Radiation Risk From Screening Mammography of Women Aged 40–49 Years

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Although direct evidence of carcinogenic risk from mammography is lacking, there is a hypothetical risk from screening because excess breast cancers have been demonstrated in women receiving doses of 0.25–20 Gy. These high-level exposures to the breast occurred from the 1930s to the 1950s due to atomic bomb radiation, multiple chest fluoroscopies, and radiation therapy treatments for benign disease. Using a risk estimate provided by the Biological Effects of Ionizing Radiation (BEIR) V Report of the National Academy of Sciences and a mean breast glandular dose of 4 mGy from a two-view per breast bilateral mammogram, one can estimate that annual mammography of 100,000 women for 10 consecutive years beginning at age 40 will result in at most eight breast cancer deaths during their lifetime. On the other hand, researchers have shown a 24% mortality reduction from biennial screening of women in this age group; this will result in a benefit-to-risk ratio of 48.5 lives saved per life lost and 121.3 years of life saved per year of life lost. An assumed mortality reduction of 36% from annual screening would result in 36.5 lives saved per life lost and 91.3 years of life saved per year of life lost. Thus, the theoretical radiation risk from screening mammography is extremely small compared with the established benefit from this life-saving procedure and should not unduly distract women under age 50 who are considering screening. [Monogr Natl Cancer Inst 1997;22: 119–124]

The risk of radiation-induced breast cancer is a consideration in determining the advisability of mammographic screening for women of any age group and may be especially important for women aged 40–49 years. Due to the relatively lower breast cancer incidence in younger women, it is particularly important to assess in these women the number of lives saved versus deaths caused and the years of life expectancy gained per year of life lost through screening.

Risk Assessment

Although no women have ever been shown to have developed breast cancer as a result of mammography, not even from multiple examinations received over many years at mean glandular doses considerably higher than the current average mammographic doses of 3–4 mGy (0.3–0.4 rad), the possibility of such risk exists because excess breast cancers have been observed among populations receiving much higher doses—say, 0.25–20 Gy (25–2,000 rads). These include Japanese A-bomb survivors (*1*), North American tuberculosis sanitoria patients from Massachusetts (*2*) and Canada (*3*) who underwent multiple chest fluoroscopies, women from New York State (*4*) and Sweden (*5*) treated with radiation therapy for benign breast conditions such as postpartum mastitis, and women who had been treated in California with radiation therapy for Hodgkin's disease (*6*).

Estimating the risk of breast cancer from low-dose radiation is complex. However, relatively similar estimates have been made by various committees over the past 20 years, most notably by the 1977 National Cancer Institute (NCI) Ad Hoc Working Group on the risks associated with mammography and mass screening for the detection of breast cancer (*7*), by the 1980 Committee on the Biological Effects of Ionizing Radiation (BEIR III) of the National Academy of Sciences (*8*), by the 1985 National Institutes of Health Ad Hoc Group to Develop Radiol-epidemiological Tables (*9*), by the National Academy of Sciences' 1990 National Research Council Committee on the Biological Effects of Ionizing Radiation (BEIR V) (*10*), and by the 1994 United Nations Scientific Committee on the Effects of Atomic Radiation (*11*). Each committee has had to base its estimate not only on the follow-up data available at that time, but also on a selection of other assessment options, such as dose-response models, length of latent period, duration of radiation effect, age-related radiation sensitivity, and absolute versus relative risk models.

Dose-Response Models

Because radiation-induced and spontaneously occurring breast cancers cannot be distinguished histologically (*12,13*), the presence of radiation-induced tumors can only be established statistically if a significant number of excess cancers are observed in an exposed population. This type of inference becomes harder and harder to establish as lower and lower doses are considered, since the number of exposed women required to demonstrate an effect is related to the inverse square of dose. For example, if 1,000 exposed and 1,000 control women are needed to demonstrate an effect at 1 Gy, then two groups of 100,000 women each are necessary at 0.1 Gy and two groups of 10,000,000 women each are necessary at 1 cGy, assuming a linear dose-response relationship (*14*).

If there is any risk to the breast from doses in the mammographic range (3–4 mGy per two-view exam) or even from doses

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of 100 mGy (10 rad) or less, the magnitude of the risk may be estimated by means of dose-response curves, which describe the possible relationship between radiation dose and radiogenic cancer incidence (Fig. 1). In the linear dose-response model, incidence is directly proportional to dose: if the dose is diminished by a factor of 10, the excess cancer incidence will also be reduced by the same factor. With the quadratic dose-response relationship, the effect is proportional to the dose squared: if the dose is reduced by a factor of 10, the number of excess cancers would be reduced by a factor of 100. The linear-quadratic dose-response relationship predicts a risk between the risks expected from pure linear and pure quadratic models.

