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Radiation Doses and Cancer Risks from Breast Imaging Studies[1]

R. Edward Hendrick, PhD

Purpose: To compare radiation doses and lifetime attributable risks (LARs) of radiation-induced cancer incidence and mortality from breast imaging studies involving the use of ionizing radiation.

Materials and Methods: Recent literature on radiation doses from radiologic procedures and organ doses from nuclear medicine procedures, along with Biologic Effects of Ionizing Radiation (BEIR) VII age-dependent risk data, is used to estimate LARs of radiation-induced cancer incidence and mortality from breast imaging studies involving ionizing radiation, including screen-film mammography, digital mammography, digital breast tomosynthesis, dedicated breast computed tomography, breast-specific gamma imaging (BSGI), and positron emission mammography (PEM).

Results: Two-view digital mammography and screen-film mammography involve average mean glandular radiation doses of 3.7 and 4.7 mGy, respectively. According to BEIR VII data, these studies are associated, respectively, with LARs of fatal breast cancer of 1.3 and 1.7 cases per 100 000 women aged 40 years at exposure and less than one case per one million women aged 80 years at exposure. Annual screening digital or screen-film mammography performed in women aged 40–80 years is associated with an LAR of fatal breast cancer of 20–25 cases in 100 000. A single BSGI study involving a label-recommended dose of 740–1100 MBq (20–30 mCi) of technetium 99m–sestamibi is estimated to involve an LAR of fatal cancer that is 20–30 times that of digital mammography in women aged 40 years. A single PEM study involving a labeled dose of 370 MBq (10 mCi) of fluorine 18 fluorodeoxyglucose is estimated to involve an LAR of fatal cancer that is 23 times higher than that of digital mammography in women aged 40 years.

Conclusion: A single BSGI or PEM study is associated with a fatal radiation-induced cancer risk higher than or comparable to that of annual screening mammography in women aged 40–80 years.

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The risks and benefits of screening mammography are under constant scrutiny. An obvious risk, and a barrier to some women undergoing screening mammography, is the risk of radiation-induced breast cancer (1). Recently, the increased use of imaging modalities such as computed tomography (CT) has raised concerns about potential cancer induction (2–5). Meanwhile, recently introduced breast imaging modalities such as breast-specific gamma imaging (BSGI) and positron emission mammography (PEM) have been approved by the U.S. Food and Drug Administration and introduced into clinical use as diagnostic adjuncts to mammography and breast ultrasonography (US). These modalities may be considered for breast cancer screening, particularly in women at higher risk for breast cancer. Other recently introduced breast imaging modalities such as digital breast tomosynthesis and dedicated breast CT are the focus of clinical investigation for U.S. Food and Drug Administration approval and also may be considered for screening in some women, such as those with dense breasts, since they offer the potential to unmask cancers obscured by dense fibroglandular tissue on mammograms.

Recent reports have updated dose estimates from screen-film mammography (SFM) and digital mammography (DM), indicating that two-view screening with DM delivers a slightly lower dose than does SFM (6). Relatively recent clinical studies indicate that the mean glandular dose (MGD) from dedicated breast CT is comparable to that from two-view SFM (7) and that a single digital breast tomosynthesis view involves an MGD comparable to that with two-view DM (8). The total radiation dose delivered at digital breast tomosynthesis will depend on the image acquisition strategy: whether single-view digital breast tomosynthesis, two-view digital breast tomosynthesis, or a combination of digital breast tomosynthesis and planar DM views are acquired.

Estimates of the risks of radiation-induced cancers and cancer deaths are based on the results of long-term studies involving the follow-up of women receiving sizable radiation doses. Investigators in these studies have monitored the cancer incidence and mortality rates within each study cohort and compared these rates with those in comparable unexposed or low-exposure cohorts. The most important source of radiation risk data is the follow-up of 76 000 Japanese atomic bomb survivors from Hiroshima and Nagasaki for over 50 years (9–12). On the basis of data from these and other high-dose cohorts, revised estimates of cancer risk have been released recently from two groups: the United States National Academy of Sciences Biologic Effects of Ionizing Radiation (BEIR) VII Group, which has estimated radiation risks to the U.S. population, and the International Commission on Radiological Protection (ICRP) (12,13). Investigators in these studies used a linear, no-threshold dose-response relationship between radiation dose and risk of radiation-induced solid cancers, including breasts cancers.

