Screening Mammography for Frail Older Women

What are the Burdens?

Louise C. Walter, MD, Catherine Eng, MD, Kenneth E. Covinsky, MD, MPH

OBJECTIVE: The potential benefits and harms of screening mammography in frail older women are unknown. Therefore, we studied the outcomes of a screening mammography policy that was instituted in a population of community-living nursing home-eligible women as a result of requirements of state auditors. We focused on the potential burdens that may be experienced.

METHODS: Between January 1995 and December 1997, we identified 216 consecutive women who underwent screening mammography after enrolling in a program designed to provide comprehensive care to nursing home-eligible patients who wished to stay at home. Mammograms were performed at 4 radiology centers. From computerized medical records, we tracked each woman through September 1999 for performance and results of mammography, additional breast imaging and biopsies, documentation of psychological reactions to screening, as well as vital status. Mean follow-up was 2.6 years.

RESULTS: The mean age of the 216 women was 81 years. Sixty-three percent were Asian, 91% were dependent in at least 1 activity of daily living, 49% had cognitive impairment, and 11% died within 2 years. Thirty-eight women (18%) had abnormal mammograms requiring further work-up. Of these women, 6 refused work-up, 28 were found to have false-positive mammograms after further evaluation, 1 was diagnosed with ductal carcinoma in situ (DCIS), and 3 were diagnosed with local breast cancer. The woman diagnosed with DCIS and 1 woman diagnosed with breast cancer were classified as not having benefited, because screening identified clinically insignificant disease that would not have caused symptoms in the women's lifetimes, since these women died of unrelated causes within 2 years of diagnosis. Therefore, 36 women (17%; 95% confidence interval [CI], 12 to 22) experienced burden from screening mammography (28 underwent work-up for false-positive mammograms, 6 refused further work-up of an abnormal mammogram, and 2 had clinically insignificant cancers identified and treated). Forty-two percent of these women had chart-documented pain or psychological distress as a result of screening. Two women (0.9%; 95% CI, 0 to 2) may have received benefit from screening mammography.

CONCLUSION: We conclude that screening mammography in frail older women frequently necessitates work-up that does

not result in benefit, raising questions about policies that use the rate of screening mammograms as an indicator of the quality of care in this population. Encouraging individualized decisions may be more appropriate and may allow screening to be targeted to older women for whom the potential benefit outweighs the potential burdens.

KEY WORDS: screening mammography; frail elderly; burdens.

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During the past 2 decades, the elderly population has grown dramatically, including the segment of frail older adults who have multiple chronic illnesses and require some assistance with activities of daily living (ADLs).¹ As the number of frail older adults continues to grow, it becomes increasingly clear that the outcomes of specific preventive services in this group, such as screening mammography, must be determined.

Currently, the potential benefits and burdens of screening mammography in frail older women are unknown, since few frail women over age 70 have been included in randomized clinical trials of mammography.^{2,3} While it is generally agreed that the likelihood of benefit from screening mammography declines as life expectancy decreases,⁴⁻⁷ the burdens older women may experience from screening have not been well described. There have been no studies of screening mammography in populations of frail older women regarding the types of burdens that may result from screening. Despite the uncertainties surrounding screening mammography in older women, some payers and regulators consider the rate of screening mammography to be a standard quality indicator in this population, citing authorities such as the American Cancer Society that recommend screening mammography for older women without an upper age limit.⁸

To address these issues, we studied the outcomes of a screening mammography policy instituted at On Lok, which is a capitated health plan⁹ for frail older adults funded by Medicare and MediCal. On Lok receives oversight from the California Department of Health Services for compliance with standard quality indicators, including the scope of preventive health services, such as cancer screening. Initially, screening mammography decisions were left to the judgment of clinicians at On Lok, who frequently felt that screening was not indicated in this population of frail older women whose average life expectancy is 4 years after enrollment. However, in the late 1980s state auditors required that On Lok implement a program of screening mammography for its enrollees. As a result, On Lok instituted a policy of performing at least 1 screening mammogram on all women, regardless of age or frailty,

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Address correspondence and reprint requests to Dr. Walter: Division of Geriatrics, VA Medical Center 111G, 4150 Clement St., San Francisco, CA 94121 (e-mail: louise.walter@itsa.ucsf.edu).

who have no prior history of mammography and continuing biennial screening of women who have a prior history of mammography until age 75.