Most but not all experiments on a wide variety of radiation-induced tumors in laboratory animals exhibit a quadratic dose-response relationship at doses below 0.5 Gy (50 rads) (*10*). However, a similar relationship may not necessarily hold for breast cancer in humans.

Most studies on radiation-induced breast cancer in humans contain a paucity of data on doses below 0.5 Gy (50 rads), and not one provides direct information concerning risks from doses less than 0.1 Gy (10 rads) (*15*). However, results from a linear regression analysis over a wide range of doses found data highly consistent with a linear model; the data also fit a linear-quadratic model fairly well when a strong linear component is present (*1*). Nevertheless, a quadratic dose-response function at doses below 0.05 Gy (5 rads) cannot be excluded at the 95% confidence level (*1*). Therefore, the linear model is most often used to estimate risk at low doses. Lower risk estimates would be obtained with other types of dose-response relationships. Although an appropriate upper confidence limit of a linear coefficient represents the upper limit of risk, a point estimate of the slope of a linear fit provides a reasonable estimate of risk.

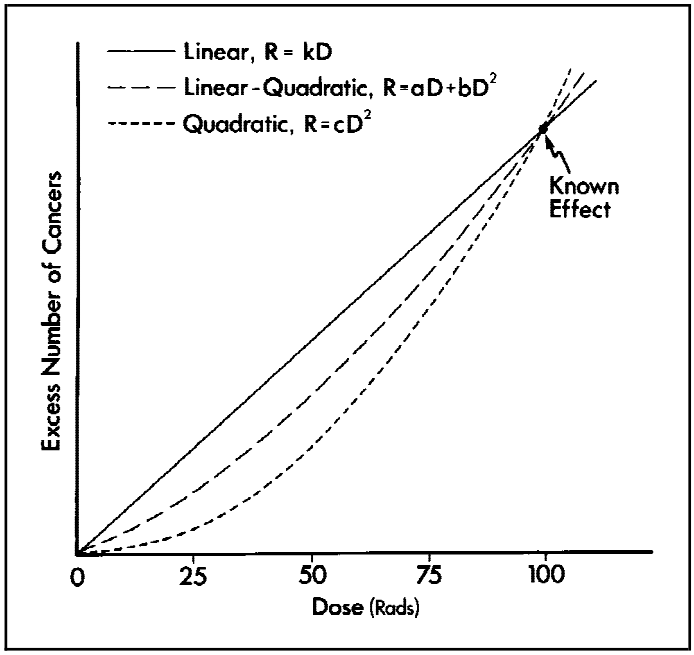

Fig. 1. Models for possible dose-response relationships at low doses. Most estimates for the hypothetical breast cancer risk from mammography have employed a linear dose-response model with the understanding that this projection represents the upper limits of such risk. R = risk per rad.

Latent Period and Duration

The latent period refers to the minimal length of time between exposure and earliest demonstration of excess cancers in a population. Because radiogenic breast cancers do not occur earlier than the spontaneous variety, the latent period may depend on age at exposure. Most reports have assumed latent periods of at least 10 years and a lifetime persistence of radiation risk in the exposed population. The BEIR V Report assumed that there is a latent period of about 10 years after exposure before the risk of radiation-induced breast cancer is non-negligible. The Report also assumed that the period of excess risk may persist for the patient's lifetime, since all populations have continued to exhibit excess breast cancer risk on the longest follow-up studies—those following subjects 30–45 years after exposure (*1–4*).

Age at Exposure

All but one of the studies of radiogenic risk found decreased risk with increasing age at exposure (*1–3,5,6*) (Fig. 2). New York women treated with radiotherapy for postpartum mastitis (*4*) constitute the only group that has not shown any relationship between risk and age at exposure. Their breasts were, however, in a proliferative state, with elevated hormonal stimulation due to parturition and lactation. The BEIR V Report concluded that ''there is little evidence of any increased risk to women exposed after age 40'' (*10*).