Like previous ICRP reports, the updated 2007 ICRP report quantifies radiation risk by using the concept of effective dose (13–15). Effective dose is the ionizing radiation exposure to the entire body that would result in equivalent detriment as exposure over a more limited region of the body. In the case of mammography, the primary risk is that of breast cancer induction and resultant mortality due to the exposure of fibroglandular breast tissue to ionizing radiation (16). ICRP has varied its estimate of the contribution of breast radiation exposure to total body detriment over time. The ICRP tissue-weighting factor for breast tissue changed from 0.15 in 1977 to 0.05 in 1991 and 0.12 in 2007. Meanwhile, the ICRP has modified the lifetime attributable risk (LAR) per unit of effective dose for fatal cancer induction in adults from 1.25% per sievert in 1977 to 4.8% per sievert in 1991 and to 4.1% per sievert in 2007 (13–15). Together, the 2007 ICRP breast-weighting factor and risk factor approximately double the ICRP-estimated risk of radiation-induced breast cancer death due to exposure of breast tissue to ionizing radiation compared with the 1977 and 1991 estimates.

A limitation of the 2007 ICRP risk estimates is that they are sex and age

Advances in Knowledge

- According to the most recent radiation risk estimates, a single bilateral two-view digital or screen-film mammography examination is associated with a lifetime risk of inducing fatal breast cancer due to radiation exposure of 1.3–1.7 cases in 100 000 women aged 40 years at exposure and of less than one case in one million in women aged 80 years at exposure.

- Digital breast tomosynthesis and dedicated breast CT involve cancer risks that are one to two times those of digital or screen-film mammography.

- A single breast-specific gamma imaging (BSGI) or positron emission mammography (PEM) examination involves a lifetime risk of inducing fatal cancer greater than or comparable to that of a lifetime of annual screening mammography in women starting at age 40 years.

Implication for Patient Care

- When referring patients for recently introduced breast imaging studies such as BSGI and PEM, one should consider the radiation risks as well as the potential benefits of these modalities.

averaged for adults. Sex averaged means that the risks are averaged for male and female patients. Age averaged means that the patient's age at the time of radiation exposure is not included as a covariate in the risk estimates. It is well established, however, that age at exposure, which affects cell proliferation rates in most organs, is an important factor in the cancer induction risk from ionizing radiation (9–12).

The BEIR VII Group has updated previous risk estimates of radiation-induced cancer incidence and mortality, including the age dependence of both risks (12). In light of these new radiation risk estimates, it seems timely to re-evaluate and summarize radiation doses and the resultant cancer risks associated with all breast imaging modalities that involve the use of ionizing radiation. Because use of the effective dose is not recommended for the evaluation of sex-specific risks and because of the importance of the patient's age at exposure in terms of breast cancer risk and other solid cancer induction risks, BEIR VII risk estimates rather than ICRP effective dose methods are used to estimate the risks of radiation-induced cancer incidence and mortality from breast imaging studies. Breast imaging modalities that do not involve the use of ionizing radiation—and therefore are not associated with any known risk of cancer induction—such as breast US and magnetic resonance (MR) imaging, are not discussed in this article.

Materials and Methods

The author is a consultant to GE Healthcare (Milwaukee, Wis) regarding digital breast tomosynthesis and a member of the medical advisory boards of Koning (Rochester, NY) (dedicated breast CT) and Bracco (Milan, Italy) (MR contrast agents). No support from any industry source was provided for this study, and the study results have not been shared with or in any way influenced by commercial entities.

