Five-year and Lifetime Risk of Breast Cancer among U.S. Subpopulations: Implications for Magnetic Resonance Imaging Screening

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Abstract

Background—Guidelines from the American Cancer Society recommend annual breast MRI screening for women with a projected lifetime risk of ≥20% based on risk models that use family history. Since MRI screening is costly and has limited specificity, estimates of the numbers of U.S. women with breast cancer risk ≥20% would be useful.

Methods—We used data from the 2000 and 2005 National Health Interview Survey and the National Cancer Institute's (NCI) Breast Cancer Risk Assessment Tool (i.e. Gail Model 2 with a revision for African Americans) to calculate estimates of U.S. women by age and race/ethnicity categories with a lifetime absolute breast cancer risk of ≥20%. Distributions of 5-year and lifetime absolute risk of breast cancer are compared across demographic groups.

Results—We estimated that 1.09% (95% CI = 0.95% to 1.24%) of women aged 30–84 years have a lifetime absolute breast cancer risk of ≥20%, which translates to 880,063 U.S. women eligible for MRI screening. The 5-year risks are highest for White non-Hispanics and lowest for Hispanics. The lifetime risks decrease with age and are generally highest for White non-Hispanics, lower for African American non-Hispanic and lowest for Hispanics.

Conclusion—We provide national estimates of the number of U.S. women who would be eligible for MRI breast screening and distributions of 5-year and lifetime risks of breast cancer using the NCI Breast Cancer Risk Assessment Tool.

Impact—These estimates inform the potential resources and public health demand for MRI screening and chemo-preventive interventions that might be required for U.S. women.

Introduction

In response to new data on the sensitivity and specificity of magnetic resonance imaging (MRI) to screen and diagnose high risk women for breast cancer, the American Cancer Society updated guidelines for the use of MRI as an adjunct to mammography in breast cancer screening (1). These guidelines recommend annual breast MRI for women who carry, or have a first-degree relative who carries a mutation in the BRCA1 or BRCA2 genes, women in families with rare familial syndromes such as the Li and Fraumeni syndrome, or women who received therapeutic chest radiation at ages 10–30 and women with a projected lifetime risk of 20% or greater based on "risk models that are largely dependent on family history." A number of models are available for predicting lifetime risk (2). One such model, the National Cancer

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Institute (NCI) Breast Cancer Risk Assessment Tool, which is sometimes called the Gail Model 2, is a widely used tool to identify women at high risk of breast cancer for multiple purposes (2–4). This model includes age at menarche, age at first birth, personal history of benign breast biopsies and of atypical hyperplasia, in addition to family history of breast cancer. Since MRI breast cancer screening is costly and has been shown to have limited specificity (5,6), it would be useful to provide health researchers and policy analysts with nationally representative estimates of the numbers of U.S. women with a breast cancer risk estimate that would meet the ACS's criterion of ≥20% lifetime risk for breast cancer screening with MRI. In this paper we present the numbers and percentages of women who meet this criterion and also present estimated distributions of 5-year and lifetime absolute risk of breast cancer using smaller cutoffs such as the 1.67% 5-year absolute risk used to determine eligibility for tamoxifen in the Breast Cancer Prevention Trial (7). Little work has been done to compare these distributions of absolute risk across race/ethnic groups and age groups. These population estimates of the numbers of women who are at various levels of elevated risk of breast cancer provide public health researchers with determinants of future demand for chemo-preventive agents and for breast cancer screening. We combine data collected in National Health Interview Survey (NHIS) conducted in 2000 and 2005 to calculate the percentage and number of U.S. women with a lifetime absolute risk estimate of breast cancer based on the NCI Breast Cancer Risk Assessment Tool separately for White, African American and Hispanic women in various age categories.