Additive and Relative Risk Models

Additive and relative risk models represent two different ways of estimating excess risk (defined as either excess breast cancer incidence or mortality) following radiation. Additive (or absolute) risk estimates are given as a number of excess cancers/million women/year/cGy (rad). Relative risk estimates are given as the percentage increase in the natural breast cancer incidence/year/cGy (rad). BEIR V used a time-dependent relative risk model in which relative risk varied over time during the follow-up, reaching a peak at 15–20 years after exposure and then declining (*10*). Recent studies suggest that the complexity of BEIR V model may not be necessary to explain these data (*1*). BEIR V used the relative risks derived from mortality data from the Japanese and non-Nova Scotia Canadian populations to provide an absolute risk estimate for mortality among North American women according to age at exposure. Although the excess relative risk for Japanese women was 2 to 3 times that for non-Nova Scotia Canadian women, this difference was not statistically significant ($P = 0.12$). Although Japanese background breast cancer rates are considerably lower than those in Canada, the additive excess risk per unit dose was not significantly less than that for non-Nova Scotia women ($P>.5$) (*10*).

Quantifying Benefits and Risks

Using the 1985 NIH relative risk estimate, Feig and Ehrlich found that a single screen of women at ages 40–44 and 45–49 with a dose of 2.5 mGy and 20% reduction in breast cancer mortality due to screening would result in benefit/risk ratios of 35 and 90 years of life expectancy gained per year of life lost respectively (*15*).

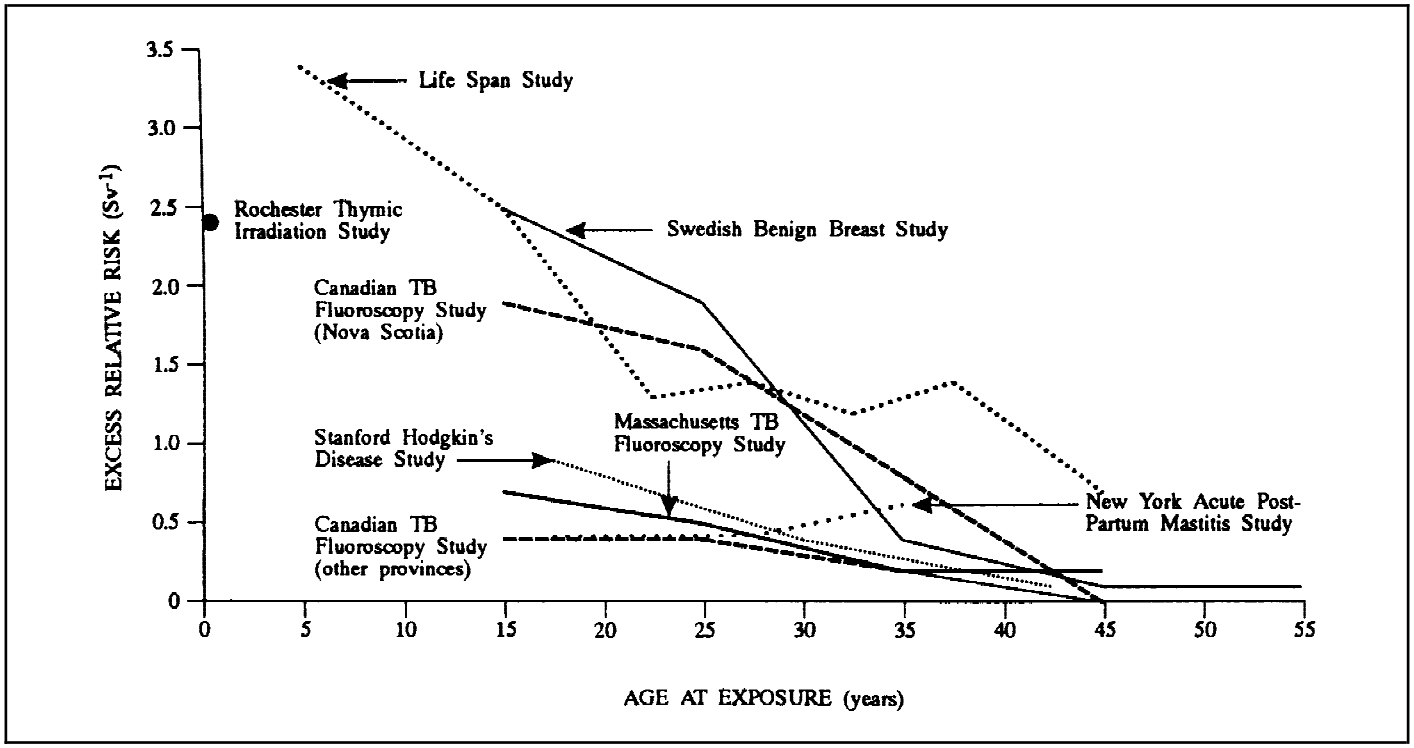

Fig. 2. Excess relative risk per 0.1 Sievert (0.1 Gy absorbed dose) for breast cancer incidence according to age at exposure. From reference *(11)* with permission.

