

## Study of limitation of mammogram

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### **Abstract:**

**Purpose:** The purpose of the study is that mammography screening for breast cancer is widely available in many countries. The goal of screening mammography programs is to decrease mortality from breast cancer. Initially praised as a universal achievement to improve women's health and to reduce the burden of breast cancer, the benefits and harms of mammography screening have been debated heatedly in the past years. Although much attention has been paid to the female breast and its pathologic conditions, the male breast is often times ignored given its rudimentary and nonfunctional nature. However, the male breast is the source of a wide variety of benign and malignant conditions, and particular attention must be paid to palpable abnormalities of the male breast to ensure accurate characterization and diagnosis of these lesions. Mammography has been traditionally used as the imaging modality of choice in the evaluation of the male breast, particularly in distinguishing between gynecomastia and breast carcinoma.

**Method:** The researchers reviewed of several researches discusses the benefits, limitations and harms of mammography screening in light of findings from randomized trials and from more recent observational studies performed in the era of modern diagnostics and treatment.

**Results:** The main benefit of mammography screening is reduction of breast-cancer related death. Relative reductions vary from about 15 to 25% in randomized trials to more recent estimates of 13 to 17% in meta-analyses of observational studies. In an update of the 2006 review, Gøtzsche and Nielsen reassessed screening mammography's effect on mortality and morbidity. Eight eligible trials were identified, with one trial excluded due to bias, providing an analysis with 600,000 women. Consistent with the findings of the 2006 review, the three trials with adequate randomization did not show a significant reduction in breast cancer mortality at 13 years (RR= 0.90, 95% CI: 0.79-1.02). These trials did not find an effect of screening on cancer mortality, including breast cancer, after 10 years (RR=1.02, 95% CI: 0.95-1.10) or on all cause mortality after 13 years (RR=0.99, 95% CI: 0.95 -1.03). According to the authors, "Screening is likely to reduce breast cancer mortality. As the effect was lowest in the adequately randomized trials, a reasonable estimate is a 15% reduction corresponding to an absolute risk reduction of 0.05%. Screening led to 30% over diagnosis and overtreatment, or an absolute risk increase of 0.5%. It is thus not clear whether screening does more good than harm

**Conclusion:** Researchers concluded that evidence from studies of varied quality indicate that, overall, mammography screening has a modest effect on breast cancer mortality. When analyzed in absolute terms, the death rate is reduced by just 0.05%. Like with all medical interventions, there are harms associated with screening mammography such as misdiagnosis and overtreatment. Screening mammography can produce inaccurate results, and as a result, many women receive false-positive or false-negative results. A false-positive result occurs when a mammogram shows a suspicious image, but there is actually no breast cancer. A false-negative result occurs when a woman's mammography results are normal, but she actually has breast cancer.

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### **I. Introduction:**

A mammogram is an x-ray of the breast that can reveal abnormalities (benign or malignant)(figure 1). The procedure involves compressing the breast between two plates and then applying a small dose of radiation to produce an x-ray image. Mammograms can be used for screening and for diagnosis.

Screening Mammogram - is performed to attempt to detect breast cancer before symptoms occur. The goal of screening mammography programs is to decrease mortality from breast cancer. Diagnostic Mammogram - is performed to help detect breast cancer if a woman has symptoms, such as a lump that can be felt in her breast. Screening Guidelines In 2009, the U.S. Preventive Services Task Force (USPSTF) issued new mammography screening guidelines with a recommendation that women under age 50 do not need routine screening mammography, whereas its earlier stance was in accordance with American Cancer Society

guidelines which recommended mammography every one to two years for all women age 40 and older (1). The USPSTF recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take into account patient context,

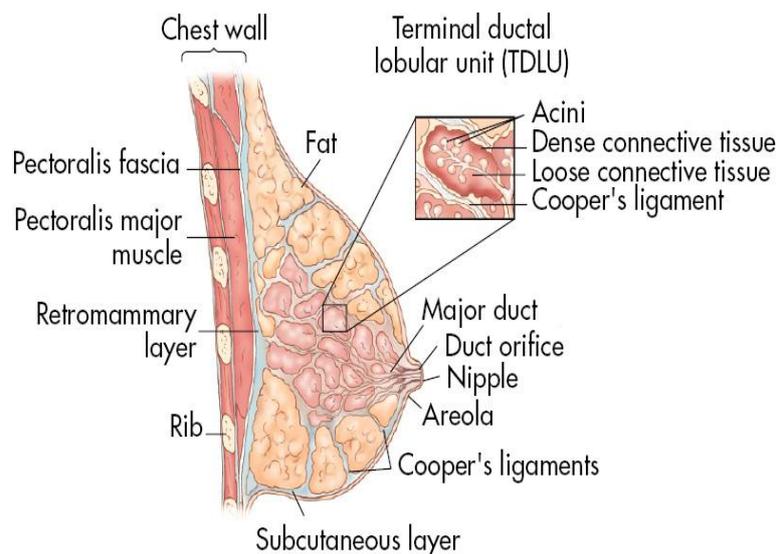
including the patient's values regarding specific benefits and harms. The USPSTF recommends biennial screening mammography for women between the ages of 50 and 74 years (1).

