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LEGACY HEALTH
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Co-Chair Senator Lee Beyer
Co-Chair Representative Rob Nosse
Joint Committee on Ways and Means Subcommittee on Human Services
Emailed to: jwmhs.exhibits@oregonlegislature.gov

March 21, 2019

Dear Senator Beyer, Representative Nosse, and members of the Joint Committee on Ways and Means Subcommittee on Human Services –

We would like to show our support of funding the Oregon ScreenWise program at $1.3 million, the level proposed by Susan G. Komen Oregon & SW Washington and American Cancer Society Cancer Action Network. This amount, which is more than the $822k proposed by the Oregon Health Authority in HB5525, will provide ScreenWise enough funding to provide much-needed breast and cervical cancer screening and diagnostic exams to women 40 and over.

The Oregon ScreenWise (Breast and Cervical Cancer) Program provides critical breast and cervical cancer screening and diagnostic services to low-income (at or below 250% FPL), uninsured or underinsured, women who do not qualify for Medicaid. ScreenWise is funded, federally, by the Centers for Disease Control (CDC) and, locally, by the State of Oregon General Fund and Susan G. Komen Oregon & SW Washington.

Due to 2018 reductions in federal and state funding, the ScreenWise program needed to create cost-containment strategies which included limiting breast and cervical cancer screening services to women over 50, with diagnostic services to women over 21. We are concerned that this could potentially leave high risk women under 50 without access to breast and cervical cancer screening services that could save their lives.

We know that early detection saves lives. The Affordable Care Act ensures that breast cancer screenings be covered for insured women, beginning at age 40, as a preventive service. Without access to breast cancer early detection programs, many uninsured and underserved women are forced to delay or forego screenings, which could lead to late-stage breast cancer diagnoses. This delay could mean that a woman might not seek care until the cancer is advanced, making it up to five times more expensive and much harder to successfully treat.

For these reasons, we would like to see the Oregon ScreenWise program funded at $1.3 million in HB5525 for the 2019-2021 biennium, and we respectfully request your support, as well.

Sincerely,

Dr. Jennifer Garrett
Legacy Medical Group Surgical Oncology

The American Journal of Surgery 215 (2018) 848–851

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Breast cancer in women under 50: Most are not high risk

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ARTICLE INFO

Article history:
Received 20 November 2017
Received in revised form
2 January 2018
Accepted 2 January 2018

Keywords:
Screening mammography
screening recommendations
low risk patients
mammograms in young women

ABSTRACT

Background: In 2009, the United States Preventive Services Task Force changed the recommended starting age for annual screening mammography from 40 to 50 for non-"high risk" women. In 2015, the American Cancer Society issued similar guidelines, with a starting age of 45. Our hypothesis is that most women diagnosed with breast cancer in this age group do not fall into a "high risk" category.
Methods: A retrospective review of women less than 50 years of age diagnosed with breast cancer in the Legacy Health Care System was performed for January 2013 through December 2015. Validated risk assessment models were used to quantify risk. High risk was defined as lifetime risk of breast cancer greater than 20%.
Results: 249 women were identified. Of these, 79 (32%) of women were high risk. 170 (68%) did not fall into the high risk category.
Conclusion: In our population, approximately two thirds of women with breast cancer under 50 are non-"high risk". We argue that women should receive annual mammograms starting at age 40, because low risk is not protective.

1. Introduction

Since the mid-1980s, the use of screening mammograms in the United States has increased significantly,[1,2] and has been associated with a reduction in mortality of up to 30%.[1] This mortality benefit is even seen in younger women, aged 40–50,[3–5] and for this reason it was initially recommended that women get annual mammograms starting at the age of 40. Recently, there has been concern that screening mammograms may cause more harm (in terms of call-backs, over-treatment, unnecessary biopsies, patient anxiety) than good in this younger age group.[6–8] In 2009, the United States Preventive Services Task Force (USPSTF) changed its recommendations for screening mammography and suggested that women should not start until the age of 50 unless they were considered high risk, in which case they should start screening earlier.[9] In 2015, the American Cancer Society also changed their recommendations for screening, stating that average risk women should start screening at age 45. It was stated that women between 40 and 44 should have the option to start annual screening mammograms.[10] Many societies, including the American College of Radiology and American College of Obstetrics and Gynecology, continue to recommend that women receive mammograms annually starting at age 40, as the data support that benefits for mammograms are still significant in this age group. Anecdotally, we noticed that many breast cancer patients, even those in their 40s, had no significant risk factors. Following the USPSTF suggestion to screen only 'high' risk women under 50, it was our concern that these women might have been diagnosed at a more advanced stage had those guidelines been followed. We hypothesized that the majority of women diagnosed with breast cancer under the age of 50 would not have been considered high risk using our current risk-stratification tools.