This study examines the consequences of this screening mammography policy in a cohort of frail elderly women. We chose to focus on the burdens of screening since burdens occur immediately and may affect every screened patient, whereas benefit is more difficult to ascertain, because it only occurs in patients who get breast cancer and it takes several years before a reduction in mortality may occur between screened and unscreened groups.¹⁰ Providing a better understanding of the potential burdens of screening mammography in frail older women allows these burdens to be weighed with the estimated potential benefits of mammography in order to make more informed screening decisions.

METHODS

Subjects and Program Site

We conducted a cohort study of 216 consecutive women who underwent screening mammography after enrolling in On Lok, which is a long-term care delivery system available to frail community-dwelling elderly persons living in San Francisco. On Lok currently employs 10 internists and 6 nurse practitioners and is comprised of 6 clinics and adult day health centers. The program originated in 1971 and gave rise to the nation-wide Program of All-inclusive Care for the Elderly (PACE). To enroll in On Lok a person must be 55 years of age or older, be certified by the state as eligible for nursing home care, and live in San Francisco.⁹

Three hundred ninety-six women enrolled in 1 of the 6 On Lok sites between January 1, 1995 and December 31, 1997. Two hundred fifty-two women (64%) had a mammogram after enrollment, but mammography was not considered a screening exam in 36 of these women (16 complained of breast pain or mass, 4 had a prior abnormal mammogram, and 16 had a history of breast cancer), since screening is defined as an exam performed on an asymptomatic woman. An additional 144 women (36%) did not have a mammogram after enrollment in On Lok (33 refused, 28 were felt to have a limited life expectancy, 12 required no further screening, 9 disenrolled from On Lok, and 62 lacked documentation about why screening mammography was not performed). This left 216 women who underwent screening mammography after enrollment in On Lok.

Data Collection

We abstracted data from computerized medical charts, which were reviewed by one geriatrics fellow (LW). On Lok uses a computerized medical records system, which contains notes from all physician, nurse, social work, and physical therapy visits. The chart also contains a preventive health section that details the performance, results, and work-up of all screening mammograms and clinical

breast exams. Since On Lok provides comprehensive capitated care to its patients, the results of all screening tests and subspecialty clinic visits are documented in the chart even if they are performed by outside physicians.

For each woman in the cohort, we collected data on prior history of mammography and recorded the results of the first screening mammogram and clinical breast exam performed after enrollment. All mammograms were performed at 1 of 4 radiology centers in San Francisco. We defined an abnormal mammogram as one that required further diagnostic testing, which is the standard definition that has been used in previous studies.¹¹ We recorded the follow-up of abnormal screening mammograms and obtained biopsy results from pathology reports. We also noted if additional follow-up was recommended but the patient or family declined, and we recorded whether the chart contained documentation of pain, anxiety, or depressive symptoms expressed by the patient as a result of screening or subsequent work-up. We tracked each woman through October 1, 1999 to record vital status and all breast cancer diagnoses and treatments during this time period.

Finally, we collected data on patient demographics, comorbid illnesses, medications, and functional status on enrollment. Functional status was recorded as independence in 7 ADLs: bathing, dressing, grooming, toileting, transferring, walking, and feeding.¹²

This research protocol was approved by the Committee on Human Research at the University of California, San Francisco.

Definition of Screening Burden and Benefit

Our operational definition of screening burden was a patient who was worse off for having been screened. A patient was considered to have experienced burden from breast cancer screening if they had any one of the following events: 1) additional diagnostic procedures due to false-positive results, 2) identification of an abnormality on screening exam but further work-up declined, or 3) identification of a clinically unimportant cancer. False-positive results were defined as abnormal screening results for which work-up did not reveal cancer or a precursor of cancer. We considered this a burden because false-positive results subject patients to physical and psychological discomforts from additional testing and procedures that would not have been necessary if they had not been screened. Patients were also considered to have experienced a burden from screening if they had an abnormal screening result but refused further evaluation, since this is usually a stressful decision for a patient or family and patients are left with the knowledge that they have some type of abnormality. Finally, we considered that a patient experienced burden if screening led to the identification and treatment of a cancer that would not have become symptomatic in the patient's lifetime. Since the mean duration that a mammographically-detectable breast cancer remains asymptomatic is approximately 3.4

years (95% confidence interval [CI], 2 to 8) for women aged 70 to 74,¹⁰ we conservatively chose to define clinically unimportant cancer as those cancers identified by screening in patients who lived less than 2 years after diagnosis.