Using the 1990 BEIR V relative risk estimate, Feig et al. (*16*) calculated that a single mammographic screening of women at age 45 with a dose of 2.5 mGy and breast cancer mortality reductions of 20% and 40% due to screening would avert 30 and 60 deaths per death caused respectively. Assuming that some radiogenic cancers would be detected by subsequent screening, the benefit/risk ratios from the single screen would be 37.5 and 100 respectively at the same levels of benefit.

Law calculated that a single mammographic film per breast with a dose of 1 mGy at age 40–49 would detect 186 times more breast cancers than it might induce (*17*).

Based on the 1994 Radiation Effects Research Foundation (RERF) relative risk estimate, Mettler et al. developed benefit/risk ratio tables comparing fatal cases of breast cancer prevented by screening mammography to those caused by screening mammography (*18*). Mortality reductions of 15% for screening women age 40–49 and 25% for screening women age 50–75 were assumed along with a dose of 2.8 mGy per two-view mammographic examination. The authors calculated that if a woman began annual mammography at age 40, mammographic examination at age 44 would provide 850 times more benefit than the potential harm from all of her mammographic examinations combined.

Current Estimates of Screening Benefit

More accurate quantitative information on reduction in breast cancer screening mortality through screening has become available during the past several years through longer-term follow-up of women enrolled in randomized controlled trials (RCTs). Two separate meta-analyses of data from seven population-based RCTs have both shown a breast cancer mortality reduction of about 24% from screening women aged 40–49 years at entry in intervals of generally every two years (range = 12–28 months) (*19,20*). Specifically, a relative mortality reduction of 0.76 (95% confidence interval [CI]: 0.61–0.98) was found by Smart et al. (*19*), and a reduction of 0.76 (95% CI: 0.62–0.93) was found by the Organizing Committee, Falun Sweden Screening Meeting (*20*). For women aged 50 and over invited for biennial screening in the Swedish Two-County Trial, a statistically significant 39% reduction in breast cancer mortality has been observed (*20*).

Based on relative death hazards found for cancers detected at screening, for interval cancers, for cancers found among study group women who refused to be screened, and for those among control group women, it has been calculated that if all study group women in the two-county trial had been screened every year, a breast cancer mortality reduction of 36% could be expected for those aged 40–49 years at entry (*20,21*), and a 45% mortality reduction in breast cancer mortality could be expected for those aged 50–74 years at entry (*20*).

Current Radiation Risk Estimates

Recently, it has been suggested that the mean glandular dose for a two-view per breast mammographic examination could be 3–4 mGy higher than the previous estimate of 2.5 mGy. This higher estimate is due to a larger estimated compressed breast thickness (5–5.7 cm vs. 4.2 cm) (*17,22*) and increased x-ray exposures to attain higher average optical densities (1.4–1.8 vs. 1.3) on the mammographic film. Higher optical densities have been shown to result in earlier detection of breast cancer (*23*).

The BEIR V Report estimated mortality from radiation-induced cancers based on a combined analysis of data from Japanese atomic bomb survivors and non-Nova Scotia Canadian

tuberculosis patients receiving multiple chest fluoroscopies. Using an age-at-exposure–dependent and time-since-exposure–dependent relative risk model, a linear dose-response relationship, and a 10-year latent period, the BEIR V Committee estimated that if 100,000 U.S. women aged 40–49 years received a single dose of 10 rem (100 mGy), at worst no more than 20 excess breast cancer deaths might occur during the lifetimes of those 100,000 women.

Based on this estimate, it can be calculated that if 100,000 women were to receive annual mammography for 10 consecutive years beginning at age 40 with a dose of 4 mGy per examination, at most 8 breast cancer deaths might result over the lifetimes of these 100,000 women. However, if these women continued to be screened after age 50, some radiation-induced breast cancers would be detected at a curable stage at a subsequent screen. Assuming mortality reductions of 39% for biennial screening and 45% for annual screening of women age 50 and over, one can estimate the number of breast cancer deaths potentially caused by annual screening of 100,000 women in their forties to be 4.9 deaths and 4.4 deaths respectively (Table 1).