In this study, the estimated MGD for two-view SFM and DM from peer-reviewed literature was used to estimate the average MGD and range of

MGDs to the U.S. screening population (6,17–19). By using this average MGD, the LAR of radiation-induced breast cancer incidence and mortality is estimated on the basis of the sex-specific, age-dependent BEIR VII estimates (12). BEIR VII data are also used to estimate the risk of radiation-induced breast cancer incidence and mortality from various mammographic screening strategies.

By using the best available information on the design and intended use of digital breast tomosynthesis and dedicated breast CT, the likely breast radiation doses and LARs from these recently introduced breast imaging modalities are estimated (7,8,20–22). Digital breast tomosynthesis involves the acquisition of 10–20 low-dose digital projection views through a compressed breast over a 15°–50° angle by using x-ray beam qualities similar to those used in DM (8,20). These limited-angle acquisitions enable the reconstruction of thin sections through the breast in planes perpendicular to the central (0°) x-ray, decreasing the interfering structured noise caused by overlying tissues outside each reconstructed plane. Dedicated breast CT involves a single 360° data acquisition in each breast with use of an x-ray beam that is harder than that used for SFM and DM (7,21,22). The 360° data set enables CT reconstruction of planar images in any plane through the breast. Reported doses are taken from the literature (7,8,20–22), and BEIR VII data (12) are used to estimate the LARs from digital breast tomosynthesis and dedicated breast CT.

BSGI involves the use of a dedicated gamma radiation detector placed under the breast, with mild compression applied to immobilize the breast to acquire projection images after administration of technetium 99m (^{99m}Tc) sestamibi, the radionuclide used for cardiac stress tests. PEM involves the use of a pair of dedicated gamma radiation detectors placed above and below the breast and mild breast compression to detect coincident gamma rays after administration of fluorine 18 fluorodeoxyglucose (FDG), the positron-emitting radionuclide used in whole-body positron emission tomography studies for the detection of metastatic cancer. BEIR VII estimates (12), along with organ doses from radionuclide labeling literature and other recent publications, are used to estimate age-dependent LARs of radiation-induced cancer incidence and mortality for women undergoing BSGI and PEM. These results are compared with the recent effective dose and risk estimates from other authors (17,23–26). Sex-specific, age-dependent risk estimates based on BEIR VII data are used to compare the LARs associated with various breast imaging studies involving ionizing radiation.

Results

SFM delivers an MGD ranging from 0.25 to 5.0 mGy per view, with higher doses for thicker compressed breasts (Figure) (18). The U.S. average compressed breast thickness during mammography is approximately 5.3 cm (6,27). At this average thickness, the average MGD
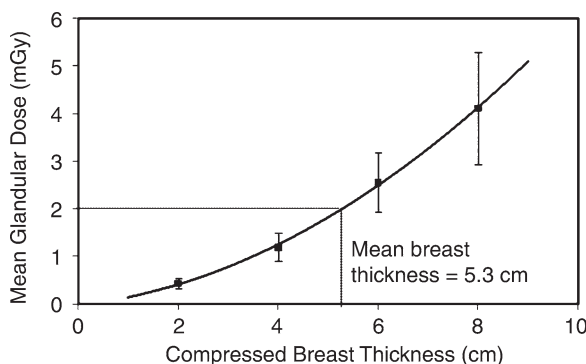
MGD per view as function of compressed breast thickness, measured by using material equivalent to 50% glandular tissue, 50% fatty tissue (18), for 38 SFM units. Error bars represent 1 standard deviation in measured MGDs at each compressed breast thickness across all 38 SFM units. Solid line is best quadratic fit of MGD versus compressed breast thickness.

from two-view SFM was found to be approximately 4 mGy, twice the average MGD from a single view. Investigators in the American College of Radiology Imaging Network (ACRIN) Digital Mammographic Imaging Screening Trial (DMIST) summarized the paired SFM and DM exposures to over 5000 women, reporting an average MGD from SFM of 4.7 mGy (6). With use of the 2007 ICRP breast tissue–weighting factor of 0.12 (13), this MGD corresponds to an average effective dose of 0.56 mSv.