Breast diseases, both benign and malignant, affect many women worldwide. To enhance early detection, women are encouraged to undergo routine screening by mammography (MG) (2). Breast density represents the proportion of different tissue types within a woman's breast. Specifically, breast and connective tissues are denser than fat, and this difference is apparent by MG. When breast density is high (that is, when there is a greater amount of breast and connective tissues compared with fat), mammograms are more difficult to interpret because

a lesion may be shadowed by the dense tissues. Moreover, research has shown that women with high breast density are at increased risk of developing breast cancer (3). Breast density varies by race, and many Chinese women have dense- or intermediate mixedtype breast density (4). Thus, MG may fail to accurately identify tumors within this population. In some countries, doctors have begun to implement alternative methods for women with dense breasts. Such measures

include the use of ultrasonography (US) and magnetic resonance imaging (MRI) (5,6). MRI is a useful tool to assess breast diseases and has been shown to have a higher sensitivity than MG (5,6). However, MRI is expensive and waiting lists are often long, limiting its use in underdeveloped areas of China. In contrast, US might be more accurate than MG and is cheaper than MRI for the preoperative evaluation of breast diseases in women (5,6)

The normal male breast consists mainly of fatty tissue with few subareolar ductlike structures overlying a prominent pectoralis muscle. Lobule formation is not usually seen in male breast development(7). Sonographically, the male breast appears as isoechoic fat lobules representing the subcutaneous fatty tissue. The pectoralis muscle is seen underlying the subcutaneous fat (Figure 3). Imaged mammographically, the normal male breast is homogeneously radiolucent with a prominent pectoralis muscle (Figure 3). Unlike the female breast, there are no echogenic suspensory ligaments of Cooper in the male breast.



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**Figure(1) Anatomy of the Breast**