We also examined the medical charts to see if there was documentation that patients experienced psychological distress due to screening. We specifically looked for documentation of depressive symptoms, anxiety, or pain related to the screening experience.

Patients were considered to have potentially benefited from mammography if they were diagnosed with cancer as a result of the screening test and lived more than 2 years after detection and treatment. We also looked to see if the chart documented that the patient requested the test or indicated any psychological relief from having a normal screening test, but this was not documented for any of the patients in our cohort.

RESULTS

The mean age of the 216 women was 81 years, and 34% were over age 85 (Table 1). The women were ethnically diverse (63% Asian, 11% white, 10% African American, 16% Latino), and the majority were widowed or divorced (84%). Most patients had more than 5 comorbid conditions (83%) and were dependent in at least 1 ADL (91%). Forty-nine percent had a diagnosis of cognitive impairment (mean number correct on the 10-item Short Portable Mental Status Questionnaire¹³ was 3.9 ± 2.7). A history of previous screening mammography was very low in this cohort, with only 13% having had a mammogram prior to enrollment. Only 6% reported having a Pap smear prior to enrollment. The mean follow-up time was 2.6 years from the time of first screening mammogram until October 1, 1999. The 2-year mortality rate from the time of enrollment in On Lok was 11%.

One hundred seventy-eight of the women (82%) had a normal mammogram, while 38 (18%) had an abnormality for which further work-up was recommended (Fig. 1). Six of the 38 women (16%) who had further work-up recommended refused further diagnostic tests. Three of these women had severe dementia, and their families felt that work-up would cause too much agitation and discomfort. Another woman had such severe arm contractures that further breast evaluation was felt to be too difficult. The other 2 women experienced acute worsening of their medical conditions, which caused them to decline further work-up. Seventeen women (45%) with abnormal mammograms underwent 1 additional test, 9 women (24%) had 2 tests, and 6 women (15%) had 3 or more tests. Of the 32 women who agreed to further diagnostic testing after an abnormal mammogram, 29 (90%) had 1 or more diagnostic mammograms, 9 (28%) had an ultrasound, 4 (13%) had a fine-needle aspiration (FNA), and 4 (13%) had an excisional biopsy. Of the women who had further testing, 28 of 32 (88%) had negative evaluations and were considered to have had a false-positive mammogram. Three women (9%)

Table 1. Demographics of Women Who Had Screening Mammography

Characteristic (N = 216)	n (%)
Age, y	
55-65	15 (7)
65-75	43 (20)
75-85	85 (39)
85-95	66 (31)
>95	7 (3)
Ethnicity	
Asian	136 (63)
White	24 (11)
African American	22 (10)
Latino	34 (16)
Education	
Less than elementary	54 (25)
College	12 (6)
Marital status	
Married	23 (11)
Widowed/divorced	182 (84)
Never married	11 (5)
Lives alone	99 (46)
Immigrant	172 (80)
Functional status	
Totally independent in 7 ADL	20 (9)
Partially dependent in ADL	173 (80)
Totally dependent in 7 ADL	23 (11)
Takes ≥ 5 medications	75 (35)
Takes estrogen (oral/vaginal)	6 (3)
Comorbid conditions	
Diabetes	67 (31)
Cognitive impairment	106 (49)
Stroke with hemiparesis	45 (21)
Chronic obstructive pulmonary disease	20 (9)
Hypertension	139 (64)
Congestive heart failure	36 (17)
Coronary artery disease	47 (22)
Gastrointestinal bleed	37 (17)
Depression	68 (31)
Has ≥ 5 medical problems	179 (83)
History of mammogram before enrollment	29 (13)
History of Pap before enrollment	13 (6)
Hysterectomy before enrollment	43 (20)
Pap smear after enrollment	99 (46)

were diagnosed with stage I invasive ductal carcinoma, and 1 (3%) was diagnosed with ductal carcinoma in situ (DCIS), which is a lesion that progresses to invasive cancer in less than 25% of cases over 5 to 10 years.¹⁴