Methods

The NHIS is a nationally representative annual household survey that collects health-related data using stratified multistage cluster probability sampling of the noninstitutionlized civilian U.S. population (8,9). The survey is conducted by the National Center for Health Statistics, using interviewers from the U.S. Bureau of the Census and collects data for all family members from a sampled household. The survey provides national data on basic demographics, incidence of illness and accidental injuries, prevalence of chronic conditions and impairments, and usage of health services. The data in these analyses come from two surveys conducted during the years 2000 and 2005 (8,9). During those years the NHIS contained a Cancer Control Survey Module (CCM), which was designed and funded by the National Cancer Institute and the Centers for Disease Control and Prevention. This module collected additional data on risk factor and screening practices related to cancer from one randomly sampled adult 18 years and older from each sampled family in a sampled household. For the 2000 NHIS, 39,264 families were interviewed from which 39,201 eligible adults were sampled for the CCM with data collected from 32,374. For the 2005 NHIS, 39, 284 families were interviewed from which 39,227 eligible adults were sampled for the CCM with data collected from 31,321. The overall response rates for 2000 and 2005 CCM were 72.1% and 69.0% respectively.

Statistical Methods

The 2000 and 2005 NHIS CCM included questions for the risk factors that were included in the original model of Gail et al (10,11). These risk factors were age, age at first live birth, age at menarche, number of first-degree relatives with breast cancer, and number of breast biopsies. About 13% of women had missing values for one or more of these risk factors. In these cases, the missing risk factors were coded to the lowest category of risk. This model, which has been validated in multiple settings, calculates a women's absolute risk of developing breast cancer for different time intervals (e.g., 5 years, 10 years, and lifetime). NCI's Breast Cancer Risk Assessment Tool uses the modified version of this model (Gail Model 2) given by Costantino et al. (3) and Anderson et al. (12) to calculate risks for White non-Hispanic women. For non-Hispanic African Americans, the NCI's Breast Cancer Risk Assessment Tool uses the version of Gail et al. (13) that was specifically modified to produce risk estimates for this racial group.

NCI's Breast Cancer Risk Assessment Tool makes projections for Hispanic women and for other racial and ethnic subgroups by combining relative and attributable risks from data from white women with breast cancer incidence and mortality rates specific for the ethnic or racial subgroup from NCI's Surveillance, Epidemiology and End Results Program. Because of small sample sizes we do not provide separate estimates of other race/ethnic groups, but include them in the estimates for all women. We use NCI's Breast Cancer Risk Assessment Tool to make the risk estimates in this paper. "Lifetime risk" was the absolute risk of breast cancer up to age 90 years. Absolute risks were computed for women 30–84 years of age who completed the CCM (n = 13,919 women from the 2000 NHIS and n = 13, 458 women from 2005 NHIS). We excluded 412 and 460 women, respectively, from the 2000 and 2005 NHIS because preexisting breast cancer was reported.

The data from 2000 and 2005 NHIS were pooled for the analyses. Since NHIS has a complex sample design that includes sample weights, all estimates are weighted by the sample weights divided by two (since two national surveys were pooled) to produce estimates for the U.S. population (14). The complex sample design of these surveys was accounted for in the estimation of standard errors and 95% confidence intervals (CI) for the pooled data. Since the estimated proportions of women with lifetime risk of ≥20% are small, as are certain age and race specific estimates of 5 year and life risk, a modified binomial CI was used when the numerators of the proportions were computed from sample sizes that were less than or equal to 50; otherwise a logit transformation was used to compute CI (14). Ninety-five percent confidence intervals based on the logit were computed for the transformed proportions and then were back transformed to produce 95% confidence intervals for the original proportions. All computations were conducted using SAS version 9.1 (15) and SAS callable SUDAAN version 9.0 (16).

Results

Table 1 shows estimates of the total number of U.S. women, by race and age groups, with a lifetime risk of ≥20%. For all 80,992,209 women aged 30–84 years in the U.S. population, 880,063 (1.09%, 95% CI = 0.95% to 1.24%) had a lifetime risk of 20% or greater. The percentages of women with this risk was 1.01% for women aged 30–39, 1.27% for women aged 40–49, 1.58% for women aged 50–59, 1.11% of women aged 60–69, and 0.11% for women aged 70–84. The percentage of non-Hispanic White women with ≥ 20% risk was 1.37% (95% CI = 1.19% to 1.57%), which was significantly higher than those for African American women 0.08% (95% CI = 0.03% to 0.21%) and Hispanic women 0.15% (95% CI = 0.07% to 0.33%).