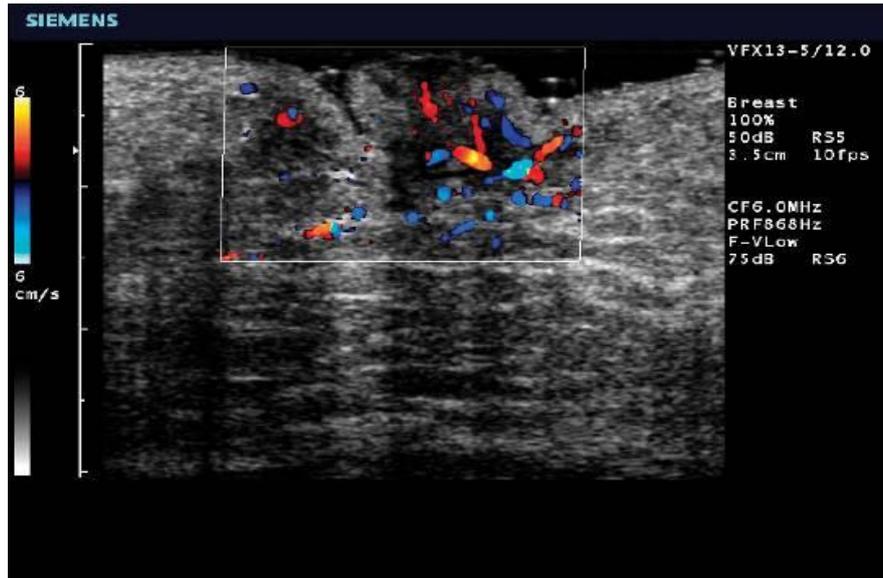
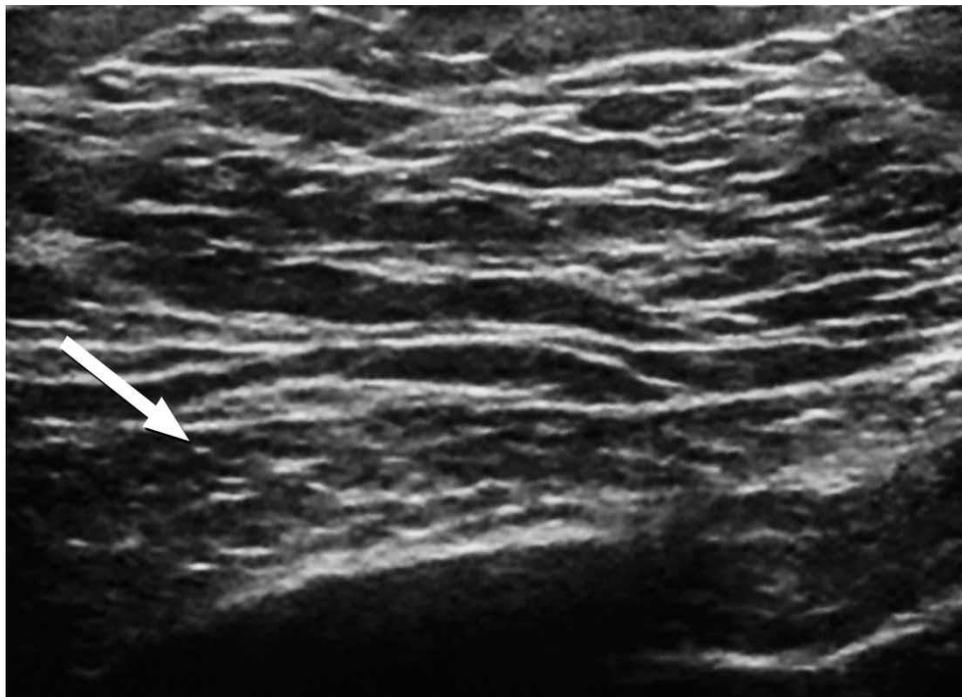
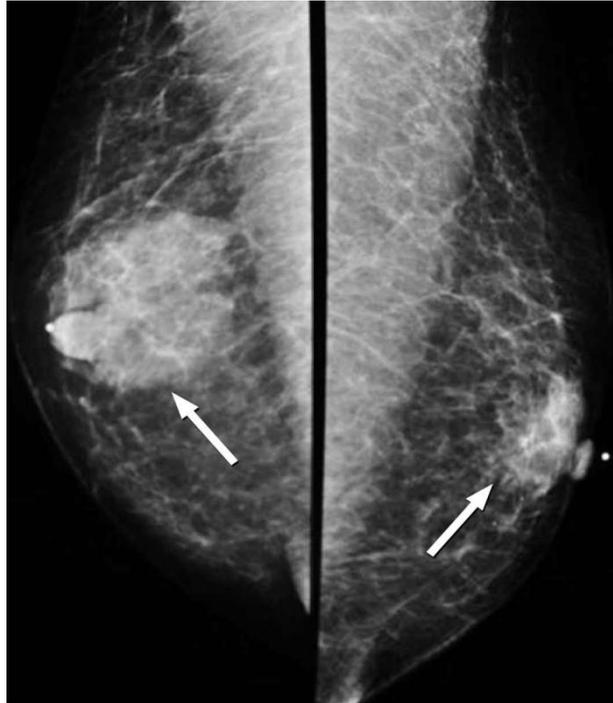


Figure (2) Sonographic Appearance



Figure( 3) Normal male breast. A, Transverse sonogram showing subcutaneous fat as isoechoic fat lobules overlying the pectoralis muscle (arrow).



**Figure (4) Mediolateral oblique mammograms of both breasts showing the common fan-shaped or at times rounded retroareolar density (arrows).**

While mammography is the best screening tool for breast cancer available today (figure 4), mammograms do not detect all breast cancers. This is called a false negative result. On the other hand, when a mammogram looks abnormal and no cancer is present, this is called a false-positive result.

Screening mammographic images themselves are often not enough to determine the existence of a benign or malignant disease with certainty. If there are abnormalities, radiologist may recommend further diagnostic studies. It is very important to realize that not all breast cancers can be seen on mammography. Interpretations of mammograms can be difficult because a normal breast looks different for each woman. Also, the appearance of an image may be compromised if there is powder or salve on the breasts or if have undergone breast surgery. Because some breast cancers are hard to visualize, a radiologist may want to compare the image to views from previous examinations. Increased breast density has attracted attention from a number of state legislatures and more recently the federal government for multiple reasons, including: Increased breast density makes it difficult to see a cancer on mammography.