DM has been reported to involve MGDs that are somewhat lower than those with SFM (17,18). Recently reported data from the ACRIN DMIST show breast doses from DM to be 22% lower per view than those from SFM, with two-view DM MGDs averaging 3.7 mGy (6). This MGD corresponds to an average effective dose of 0.44 mSv.

Table 1 shows age-dependent LARs of breast cancer incidence and mortality based on BEIR VII estimates for a typical two-view mammographic examination of each breast at an MGD of 3.7 mGy (DM) to 4.7 mGy (SFM). A 40-year-old woman who undergoes two-view screening mammography of both breasts has an LAR of breast cancer incidence of approximately five to seven cases per 100 000 and an LAR of breast cancer mortality of approximately 1.3–1.7 cases per 100 000.

Since regular screening mammography is recommended in the United States, Europe, and several other developed countries, BEIR VII data have been used to estimate LARs of breast cancer incidence and mortality from annual screening in women starting at various ages up to 80 years (Table 2). Since a linear no-threshold model is assumed, the LARs associated with screening mammography involving lower-dose techniques would scale linearly with the MGD. Biennial screening is associated with LARs that are approximately one-half those cited in Table 2. Whether screening ends at age 80 years or at a more advanced age has little effect on estimated LARs from regular screening since most of the risk is attributed to screening at younger ages. Digital breast tomosynthesis involving breast doses comparable to those from two-view mammography is being developed. Depending on the specific approach taken (single-view digital breast tomosynthesis versus two-view digital breast tomosynthesis in craniocaudal and mediolateral oblique projections), radiation doses from digital breast tomosynthesis are in the range of one to two times the doses from two-view mammography (8,20).

Dedicated breast CT radiation doses similar to those with two-view mammography are being targeted, so the doses recommended on commercial product labels are likely to be equal to or slightly higher than two-view mammography doses (7,21,22). Since only prototype dedicated breast CT systems are available, it is assumed that the doses recommended on commercial product labels will be one to two times the two-view mammography doses. Like mammographic doses, the radiation doses from digital breast tomosynthesis and dedicated breast CT are largely restricted to breast tissue (16). The LARs associated with both digital breast tomosynthesis and dedicated breast CT are estimated to be one to two times those associated with two-view mammography.

BSGI involves a label-recommended administration of 740–1100 MBq (20–30 mCi) of ^{99m}Tc-sestamibi, the dose administered for single-day cardiac stress tests. Effective dose estimates for 1100 MBq of ^{99m}Tc-sestamibi range from 8.9 to 9.4 mSv (17,23,24). The highest doses to the organs are those to the large intestine wall (40.0–55.5 mGy or mSv, since the weighting factor for photons is one), kidneys, bladder wall, and gallbladder wall (20 mGy each) (25). Breasts receive about one-tenth this dose (2 mGy) from 1100 MBq of ^{99m}Tc-sestamibi. The administration of 740–1100 MBq of ^{99m}Tc-sestamibi results in an effective dose of 5.9–9.4 mSv. Risk estimates based on BEIR VII age-dependent organ risks for female patients indicate that an administered dose of 740–1100 MBq of ^{99m}Tc-sestamibi is associated with an LAR of induced fatal cancer of 26–39 cases in 100 000 women aged 40 years at exposure, which decreases to 10–15 cases in 100 000 women at age 80 years at exposure (Table 3). The data in Table 3 show that the age-specific risk of radiation-induced cancer death from a single BSGI study involving 740–1100 MBq of ^{99m}Tc-sestamibi is 20–30 times greater than that from a single DM study in women aged 40 years, with this risk ratio increasing to 132–198 times greater at age 80 years.