2. Methods

Data were obtained via a query of the prospectively maintained Legacy Health System Breast Cancer Database from January 2013 to December 2015. The principal inclusion criteria were females diagnosed with DCIS, IDC, or ILC at age less than 50. The only exclusion criterion was a prior diagnosis of breast cancer. Data points captured included age at diagnosis, breast quadrant location of primary, histology, grade, stage, ER status, and HER2/neu receptor status. Retrospective chart review was used to capture the

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https://doi.org/10.1016/j.amjsurg.2018.01.003
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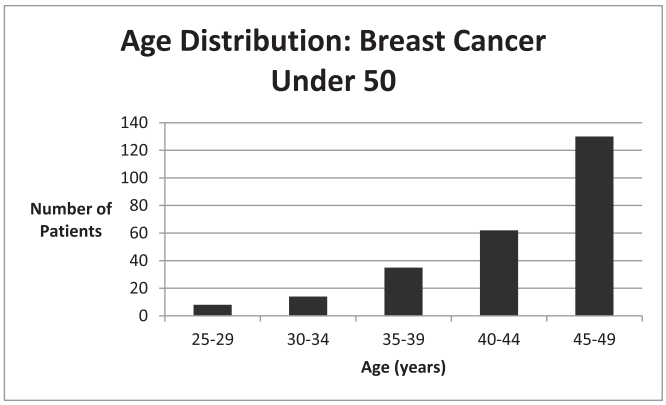

Fig. 1. Age distribution of patients diagnosed with breast cancer under the age of 50, by 5 year increments from 25–29 up to 45–49.

variables of method of breast cancer detection and lifetime risk of breast cancer. Lifetime risk was assessed primarily with the Hughes RiskApps™ standardized risk assessment tool, which is frequently utilized in new diagnoses of breast cancer at our institution. The Hughes tool gives the estimated lifetime risk of breast cancer per the Gail, BRCAPRO, Tyrer-Cuzick v6, Tyrer-Cuzick v7, and Claus Models. When the Hughes risk assessment was not utilized, the Gail model was used to calculate lifetime risk based on patient historical data collected from chart review. The highest level of lifetime risk as estimated in any model was used for patient stratification into high risk and non-high risk groups for the purposes of analysis. Patients with a lifetime risk of breast cancer greater than or equal to 20% were classified as high risk, and those with a less than 20% lifetime risk were classified as non-high risk. Data were analyzed using SAS version 9.4. Chi-squared test and Student's t-test were used to examine differences in stage, receptor status, and age between risk groups.

3. Results

Two hundred and fifty-five women met the inclusion criteria of breast cancer under the age of 50; 6 were excluded due to a prior diagnosis of breast cancer. Fig. 1 shows the age distribution of these patients. One hundred and ninety-two (77.1%) patients were 40 or older; 142 (74%) of these patients had their disease detected on routine screening mammography. Seventy-nine (31.7%) of all identified patients were classified as high risk, while 170 (68.3%) fell into the non-high risk category. The Hughes risk assessment tool was utilized in 206 (82.8%) of patients, with the Gail model alone used in 43 (17.2%). Ultimately, 131 patients (52.6%) were risk stratified using the BRCAPRO model, 61 (24.5%) were stratified using the Tyrer-Cuzick models, and 57 (22.9%) were risk stratified based on the Gail model. Compared to the other models, the Claus model did not yield a higher lifetime risk in any patient. Table 1 includes descriptive statistics of these two groups. Both risk groups had similar distributions of stage, ER status, PR status, Her2/neu status, and had similar mean ages. Eighty-nine percent of patients in each risk group had stage II disease or lower. Differences with respect to stage and receptor status were not statistically significant on chi-squared test, and the difference in mean age between groups was not statistically significant on Student's t-test.