The prevalence of five-year absolute risk greater than or equal to 1.67%, 2%, 3%, and 4% are presented in Tables 2a. In general, these prevalences are highest for White non-Hispanics, lower for African American non-Hispanic and lowest for Hispanics. The prevalences for the various risk levels increase with age except for Hispanics, which show a reduction in prevalences between the 60–69 and the 70–84 year old age groups. Forty percent or more of the White non-Hispanics and African American non-Hispanics had absolute risks that were greater than or equal to 1.67%, which was the risk level used for inclusion in the breast cancer chemoprevention trials. The prevalences of lifetime risks greater than or equal to 6, 8, 10, 12, 14, and 16 percent are presented in Table 2b. These prevalences decrease with age because an older breast-cancer free woman has a shorter risk interval to age 90 than a younger breast-cancer free woman. The prevalences are generally highest for White non-Hispanics, lower for African American non-Hispanic and lowest for Hispanics.

Discussion

In April of 2007, the American Cancer Society reviewed the evidence and published guidelines for breast screening MRI based defined levels of risk. These guidelines recommended annual breast screening with MRI as an adjunct to mammography for women with approximately 20–25% or greater lifetime risk of breast cancer, and women who were BRCA gene mutation carriers or were first-degree relatives of BRCA gene carriers. To assist in the evaluation of the impact that these guidelines may have on public health resources, we provide the first national estimates of the number of U.S. women who would be eligible for MRI breast screening based on ACS guidelines of ≥20% lifetime risk calculated with the NCI Breast Cancer Risk Assessment Tool. We calculated that 1.09% (95% CI = 0.95% to 1.24%) of women aged 30–84 years in the U.S. had this level of risk, which translates to 880,063 women eligible for MRI screening.

The NCI Breast Cancer Risk Assessment Tool has been validated in multiple settings, including among women at elevated risk, and has been shown to accurately predict the number of observed breast cancers over various time intervals (3,17–21). Perhaps because this model does not incorporate second-degree relatives, including paternal relatives, or age of onset of breast cancer in relatives, the ACS guidelines did not recommend it to determine an individual woman's lifetime risk for annual MRI screening. The guidelines in Table 1 of (1) recommended "BRCAPRO or other models that are largely dependent on family history." Such models include BRCAPRO (22), the Claus Model (23), BOADICEA (24), and the Tyrer-Cuzick Model (25). None of these models has been tested for calibration in the general population. Amir et al. (26) provide a comprehensive review of these and other models. One small study in a high risk clinic population with only 64 cases found that the expected numbers of cases agreed with the observed cases for the Tyrer-Cuzick Model, but that predictions were somewhat too low for the NCI Breast Cancer Risk Assessment Tool, Claus Model and BRCAPRO (27). A comparison of several scenarios, including families with multiple affected relatives indicated that the Breast Cancer Risk Assessment Tool and Tyrer-Cuzick Model usually gave the highest risks in families with at least one affected relative, and BRACAPRO gave the lowest risk (28). Euhus (29) had previously shown that the Claus Model and BRCAPRO usually give lower risks than the NCI Breast Cancer Risk Assessment Tool in a high risk clinic population. Another study comparing the NCI Breast Cancer Risk Assessment Tool and Claus Model in 491 women with a family history of breast cancer, found that the average lifetime risk was higher in the Breast Cancer Risk Assessment Tool (13.2%) than the Claus Model (11.2%) (30). Atypical hyperplasia was not reported in the NHIS, which could lead to underestimation of risk of breast cancer in this paper. For these reasons, we believe that the Breast Cancer Risk Assessment Tool is useful to estimate an approximate number of women with a lifetime risk of ≥20% in the general the population, though our calculation may underestimate the actual number.