PEM involves a label-recommended administration of 370 MBq (10 mCi) of FDG. This administered dose results in

Table 1

LARs of Breast Cancer Incidence and Mortality

Patient Age at Exposure (y)	Incidence	Mortality
20	16–20	4–5
30	9–12	1.9–2.4
40	5–7	1.3–1.7
50	2.6–3.3	0.7–0.9
60	1.2–1.5	0.3–0.4
70	0.4–0.6	0.2
80	0.1–0.2	<0.1

Note.—Data are BEIR VII–based (12) estimates of LAR of breast cancer incidence and mortality per 100 000 women exposed to MGD of 3.7 mGy (DM) to 4.7 mGy (SFM). Data reported in number of cases per 100 000 women.

Table 2

LARs of Breast Cancer Incidence and Mortality in Women Undergoing Annual Screening Mammography

Patient Age Range for Annual Screening Regimen (y)	Incidence	Mortality
25–80	204–260	48–62
30–80	147–187	36–46
35–80	104–133	27–35
40–80	72–91	20–25
45–80	48–61	14–18
50–80	31–40	10–12

Note.—Data are BEIR VII–based (12) estimates of LAR of breast cancer incidence and mortality per 100 000 women undergoing annual screening mammography starting at various ages, with assumption of MGD of 3.7 mGy (DM) to 4.7 mGy (SFM) per examination. Data reported in number of cases per 100 000 women over stated age range.

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an estimated effective dose of 6.2–7.1 mSv (17,23,26). The highest organ doses are those to the bladder (59 mGy or mSv), uterus (8 mGy), and ovaries (5 mGy) owing to a high accumulation of FDG in the bladder before elimination (26). All other organs receive radiation doses of between 2.5 mGy (breast) and 4.8 mGy (colon). Risk estimates based on BEIR VII age-dependent organ risks for female patients indicate that an administered dose of 370 MBq of FDG is associated with an LAR of fatal cancer of about 30 cases in 100 000 women aged 40 years, which decreases to almost half this risk by age 80 years (Table 4). The data in Table 4 show that the age-specific risk of radiation-induced cancer death from a single PEM study compared with that from a

single DM study is more than 20 times greater at age 40 years, more than 75 times greater at age 60 years, and more than 175 times greater at age 80 years.

BEIR VII–based (12) age-dependent estimates of the lifetime risk of radiation-induced fatal cancer due to various breast imaging procedures performed in a 40-year-old woman are summarized in Table 5. The lifetime risk of radiation-induced breast cancer death from a single BSGI or PEM study is higher than or comparable to that from an annual screening mammographic examination in women aged 40–80 years. A single BSGI or PEM study is comparable, in terms of delivered effective dose and lifetime risk of cancer induction, to a single chest, abdominal, or pelvic CT examination (5,17,23).

Discussion

The typical MGD to the breast from two-view screening mammography at 3.7–4.7 mGy would increase slightly if recalls based on screening findings were included. On average, approximately 10% of women in the United States are recalled on the basis of screening mammography findings (28), and a typical diagnostic evaluation involves two to three views. Because some of these views are magnification and spot-compressed views, they involve a total radiation dose comparable to two to four screening views. Thus, the population dose and risk are increased, on average, an additional 5%–10% beyond those associated with screening mammography (dose increase to 3.9–5.2 mGy) when the MGDs of recall examinations prompted by screening are included.

Digital breast tomosynthesis and dedicated breast CT are not clinically approved for use in the United States at this time. The final design parameters, acquisition techniques, and clinical roles of these devices are still under investigation. Thus, there may be substantial variations between the estimated MGDs and cancer risks associated with these devices reported herein and those associated with their eventual clinical use.

Average MGDs to the breast from screening mammography can be compared with the measured doses delivered directly to the breast from whole-body CT scanning, which are 5.7–19.1 mGy for three specific CT protocols (26). Doses delivered directly to the breast have been reported to be 20–60 mGy from high-spatial-resolution chest CT for pulmonary embolism, 50–80 mGy from CT coronary angiography, and 10–20 mGy (to inferior aspect of breast) from abdominal CT (17).