On the other hand, 5 biennial screenings of 100,000 women beginning at age 40 might at worst result in 4 excess breast cancer deaths. Subsequent biennial or annual screening beginning at age 50 would reduce the number of deaths from breast cancers potentially induced by screening 100,000 women age 40–49 to 2.4 deaths and 2.2 deaths respectively (Table 1).

Benefit/Risk Ratio Expressed as Lives Saved per Life Lost

Deaths averted through screening women in their forties can be calculated among 100,000 women aged 40–49 years; a natural breast cancer incidence at 1,620 invasive breast cancers/year can be expected over the 10-year period between each woman's 40th and 50th birthdays based on the National Cancer Institute Surveillance, Epidemiology, and End Results Program (SEER) data (*24*). Assuming a 20-year relative survival rate of 50% for these invasive cancers in the absence of screening (*24*), one can expect at least 810 breast cancer deaths due to these breast cancers. At the same time, biennial screening—shown to produce a 24% mortality reduction (*19,20*)—could prevent 194 of these breast cancer deaths. Likewise, assuming a 36% mortality reduction from annual screening (*20,21*), one can estimate that 292 of these breast cancer deaths would be prevented.

Therefore, annual screening of women age 40–49 years could save 36.5 (292/8) lives for every life potentially lost due to radiation-induced breast cancer, and biennial screening could save 48.5 (194/4) lives for every life potentially lost due to a radiation-induced cancer (Table 1). This is a fairly conservative estimate, since it assumes that no radiation-induced cancers are detected at a curable stage due to screening subsequent to age 49. Subsequent biennial screening after age 50 could result in an improved benefit/risk ratio, and annual screening after age 50 would result in an even higher benefit/risk ratio for lives saved per life lost due to screening women age 40–49. If annual screening after age 50 were to reduce breast cancer deaths by 45%, benefit/risk ratios from screening women in their forties would be nearly twice as high as without screening after age 49. Given the current screening practice in the U.S., it is unlikely that a woman who went for annual or biennial screening during her forties would suddenly stop being screened after age 50. Therefore, most realistic benefit/risk ratios for women undergoing annual screening in their forties would range from 60/1–66/1 lives saved per life lost. For women undergoing biennial screening in their forties, the range would be from 81/1 to 88/1 lives saved per life lost (Table 1).

Table 1. Benefit/risk ratio expressed as lives saved due to mammographic screening of women aged 40–49 years* versus lives lost due to possible risk from radiation†

Screening interval	Screening after age 50		
	None	Biennial	Annual
Annual	36.5 (292/8)	59.6 (292/4.9)	66.4 (292/4.4)
Biennial	48.5 (194/4)	80.8 (194/2.4)	88.2 (194/2.2)

*Benefit estimate based on an average annual breast cancer incidence, a 20-year survival rate from SEER data (*24*), a 36% mortality reduction expected from annual screening (*20,21*), and a 24% mortality reduction observed from generally biennial screening in population-based randomized trials (*19,20*). Biennial and annual screening after age 50 is assumed to reduce deaths from radiation-induced breast cancer by 39% and 45%, respectively (based on data from reference *20*).

†Risk estimate based on BEIR V Report (*10*) and a mean glandular dose of 4 mGy per two-view/breast bilateral mammogram.

Benefit/Risk Ratio Expressed as Years of Life Expectancy Saved/Lost

Benefits and risks may also be compared as years of life gained through screening versus years of life potentially lost due to radiation-induced cancers. This can be better understood by means of the following calculations. Since nearly all deaths from breast cancer will occur within 20 years of diagnosis, the average death from breast cancer, whether naturally occurring or radiation induced, will occur around 10 years from diagnosis. According to BEIR V, no radiation-induced breast cancer will occur within 10 years of radiation exposure, and the most likely time of detection of radiation-induced breast cancers will be 15 years after exposure. Since the average age at death occurs 10 years after detection, the average age at death from radiation-induced breast cancers due to screening women ages 40–49 years will be around age 70. Since the normal life span is 80 years, a woman who dies from breast cancer induced by screening during her forties will have lost an average of 10 years of life expectancy. On the other hand, the average age of death from breast cancer occurring between age 40–49 years would be age 55 or perhaps slightly older. Therefore, the average life saved through screening women aged 40–49 will add around 25 years of life expectancy. The ratio of the number of years of life expectancy saved versus lost through screening women in their forties will be 2.5 (25/10) times the ratio of lives saved versus lost from screening women in this age group (Table 2).