A recent study by Murphy et al. (31) evaluated lifetime risk (≥20%) breast cancer risk among 18,190 women 40 years and older presenting for a screening mammography. Using the BRCAPRO model they found that 0.43% of this population has a combined ≥20% lifetime risk of breast cancer and >10% risk of a BRCA1 or 2 mutation. This estimate is lower than the prevalences in our Table 1 for two reasons. Our prevalence estimates are for risk ≥20% only, and not both for risk ≥20% and having a mutation. Secondly, the Breast Cancer Risk Assessment Tool usually gives higher risk estimates than BRCAPRO. Murphy et al. (31) also found that 1% of their screening population were predicted to be mutation carriers, though only 34% of these patients also had a lifetime risk of ≥20%. Their analysis cautioned that ACS guidelines may systematically exclude MRI screening for many women who have a substantial risk for BRCA mutation. We could not evaluate the number of U.S. women in the NHIS population with a predicted risk of BRCA mutation above 10% with models such as BRCAPRO

because we did not have information on family structure, second-degree relatives, and ages of cancer diagnoses.

In this paper we have used the version of NCI's Breast Cancer Assessment Tool that was modified to produce risk estimates for African American women (13). We found that the absolute risks tended to be lower for African American women than for White women and even lower for Hispanics. This agrees with race and ethnicity specific age-adjusted breast cancer incidence rates in U.S. in 2001–2005, which were reported to be 130.6, 117.5 and 90.1 per 100,000 population, respectively for White, African American and Hispanic/Latino populations (32).

This study has several strengths. It is a large population-based study that is representative of U.S. women. Because of the oversampling of the African American and Hispanic populations, it has large samples sizes for these populations from which to compute distributions of risk estimates. A possible weakness of this study is that we do not have either genetic data for BRCA carriers or family history of cancer in second or higher degree relatives from which we could infer carrier status. If we had had such data and used a model that could accommodate it, we might have found higher risk estimates in some women. Although we believe that the NCI Breast Cancer Risk Assessment Tool gives well calibrated estimates of the proportions of women with lifetime breast cancer risks above 20%, our estimates may overestimate the proportions of women who would be declared to have such risk if assessed by BRCAPRO or other models that rely mainly on family history, as recommended in the ACS guidelines, because, all such models except the Tyrer-Cuzick model tend to give lower estimates than the NCI Breast Cancer Risk Assessment Tool.

In summary, we provide the first national estimates of the number of U.S. women who would be eligible for MRI breast screening based on ACS guidelines of ≥20% lifetime risk along with the distributions of 5-year and lifetime risks if the NCI Breast Cancer Risk Assessment Tool is used to assess risk. We estimate that nearly 900,000 U.S. women may be eligible for MRI screening based on ACS guidelines if the NCI Breast Cancer Assessment Tool is used to assess risk. We believe that somewhat smaller numbers would be eligible if risk is assessed with BRCAPRO, the Claus Model or BOADICEA. Our estimates inform the resources and public health demand for MRI and chemo-preventive interventions that might be required for the U.S. population of women.

Acknowledgments

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Table 1

Estimates of the total number of U. S. women with lifetime breast cancer risk of ≥20%, by race/ethnicity and age group, using weighted data from the years 2000 and 2005 National Health Interview Survey Cancer Control Modules.

Age group, y	All women			White women			African American women			Hispanic women		
	Total No. (NHIS sample size)	No. with risk ≥20% (NHIS sample size)	Percentage eligible for MRI (95% CI)	Total No. (NHIS sample size)	No. with risk ≥20% (NHIS sample size)	Percentage eligible for MRI (95% CI)	Total No. (NHIS sample size)	No. with risk ≥20% (NHIS sample size)	Percentage eligible for MRI (95% CI)	Total No. (NHIS sample size)	No. with risk ≥20% (NHIS sample size)	Percentage eligible for MRI (95% CI)
30–84	80,992,209 (27377)	880693 (245)	1.09 (0.95, 1.24)	60,163,798 (18036)	825011 (226)	1.37 (1.19, 1.57)	9,430,809 (4198)	7738 (5)	0.08 (0.02, 0.22)	8,179,990 (4236)	12369 (7)	0.15 (0.06, 0.32)
30–39	20,671,173 (7075)	209156 (60)	1.01 (0.76, 1.35)	13,931,970 (3986)	188449 (53)	1.35 (1.00, 1.84)	2,722,054 (1210)	5207 (3)	0.19 (0.03, 0.64)	2,978,974 (1584)	944 (1)	0.03 (0.00, 0.29)
40–49	21,783,294 (6790)	276955 (76)	1.27 (1.00, 1.62)	15,763,396 (4264)	247324 (67)	1.57 (1.21, 2.03)	2,756,900 (1152)	1437 (1)	0.05 (0.00, 0.42)	2,320,635 (1126)	7175 (4)	0.31 (0.07, 0.84)
50–59	16,651,303 (5386)	262445 (71)	1.58 (1.20, 2.06)	12,731,194 (3681)	257101 (68)	2.02 (1.54, 2.65)	1,915,417 (828)	1095 (1)	0.06 (0.00, 0.56)	1,407,714 (703)	4250 (2)	0.30 (0.03, 1.14)
60–69	10,823,873 (3757)	119787 (34)	1.11 (0.77, 1.53)	8,587,960 (2707)	119787 (34)	1.39 (0.98, 1.93)	1,040,974 (510)	0 (0)	0.00 NA§	839,913 (440)	0 (0)	0.00 NA
70–84	11,062,566 (4369)	12351 (4)	0.11 (0.03, 0.30)	9,149,279 (3398)	12351 (4)	0.14 (0.03, 0.37)	995,465 (498)	0 (0)	0.00 NA	632,755 (383)	0 (0)	0.00 NA