To put dose levels from breast imaging studies in perspective, the average effective dose from natural background radiation in the United States, excluding man-made and medical sources, is about 3 mSv per year (19,29). The average effective dose from two-view mammography (0.44 mSv [from DM]) to 0.56 mSv [from SFM]) equals approximately two months of natural

Table 3

LARs of Cancer Incidence and Mortality in Women Undergoing a Single BSGI Study

Patient Age at Exposure (y)	Incidence*	BSGI-related Incidence/ DM-related Incidence†	Mortality*	BSGI-related Mortality/ DM-related Mortality†
20	88–132	5–8	37–56	10–15
30	59–89	7–10	27–40	14–21
40	55–82	11–16	26–39	20–30
50	49–73	19–28	24–36	34–51
60	40–60	35–52	21–32	63–95
70	28–42	63–95	17–25	89–133
80	14–21	95–143	10–15	132–198

* BEIR VII–based (12) estimates of LAR of cancer incidence and mortality per 100 000 women undergoing single BSGI study with use of 740–1100 MBq (20–30 mCi) of ^{99m}Tc-sestamibi. Data reported in number of cases per 100 000 women.

† Ratios of age-dependent lifetime risks of cancer incidence or mortality from single BSGI examination to these risks from single DM examination at same age at exposure.

Table 4

LARs of Cancer Incidence and Mortality in Women Undergoing a Single PEM Study

Patient Age at Exposure (y)	Incidence*	PEM-related Incidence/ DM-related Incidence†	Mortality*	PEM-related Mortality/ DM-related Mortality†
20	118	7	44	12
30	81	9	32	17
40	75	14	31	23
50	68	26	28	40
60	57	49	26	78
70	40	91	21	113
80	20	137	13	178

* BEIR VII–based (12) estimates of LAR of cancer incidence and mortality per 100 000 women undergoing single PEM study with use of 370 MBq (10 mCi) of FDG. Data reported in number of cases per 100 000 women.

† Ratios of age-dependent lifetime risks from single PEM examination to these risks from single DM examination at same age at exposure.

background radiation, while effective doses from BSGI and PEM studies (6.2–9.4 mSv) equal approximately 2–3 years of natural background radiation exposure.

This article is focused on the radiation-related risks rather than benefits of various breast imaging procedures, with its main emphasis being that radiation risks can differ markedly from one procedure to another. In terms of relative risk to a 40-year-old woman, a single BSGI or PEM study involving the use of a label-recommended radionuclide dose is associated with a higher risk of cancer induction than is a single SFM or DM examination by a factor of about 15 and with a higher risk of cancer-related mortality by a factor of about 25. This is because fibroglandular breast tissue is the only radiosensitive tissue exposed to a substantial level of ionizing radiation in mammography (16), while all body organs are irradiated with BSGI and PEM radionuclides—namely, ^{99m}Tc-sestamibi and FDG, respectively. Hence, the risk from mammography is that of induced breast cancer only, while the risks from BSGI and PEM are those of cancer induction in a number of radiosensitive organs. With BSGI and PEM, there is a reliance on both radioactive decay (^{99m}Tc gamma emissions having a 6-hour half-life, fluorine 18 positron emissions having a 110-minute half-life) and biologic clearance to reduce the quantity of radionuclide administered in the body. The distribution of these radionuclides in the bloodstream, their uptake in tissues, and their partial clearance by means of hepatobiliary uptake (for ^{99m}Tc) or renal glomerular filtration (for FDG) result in radiation exposure of radiosensitive organs in the chest, abdomen, and pelvis. The highest radiation doses and cancer risks are those to the colon (with BSGI) and bladder (with PEM).

The risk of cancer induction in breast tissue decreases more rapidly with the age at exposure than do the risks of cancer induction in other organs. This is reflected by the increased risk of cancer induction associated with radionuclides relative to DM with increased age at exposure. Moreover, the cancers that occur in the tissues at highest risk for cancer induction from radionuclide administration, such as colon, lung, and bladder cancers, are less curable than is breast cancer. Consequently, the risk ratios of BSGI and PEM to DM are greater for cancer mortality than for cancer incidence.