Assuming no further screening after age 49 and a 36% mortality reduction from annual screening, women age 40–49 will gain 91.3 years of life expectancy for every year possibly lost from radiation-induced cancers. For biennial screening, there will be 121.3 years of life expectancy gained per year potentially lost. As previously discussed, it is realistic to assume that women will continue to be screened every year or two after age

Table 2. Benefit/risk ratio expressed as years of life saved due to mammographic screening of women aged 40–49 years versus years of life lost due to possible risk from radiation*

Screening interval	Screening after age 50		
	None	Biennial	Annual
Annual	91.3	149.7	166.0
Biennial	121.3	198.9	220.5

*For mammographic screening of women aged 40–49, years of life expectancy gained/lost are 2.5 × lives saved/lost (see text for calculation). Lives saved/lost as per Table 1.

50, so that some radiation-induced cancers will be detected at a curable stage. In that case, there would be 150–166 years gained/lost from annual screening and 199–221 years gained/lost from biennial screening between age 40–49 (Table 2).

Net Benefit From Annual Versus Biennial Screening

Benefit/risk ratios for biennial screening are approximately 1.3 times higher than those for annual screening of women ages 40–49 because radiation risks from annual screening are twice that of biennial screening, whereas mortality reduction is only 1.5 times (36/24) higher. Of course, this observation does not necessarily imply that biennial screening is preferable. Net benefit, expressed as differences between lives saved and lives lost or as differences between years of life expectancy gained and years of life lost through screening, may be useful for comparing different screening regimens. Values for net benefit from annual screening shown in Table 3 are always approximately 1.5 times higher than the corresponding values for net benefit from biennial screening shown in Table 4.

Although subsequent annual or biennial screening after age 50 appears to have a substantial effect on benefit/risk ratios for screening women age 40–49 (Tables 1 and 2), such subsequent screening has relatively little effect on net benefit from screening women in their forties (Tables 3 and 4).

Radiation Risk and Other Risk Factors

Risk factors associated with radiation are incompletely known and, for some risk factors, may be extremely difficult to evaluate. For example, older age is a major risk factor for breast cancer, yet there is an inverse relationship between radiation sensitivity and age at exposure (*11*). Environmental factors are also hard to assess. For instance, although American women have a higher breast cancer incidence than Japanese women, probably due to diet and other environmental factors, absolute breast cancer risk from radiation is similar when both populations are compared, but relative risk factors are markedly different (*25*).

There are also possible genetic risk factors. One report claimed a fivefold or sixfold excess risk of breast cancer among blood relatives of patients with ataxia-telangiectasia who had received single or multiple diagnostic x-rays with an extremely low estimated dose to the breast glandular tissue of 1–9 mGy (*26*). A number of experts have expressed skepticism about these results, however, due to small sample size, inadequate assessment of radiation exposure, inconsistencies in results, presence of other confounding differences between the study and control groups, and incompatibility of this study with much larger studies showing no increase in breast cancer among women exposed to radiation after age 40 (*27–30*). Moreover, women who are heterozygous for the ataxia-telangiectasia gene represent less than 1% of the U.S. female population (*31*).

Inherited mutations in the BRCA 1 and BRCA 2 genes may be involved in 14% of breast cancers among women ages 40-49 and progressively lower percentages of breast cancers among older women (*31*). Meaningful studies of radiation sensitivity in women with inherited BRCA 1 and BRCA 2 mutations have not yet been performed and might not be feasible due to their very high baseline breast cancer incidence and the fact that they represent a relatively small proportion of the general population. Other factors, such as patient confidentiality and continued medical insurability, might also affect the ability to identify women with inherited gene mutations for these studies.

Table 3. Net lives saved due to annual mammographic screening of 100,000 women beginning at age 40 until age 49*

	Subsequent screening after age 50		
	None	Biennial	Annual
Lives saved due to screening	292	292	292
Lives lost due to radiation-induced breast cancers	8	4.9	4.4
Net lives saved	284	287.1	287.6

*Calculated using data and assumptions of Table 1.

Table 4. Net lives saved due to biennial mammographic screening of 100,000 women beginning at age 40 until age 49*

	Subsequent screening after age 50		
	None	Biennial	Annual
Lives saved due to screening	194	194	194
Lives lost due to radiation	4	2.4	2.2
Net lives saved	190	191.6	191.8

*Calculated using data and assumptions of Table 1.

Conclusion

For the general population of women ages 40–49, the theoretical radiation risk from screening mammography is extremely small compared with the established benefit from this life-saving procedure. Subgroup analysis of radiation sensitivity in high-risk women should not become a distraction from this overriding conclusion.

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