To further investigate the threshold of high risk, the distributions of lifetime risks were investigated for patients further sorted into two age subgroups: those less than 45 at diagnosis and those less than 50 years of age at diagnosis, which correspond to the population that would not be routinely screened under ACS and USPSTF guidelines, respectively. These risk distributions are graphically represented in Figs. 2 and 3. In the younger than 45 group, 65 of 114 women (57%) are low risk and would not be routinely screened under current guidelines. When women less than 40 at age of diagnosis were excluded from the analysis, the proportion of high risk patients significantly decreased; 16 (25.8%) of 62 women aged 40–44 were high risk, while 44 (22.9%) of 192 women aged 40–49 were high risk.

4. Discussion

The linchpin of the USPSTF and ACS recommendations for screening is the accurate assessment of risk for developing breast cancer. If we were able to accurately assign risk then this approach might be valid. However, our data clearly show that the majority of patients diagnosed with breast cancer in their 40s have no significant risk factors and would not be considered high risk using our current models. In our study 68% of women under age 50 with breast cancer were non-high risk. Had these patients followed the recommendations set fourth by the USPSTF and the ACS, many would have likely been diagnosed at a later stage. This may translate into the requirement for more intensive therapies.

There have been several concerns about screening mammograms in this age group including the notion that population benefit for women <50 years of age is not significant.[6,7] There are numerous studies that have shown a significant reduction in mortality in this age group with the reduction ranging from 15 to

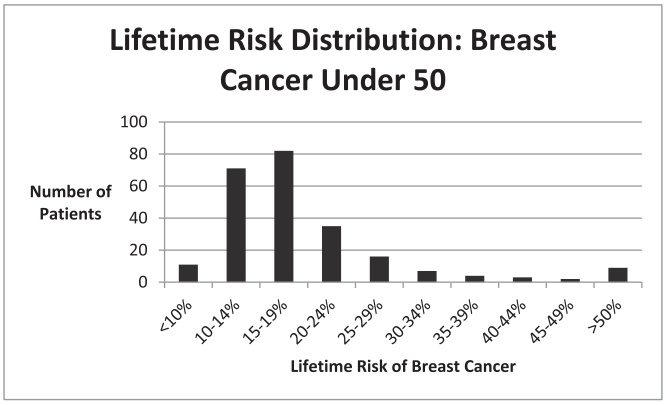

Fig. 2. Lifetime Risk Distribution for breast cancer patients under the age of 50.

Table 1
Descriptive statistics: risk, stage, prognostics, and age.

	Stage 0	Stage I	Stage II	Stage III	Stage IV	ER+	PR +	Her2/neu+	Mean Age (years)	Total
High Risk	12 (15%)	35 (44%)	23 (29%)	5 (6%)	4 (5%)	66 (84%)	63 (80%)	7 (9%)	45.1	79 (32%)
Non- High Risk	39 (23%)	60 (35%)	53 (31%)	15 (9%)	4 (2%)	139 (82%)	135 (79%)	20 (12%)	45.9	170 (68%)
Total	51 (20%)	95 (38%)	76 (30%)	20 (8%)	8 (3%)	205 (82%)	198 (80%)	27 (11%)	45.7	249

‡ Differences between the groups were not statistically significant ($p > .05$).

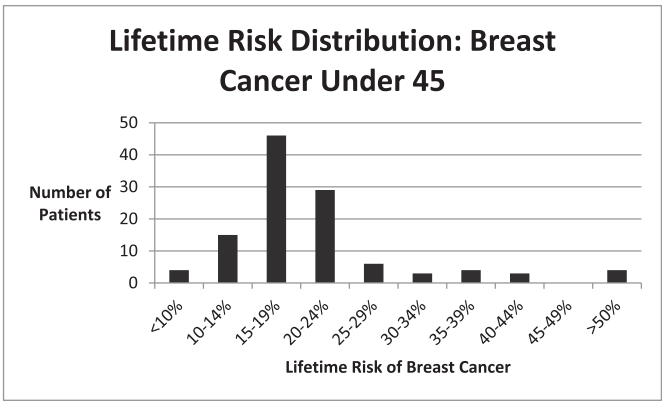

Fig. 3. Lifetime risk distribution for breast cancer patients under the age of 45.