There is continuing controversy regarding the most effective methods of screening women in different risk groups for breast cancer and the age at which screening should begin, particularly in women at higher risk because of their genetic status or family history. There is also controversy regarding women with denser breasts, for whom the risk of breast cancer is known to be higher and the sensitivity of SFM is known to be lower (30,31). The results reported herein indicate that BSGI and PEM are not good candidate procedures for breast cancer screening because of the associated higher risks for cancer induction per study compared with the risks associated with existing modalities such as mammography, breast US, and breast MR imaging. The benefit-to-risk ratio for BSGI and PEM may be different in women known to have breast cancer, in whom additional information about the extent of disease may better guide treatment.

It should be noted that there have been no direct observations of cancers resulting from single or multiple routine medical imaging exposures. In debates regarding the benefits and risks from imaging procedures involving ionizing radiation, this fact is commonly emphasized to downplay the estimated radiation risks associated with medical imaging. The risk estimates reported herein are theoretical: They are based on long-term follow-up of acute exposures to higher levels of ionizing radiation and a linear no-threshold extrapolation of risks to low doses. While there is some uncertainty regarding the linear extrapolation of risk from high-level exposures to single exposures or periodic low-dose exposures, these estimates are based on accepted methods of estimating radiation risks and communicating them to patients and referring physicians. The BEIR VII group estimated uncertainty in their radiation-induced breast cancer incidence values with a coefficient of variation of 36% (standard error of the LAR as a percentage of the LAR estimate). The greatest source of uncertainty comes from extrapolating high-dose, high-dose-rate exposures (as occurred in atomic bomb survivors) to low-dose examinations (as performed in all of the screening and diagnostic breast imaging procedures described herein) and low-dose-rate examinations (as performed in annual screening mammography) (12).

Picano (32) observed three common approaches to informed consent in clinical practice—no mention of risk, understatement of risk, and specific detailing of risk—only the last of which is acceptable. While the challenge of

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Table 5

LARs of Radiation-induced Fatal Cancer from Various Breast Imaging and Whole-Body CT Procedures

Imaging Protocol	LAR of Fatal Cancer*
Bilateral two-view mammography	
Age 40 y	1.3–1.7
Age 80 y	<0.1
Digital breast tomosynthesis, age 40 y	1.3–2.6
Dedicated breast CT, age 40 y	1.3–2.6
Annual two-view screening mammography, ages 40–80 y (41 examinations)	20–25
BSGI with 740–1100 MBq (20–30 mCi) of ^{99m}Tc-sestamibi, age 40 y	26–39
PEM with 370 MBq (10 mCi) of FDG, age 40 y	31
Pelvic, chest, or abdominal CT	25–33†

* Data are reported as number of cases per 100 000 examinations and unless otherwise noted are based on BEIR VII estimates (12).

† Based on 2007 ICRP sex- and age-averaged risk estimates (13,17).

communicating risks that accompany medical procedures is complex, the principle of patient autonomy requires that attempts be made to clearly and accurately communicate the balance between benefits and potential harms. In most cases, this balance favors the use of imaging, but it is up to the patient, in consultation with the physician, to interpret that balance. Referring physicians and patients face additional challenges when multiple competing technologies—each with different benefits and risks—are available.

BSGI and PEM devices have been shown to have reasonably high sensitivity to breast cancer, but clinical studies of these devices are limited and have involved relatively small numbers of subjects known to have breast cancers or lesions highly suspicious for breast cancer (33–36). Currently, BSGI and PEM devices are being marketed to breast centers and private physicians' offices as problem-solving adjunctive tools and, in some cases, second-look devices after mammography and US. The associated risks and potential benefits of these procedures, even as diagnostic adjuncts to mammography, should be communicated to patients through informed consent. In addition, before these modalities are considered for screening, thorough clinical investigation is needed to demonstrate that their benefits exceed their risks, including the risks of radiation-induced cancers.

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