All 4 women diagnosed with breast cancer or DCIS through screening received treatment. However, 2 of these women died within 2 years of detection. We considered these women to have experienced burden from screening. For example, an 80-year-old Chinese woman with diabetes and dementia who was functionally dependent in 5 ADLs had two 1-cm nodular densities in her right breast detected on screening mammography. She underwent an ultrasound and 2 attempts at FNA, which gave inconclusive results. She then underwent an excisional biopsy and was diagnosed with a 1-cm intraductal papilloma containing several areas of DCIS. She developed a wound infection requiring daily

FIGURE 1. Consequences of screening mammography in a cohort of 216 frail elderly women. Text in bold denotes patients who experienced burden from screening mammography.

trips to a wound clinic and complained of persistent pain. She required surgical closure of the wound 3 months later. Nine months after diagnosis she suffered a large stroke and myocardial infarction and died. The second woman was an 89-year-old African-American woman with angina and dementia who was functionally dependent in 2 ADLs and who had a circular density in the left breast discovered by screening mammography. Serial mammograms were performed every 6 months for 2 years until it was felt that the lesion was slowly growing. An FNA revealed invasive ductal carcinoma. She underwent a modified radical mastectomy with no evidence of cancer in her axillary lymph nodes. She pulled off all the bandages the night after surgery, requiring restraints, and developed a seroma. She died 15 months later of a myocardial infarction.

The 2 women who had cancer detected by screening mammography and remain alive after their lumpectomies are considered to have potentially benefited from screening mammography. For example, a 74-year-old Chinese woman with diabetes and independent in all ADLs had a 1-cm circular mass in the right breast on screening mammogram. She underwent an ultrasound, and then excisional biopsy revealed a 6-mm invasive ductal carcinoma. Surgical margins were free of tumor, and she underwent 2 months of radiation therapy and remains alive 2 years afterwards. The second woman is an 89-year-old white woman with dementia, dependency in 6 ADLs, and 3-vessel coronary artery disease, who had a 1.5-cm nodule in her left breast detected on screening mammography in April, 1997. She underwent serial mammograms, which revealed no change until March, 1999, at which time an FNA was performed and revealed cancer. She underwent a lumpectomy, and no additional treatment was recommended, given her severe coronary artery disease. She remains alive 7 months after her lumpectomy.

Sixteen of the 38 women with abnormal mammograms (42%) had chart-documented depressive symptoms, anxiety, or pain as a result of screening mammography. For example, a 98-year-old Chinese woman with dementia became very agitated following mammography, and the

daughter felt that it was “too much” for her mother and refused further work-up. An 89-year-old Chinese woman with hemiparesis was tearful after mammography for several days. As a result, her physician decided to increase her antidepressant dose. Other examples include a 70-year-old Chinese woman with hemiparesis after a stroke, who complained of severe pain and difficulty with breast positioning during the mammogram due to her inability to stand independently, and a 77-year-old white woman with severe chronic obstructive lung disease, who complained that her breasts hurt for 3 days after the mammogram.

To summarize, in this cohort of frail older women, 36 women (17%; 95% CI, 12 to 22) experienced burden from screening mammography. Twenty-eight of these women underwent work-up for false-positive mammograms, 6 refused further work-up of an abnormal mammogram, and 2 had clinically insignificant cancers identified and treated. Almost half of these women had chart-documented pain or psychological distress as a result of screening. Two women (0.9%; 95% CI, 0 to 2) may have received benefit from screening mammography.

DISCUSSION

We found that screening mammography in frail older women frequently necessitates work-up that does not result in benefit. In this cohort, 17% of women experienced burden from screening mammography due to work-up refusals, false-positive results, or identification of clinically insignificant lesions. In addition, a significant percentage (42%) of women with abnormal mammograms complained of pain, anxiety, or depressive symptoms due to screening that were severe enough to be documented in the chart. Burdens seem particularly important to consider when recommending screening mammography to frail older women, since the benefits of screening in this population are unproven.