Increased breast density may increase the risk of getting breast cancer. The radiologist reading the mammogram determines your breast density and reports it to the doctor. Some states also require the facility to notify if the patient have dense breasts. Breast implants can also impede accurate mammogram readings because both silicone and saline implants are not transparent on x-rays and can block a clear view of the tissues around them, especially if the implant has been placed in front of, rather than beneath, the chest muscles. Experienced technologists and radiologists know how to carefully compress the breasts to improve the view without rupturing the implant. Research is being done on a variety of breast imaging techniques that can contribute to the early detection of breast cancer and improve the accuracy in distinguishing non-cancerous breast conditions from breast cancers (8).

#### **Analyses of the Mammography Screening Studies:**

The studies have been subject to meta-analyses and systematic reviews by the research community. NBCC (National Breast Cancer Coalition) believes that the most thorough evaluations to date have been conducted by researchers affiliated with the Cochrane Collaboration (9-10), by researchers for the U.S. Preventive Services Task Force (USPSTF) in 2009 (11) and 2002 (12), and by Dr. Armstrong, et al. in 2007 for the American College of Physicians. (13) These scientists reviewed and evaluated the evidence on benefits and harms of mammography screening and assessed the quality of the trials.

#### **2011 Cochrane Review (9)**

In an update of the 2006 review, Gøtzsche and Nielsen reassessed screening mammography's effect on mortality and morbidity. Eight eligible trials were identified, with one trial excluded due to bias, providing an

analysis with 600,000 women. Consistent with the findings of the 2006 review, the three trials with adequate randomization did not show a significant reduction in breast cancer mortality at 13 years (RR= 0.90, 95% CI: 0.79-1.02). These trials did not find an effect of screening on cancer mortality, including breast cancer, after 10 years (RR=1.02, 95% CI: 0.95-1.10) or on all cause mortality after 13 years (RR=0.99, 95% CI: 0.95 -1.03). According to the authors, "Screening is likely to reduce breast cancer mortality. As the effect was lowest in the adequately randomized trials, a reasonable estimate is a 15% reduction corresponding to an absolute risk reduction of 0.05%. Screening led to 30% over diagnosis and overtreatment, or an absolute risk increase of 0.5%. It is thus not clear whether screening does more good than harm.(9)

### **2006 Cochrane Review(10)**

The 2006 Cochrane review by Gøtzsche and Nielsen incorporated new data since the 2002 Cochrane review and reassessed screening mammography's effect on mortality and morbidity. Using standard criteria, the researchers rated the quality of each trial's randomization methods as either adequate or suboptimal. The review included the Malmö, Canadian, New York, Two-County, Stockholm, and Göteborg trials. The Edinburgh trial was deemed biased and not included in the 2006 review. The Gøtzsche and Nielsen review concluded that only two of the trials were adequately randomized - the Malmö and Canadian trials - and these trials \*did not\* show that mammography screening decreased mortality from breast cancer. In these trials, the women who were offered mammography screening had the same breast cancer mortality (death rate) as the women who were not offered mammography screening. In contrast, the Göteborg, New York, Stockholm, and Two-County trials, which had suboptimal randomization according to the researchers, found that mammography (did) benefit women and reduced breast cancer mortality by about 25%, on average, after 13 years. The researchers then calculated an overall effect on mortality by taking into account the quality of all but the Edinburgh trial. They concluded that mammography decreases the risk of death from breast cancer by about 15% in relative terms, or 0.05% in absolute terms. This means that throughout a ten-year period, 2000 women need to get screened to prevent one death from breast cancer. Of note is the fact that the methodology to estimate the overall reduction of 15% was not disclosed. Finally, Gøtzsche and Nielsen found that mammography screening leads to more false positives, more unnecessary surgeries, and more use of aggressive breast cancer treatments. They concluded that mammography screening increased the relative risk of over diagnosis and overtreatment by 30%. This translates to an absolute risk increase of 0.5%; which means that throughout a ten-year period, for every 2000 women screened, ten healthy women will undergo unnecessary diagnostic procedures and treatment.