§Not available

Table 2a

Prevalence (%) of U.S. women of five-year absolute risks (%) of breast cancer by race and age

	≥1.67	95% CI	≥2.00	95% CI	≥3.00	95% CI	≥4.00	95% CI
All Women								
30–39 years	0.0	0.0–0.2	0.0	0.0–0.1	0.0	NA	0.0	NA
40–49 years	4.1	3.6–4.8	1.5	1.2–1.9	0.3	0.2–0.5	0.1	0.0–0.2
50–59 years	13.3	12.2–14.5	8.5	7.6–9.4	1.7	1.4–2.2	0.8	0.5–1.1
60–69 years	36.4	34.5–38.3	18.0	16.5–19.5	7.1	6.2–8.1	2.1	1.7–2.7
70–84 years	44.1	42.4–45.8	21.8	20.5–23.3	10.0	9.0–11.1	2.5	2.0–3.0
White Non-Hispanic								
30–39 years	0.1	0.0–0.2	0.0	0.0–0.1	0.0	NA	0.0	NA
40–49 years	5.2	4.5–6.0	1.9	1.5–2.5	0.3	0.2–0.6	0.1	0.0–0.2
50–59 years	15.5	14.2–16.9	10.0	9.1–11.1	2.2	1.7–2.8	1.0	0.7–1.4
60–69 years	39.1	37.0–41.2	20.6	18.9–22.5	8.7	7.6–9.9	2.6	2.1–3.2
70–84 years	47.3	45.4–49.1	25.0	23.4–26.6	11.8	10.6–13.1	2.9	2.4–3.6
Black Non-Hispanic								
30–39 years	0.0	NA[§]	0.0	NA	0.0	NA	0.0	NA
40–49 years	1.2	0.6–2.1	0.1	0.0–0.5	0.0	NA	0.0	NA
50–59 years	8.2	6.1–10.8	4.7	2.9–7.1	0.5	0.1–1.6	0.0	NA
60–69 years	36.4	30.2–43.1	6.7	3.9–10.5	1.2	0.3–3.3	0.8	0.1–3.1
70–84 years	42.3	36.8–47.9	7.4	4.7–11.1	1.6	0.4–4.0	0.6	0.0–3.1
Hispanic								
30–39 years	0.0	NA	0.0	NA	0.0	NA	0.0	NA
40–49 years	0.5	0.2–1.1	0.3	0.0–0.8	0.0	NA	0.0	NA
50–59 years	2.1	1.2–3.5	0.6	0.2–1.5	0.1	0.0–0.7	0.0	NA
60–69 years	10.3	6.6–15.2	6.8	3.9–11.0	1.0	0.3–2.5	0.6	0.1–1.8
70–84 years	6.9	4.2–10.6	3.8	2.1–6.3	0.1	0.0–1.1	0.1	0.0–1.1

[§]Not available

Table 2b

Prevalence (%) of U.S. women of lifetime absolute risks (%) of breast cancer by race and age