60%.[1,4,5,11–13] It is well established that women <50 tend to be diagnosed with more aggressive cancers and have a worse outcome, even for patients with ER + tumors. This suggests that these women are diagnosed with cancers that are more biologically aggressive.[14,15] For this reason, it is paramount that we diagnose these women as early as possible to give them the best outcomes and that their screening be on an annual basis.

Another concern for screening mammograms in this age group is the effectiveness of mammography in younger women with more breast density. One study reported that most of these women do not have their cancer diagnosed by screening mammograms but as the result of a work-up for a palpable lesion.[8] However, the majority of women in our population had their cancer diagnosed by screening mammograms. The technology for mammograms continues to improve and is effective for women with denser breast tissue. This is particularly true with the advent of tomosynthesis mammograms which has been shown to be an improved imaging modality for women with denser breast tissue.[16,17]

In addition to the assumption that we can accurately assign risk to patients under 50, another flaw in the recommendations made by the USPSTF is that their study looked at the number of women needed to invite (NNI), not the number needed to screen (NNS).[18] In this situation, all women who were offered mammograms, but did not necessarily follow through with them, were included in their screening population. As a result, they found that a significantly higher number of women, especially in the 40–50 year age group, were needed to undergo screening to save one woman's life. They decided that an NNI of 1900 in 40–50 age group was too high, compared to an NNI of 1300 in the 50–70 age group.[3,18] There are a number of studies that have shown that the NNS to save a woman's life is lower.[18] Furthermore, the number of life-years gained from screening is much greater in the 40–50 year age group as compared to other age groups.[18]

An additional concern is that screening mammograms may be more harmful in younger women, due to higher radiation exposure required to image denser breast tissue, more frequent call backs, “unnecessary biopsies”, and potential patient anxiety.[7,8] Many such biopsies find atypia that allows for chemoprevention to be considered. We believe that a biopsy is only unnecessary when we find that it is negative for any pathologic finding. As technology improves, the need for call backs and “unnecessary” biopsies will decrease. Multiple studies have already shown that the use of breast tomosynthesis mammography is associated with fewer call backs. Also, this imaging technology has been shown to be better for women with dense breasts and more likely to diagnose breast cancers at an earlier stage.[1,16,17]

5. Limitations

The present study is limited by the lack of data on lifetime risk distribution of the general population. This does not allow conclusions as to the relative efficiency of screening all women 40 and above versus screening only high-risk women under 50.

Additionally it should be noted that the Hughes risk assessment tool was utilized for risk stratification in 82.8% of all patients, with risk assigned to the remainder using the Gail model alone. Stratifying patients to risk groups based on the Gail model alone may have underestimated the lifetime breast cancer risk in these patients, compared to utilizing the highest risk predicted by the models contained within the Hughes risk assessment tool. In those who had risk assigned by the Gail model alone, 15.7% were assigned to the high risk group compared to 46.6% of patients assigned using the highest of the risk models calculated by the Hughes tool. Even if one assumes that this proportion is true for the patients who were assigned risk by the Gail model only, it would not change the ultimate findings or conclusions presented herein.

6. Conclusions

In conclusion, the present findings highlight the potential implications of the ACS and USPSTF recommendations for screening mammography on the potential for under screening women under the age of 50. Our data show that the majority of women under 50 who develop breast cancer do not have identifiable high risk features that would permit selective early screening at the current definition of high lifetime risk. Given the large proportion of patients who have cancer detected by screening mammography, the authors feel that there is a potential for harm in the current recommendations. The utility of mammography in this age group should be a topic of continued discussion between providers and their patients, as well as within the medical community as a whole.

Conflict of interest statement

The authors of this manuscript have no conflicts of interest to disclose. This research project was undertaken without financial assistance of any kind.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.01.003.

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