In this frail cohort, many of the burdens of screening mammography were related to severe comorbid conditions and functional impairments, which supports the idea that clinicians should consider these factors when making

screening decisions rather than focusing on chronological age alone.⁷ All refusals of recommended work-up for abnormal mammograms were related to comorbid illnesses. Two of the 4 patients who had cancer or DCIS detected by screening mammography died of their comorbid illnesses before the cancer would have become symptomatic, so they experienced the burden of surgery for a cancer that would not have caused symptoms in their lifetime. In addition, almost half of our cohort had cognitive impairment. Many of these women could not understand what was happening to them during mammography, and several became distressed, raising ethical issues about screening patients with dementia. For patients with dementia, caregivers need to be involved in screening decisions. In addition, patients with dementia are still able to communicate refusal.¹⁵ If mammography seems to upset or frighten the patient, the caregiver and physician should forgo screening, given the uncertain benefit and the increased risk for experiencing burdens.¹⁶

In our frail cohort, we found no difference in the rate of false-positive mammograms compared to that reported for a healthier sample of Medicare patients (1% 1-year mortality rate).¹⁷ In our cohort, 88% with an abnormal screening result did not have cancer after further work-up compared with 86% to 92% of older women in the Medicare sample. Our cohort did have a higher percentage of abnormal mammograms (18%) than reported in other studies (6% to 10%),^{11,17} but several of the women in our study refused the recommended further work-up, so their abnormal mammograms would have been missed by claim-based studies that define abnormal mammograms as those that resulted in further work-up. There is also variation among radiology centers in their thresholds for recommending further work-up after screening mammography.¹⁸

Our cohort was ethnically diverse, with a large percentage of Asian women, a group that has not been well studied. Prior studies have shown that the incidence of breast cancer is usually lower for Asian women than for white and African-American women.¹⁹ However, the breast cancer rate in our cohort, including DCIS, was 1.8% (95% CI, 0.05 to 3.6), which is similar to that found in large population-based studies (1% to 1.3%).¹⁷ The low rate of prior screening mammography in this cohort is also consistent with prior studies of the Medicare population, which have found low rates of prior screening mammography for women over age 80.²⁰ Whether the burdens experienced by our cohort are generalizable to other populations of frail older women is unclear, but the burdens found in this study were more often documented as due to comorbid illness and limited life expectancy than to cultural factors.

The small sample size is the main limitation of this study, and therefore this study provides more precise estimates of burdens than benefits. However, understanding the types of burdens experienced by frail older women who undergo screening mammography helps to

inform the decision-making process when attempting to weigh potential benefits and harms of screening. While we did not inquire about the hassles of transportation or personnel requirements for getting frail women to and from testing sites, consideration of these factors may be important in addition to the burdens we detail in this study. Whether the potential burdens of screening outweigh the potential benefits depends upon the individual being screened and the disutilities each individual places on the potential burdens.⁷ For frail patients with life expectancies <5 years, it is generally agreed that survival benefit is unlikely, and understanding that screening may result in significant burdens should lead to recommendations against screening. For frail patients with life expectancies >5 years, many screening decisions will be "close calls" and will require discussions about the potential benefits and risks of screening and consideration of patient values and preferences.²¹ Such discussions should help minimize work-up refusals, since patients who state that they would not want further work-up should not be screened.

Understanding that screening frail older women frequently results in burden raises questions about policies that use the rate of cancer screening to measure quality of care in this population. Quality assessments based rigidly on cancer screening rates have been adopted by several organizations that care for frail elders. For example, On Lok developed its cancer screening policy in response to requirements by auditors from the California Department of Health Services. Also, the Veterans Administration has adopted performance measures based on the percentage of patients over age 50 who are offered colorectal cancer screening, with no allowance for clinicians to indicate when screening is not appropriate due to a patient's limited life expectancy.²² Since quality indicators are often tied to reimbursement or sanctions/penalties, they may narrow the focus to be on increasing cancer screening rates rather than a careful consideration of the estimated burdens and benefits for a particular individual.

Misguided quality indicators that reward screening rates approaching 100% challenge clinicians who understand the tremendous variability in health status of older adults and who wish to tailor screening recommendations to each individual.²³ We believe that a better measure of the quality of medical care in frail older adults may be assessment of thoughtful decision making about cancer screening. Perhaps this would encourage individualized screening decisions, resulting in less screening of frail individuals and more screening of healthy older women, in whom screening mammography is currently underutilized.^{7,20}

In summary, our study details the burdens of screening mammography, including work-up refusals, false-positive results, and identification of clinically insignificant lesions, which have not been previously described in the frail elderly population. Given that cancer screening can lead to substantial burdens, especially in individuals with

limited life expectancies, we believe that cancer screening decisions in frail older patients should be individualized, in which the potential benefits and burdens are understood and an individual's values and preferences are considered. Quality assessments that encourage individualized decision making would support clinicians in targeting screening to older women for whom the potential benefits outweigh the potential burdens.

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