risks in any radiological examination is important to enable practitioners to identify justified examinations where there should be a net patient benefit. What this means is that the patient benefits should exceed any corresponding risks associated with a given diagnostic test, including those associated with exposures to ionizing radiation. Identification of a justified examination requires a clear understanding of radiation risks to ensure a high benefit-to-risk ratio for the patient from the exam. Balancing incommensurate risks and benefits will clearly require practitioners to make a professional judgment as to when any radiological procedure is worthwhile.

Conclusion

Overall, the excess cancer risk per unit effective dose (%/Sv) from MBSS exams are generally lower than the risk estimates for uniform whole-body irradiation. During MBSS exams, the excess risk of thyroid cancer is relatively high in patients 20 year old and younger, but falls off dramatically as patient age increases. For patients above 40 years, the excess risks to lung and RBM are predominant. The excess cancer risk ratio for female-to-male patients is age dependent, from being 3 for a 20 year old to 1.3%/Sv for an 80 year old. The highest risk ratio, ~ 10.4%/Sv, was for a 20-year-old female to an 80-year-old female. These data clearly indicate that patient age is the most important determinant of excess patient radiation risk, and much higher than that of sex.

Funding: This work was supported by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institute of Health (Grant R01 DK098222).

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

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 The research study protocol was reviewed by our IRB who deemed that informed consent should be waived as MBSSs were standard of care and de-identified prior to research use.

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