### **2002 Review by Humphrey, et al.(12)**

Similar to the Cochrane reviews, Dr. Humphrey and colleagues produced a summary review of the most up to date results from the seven trials for the USPSTF. Their analysis deemed the Canadian trial as fair or better quality, the New York, Göteborg, Stockholm Malmö and Two-County trials as fair quality, and the Edinburgh trial as poor quality (the Edinburgh trial was not included in their analysis). In their review, they conclude that screening mammography significantly reduced the risk of breast cancer mortality in screened women compared with unscreened women by 16%. (Note that this conclusion is very similar to the 15% reached by Gøtzsche and Nielsen in 2006.) For women between the ages of 40-49 years, they found a 15% relative reduction in risk associated with screening mammography. This means that throughout a fourteen-year period, 1792 women in their 40s need to get screened to prevent one death from breast cancer. However, this finding had only borderline statistical significance (RR=0.85 (CI: 0.73-0.99)). The Humphrey review concluded that "the absolute benefit of mammography screening on mortality is very small, and that biases in the trials could either erase or create it." Furthermore, they state: "even in the best screening settings, most deaths from breast cancer are not currently prevented."

### **2006 Systematic Review by Armstrong, et al.(13)**

This review for the American College of Physicians focused on screening mammography in women 40-49 years of age. It included publications from the original mammography trials as well as 117 other studies. The reviewers indicate that studies have estimated a 7% to 23% reduction in breast cancer mortality rates with screening mammography in women in this age group. They also point to rates of false-positive results as high as 20% to 56% after 10 mammograms with consequent increases in unnecessary procedures and breast cancer-related anxiety; as well as discomfort at the time of screening and exposure to low-dose radiation. They conclude that the evidence suggests that more women in the 40-49 years age range have risks that outweigh the benefits of screening mammography. Subsequently, the American College of Physicians issued detailed guidelines for screening mammography among younger women that encourage doctors to carefully assess an individual woman's risks for breast cancer, and to discuss with them the potential benefits and harms of screening mammography in order to make informed individual decisions about screening.(14)

A more recent analysis of the Norwegian screening program showed much less impact from mammography than expected.<sup>(15)</sup> Researchers compared the incidence-based rates of death from breast cancer in four groups: two groups of women who from 1996 through 2005 were living in screening programs (screening group) or without screening programs (non screening group); and two historical-comparison groups that from 1986 through 1995 mirrored the current groups. Participation in the Norwegian breast cancer screening program was associated with a 10% reduction in the rate of death from breast cancer among women 50 to 69 years of age. However, by looking at changes in mortality in groups outside of screening age ranges and looking at historical comparison groups, researchers estimated that at least two-thirds of the improvement in mortality rates was due to differences other than screening mammography, such as advances in breast cancer awareness and treatment.

### Mammography Screening:

Screening mammography can produce inaccurate results, and as a result, many women receive false-positive or false-negative results. A false-positive result occurs when a mammogram shows a suspicious image, but there is actually no breast cancer. A false-negative result occurs when a woman's mammography results are normal, but she actually has breast cancer. In the United States, it has been estimated that a woman's cumulative risk for a false-positive result after ten mammograms is almost 50% and the risk for undergoing an unnecessary biopsy is almost 20%.<sup>(16)</sup>

Although biopsies are relatively simple surgeries, they can cause distress, scarring and disfigurement, and add to health care costs. Another related potential harm of screening is overtreatment. There is a growing body of evidence that breast cancer is not one, but several diseases. Clinicians and researchers believe that some breast cancers will never spread to other parts of the body. Detecting and removing breast cancers that would never have spread to other parts of the body does not save any lives. This is an active area of research, but unfortunately, scientists have not figured out which breast cancers will eventually spread and which will not.

## II. Conclusion:

Evidence from studies of varied quality indicates that, overall, mammography screening has a modest effect on breast cancer mortality. When analyzed in absolute terms, the death rate is reduced by just 0.05%. Like with all medical interventions, there are harms associated with screening mammography such as misdiagnosis and overtreatment. Two comprehensive reviews of the evidence conclude that the overall impact in mortality is small and biases in the trials could either "erase or create it. Women should discuss with their doctors their own risk profile, the potential benefits, harms, and complexities of screening mammography, and make informed

decisions about screening. Mammography may provide benefits for some women, but it may also harm others. Women need honest information regarding the value of all medical interventions. Public health resources need to be used with certainty to improve the public's health. The reality is that screening has not been effective. While the incidence of ductal carcinoma in situ and localized invasive breast cancer increased substantially as a result of screening programs, the incidence of regional or distant stage disease has not.

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