	≥6.00	95% CI	≥8.00	95% CI	≥10.00	95% CI	≥12.00	95% CI	≥14.00	95% CI	≥16.00	95% CI
All Women												
30–39 years	93.5	92.9–94.1	72.4	71.2–73.6	47.6	46.2–48.9	18.3	17.3–19.4	5.9	5.2–6.7	4.5	3.9–5.1
40–49 years	95.5	94.9–96.0	69.9	68.4–71.3	41.8	40.3–43.2	20.5	19.5–21.7	10.4	9.6–11.3	7.0	6.4–7.8
50–59 years	81.3	80.0–82.4	49.6	48.0–51.2	22.3	20.9–23.7	12.6	11.6–13.7	8.9	8.1–9.9	4.6	4.0–5.2
60–69 years	48.9	47.0–50.8	18.8	17.3–20.5	10.8	9.7–12.1	6.4	5.5–7.4	2.8	2.3–3.5	2.1	1.6–2.6
70–84 years	10.6	9.6–11.8	4.3	3.7–5.1	1.7	1.4–2.2	0.8	0.6–1.2	0.4	0.2–0.7	0.3	0.1–0.5
White Non-Hispanic												
30–39 years	100.0	NA§	83.8	82.5–85.1	63.8	62.1–65.5	24.4	23.0–26.0	7.7	6.7–8.8	6.3	5.5–7.3
40–49 years	100.0	NA	77.6	76.1–79.0	51.9	50.2–53.6	25.4	24.0–26.8	12.8	11.7–13.9	9.3	8.4–10.3
50–59 years	85.2	83.8–86.4	54.7	52.8–56.5	26.5	24.9–28.1	15.2	14.0–16.5	11.2	10.1–12.3	5.8	5.0–6.6
60–69 years	53.0	50.8–55.2	21.8	19.9–23.7	13.0	11.6–14.5	7.7	6.7–9.0	3.4	2.7–4.1	2.4	1.9–3.1
70–84 years	12.2	11.0–13.5	5.0	4.3–5.9	2.0	1.6–2.6	1.0	0.7–1.4	0.5	0.3–0.9	0.3	0.1–0.6
Black Non-Hispanic												
30–39 years	100.0	NA	63.9	60.9–66.8	4.9	3.8–6.4	2.8	1.8–4.3	2.8	1.7–4.2	0.6	0.2–1.4
40–49 years	100.0	NA	68.2	64.7–71.5	11.8	9.7–14.2	5.4	4.0–7.2	4.5	3.2–6.1	0.5	0.1–1.3
50–59 years	88.0	85.3–90.2	42.8	39.3–46.4	8.0	6.0–10.6	4.9	3.2–7.3	0.7	0.1–2.0	0.5	0.1–1.6
60–69 years	40.6	35.9–45.4	6.2	3.8–9.6	3.2	1.6–5.7	1.2	0.3–3.3	1.0	0.1–3.1	1.0	0.1–3.1
70–84 years	4.0	2.0–7.0	0.6	0.0–3.1	0.6	0.0–3.1	0.0	NA	0.0	NA	0.0	NA
Hispanic												
30–39 years	55.1	52.0–58.1	22.0	19.5–24.8	3.7	2.7–5.0	2.5	1.7–3.5	1.0	0.5–1.9	0.2	0.0–0.7
40–49 years	57.4	53.9–60.9	19.8	17.2–22.6	8.3	6.7–10.4	4.8	3.5–6.6	1.4	0.7–2.7	0.3	0.1–0.9
50–59 years	35.1	30.4–40.1	11.7	9.1–14.9	5.8	3.9–8.3	1.6	0.8–3.3	0.5	0.1–1.4	0.5	0.1–1.4
60–69 years	15.4	11.5–20.4	7.0	4.2–10.9	1.6	0.6–3.2	1.0	0.3–2.5	1.0	0.3–2.5	0.7	0.1–2.0
70–84 years	1.0	0.3–2.6	0.1	0.0–1.1	0.1	0.0–1.1	0.1	0.0–1.1	0.0	NA	0.0	NA

§Not available