

Consensus Statement on Screening Mammography

Purpose: To outline mammogram screening guidelines for asymptomatic women

Associated ASBrS Guidelines or Quality Measures :

1. None (prior statement from 2011)

<u>Methods</u>: Literature review inclusive of recent randomized controlled trials evaluating the benefit of screening mammography both 2D and 3D. This is not a complete systematic review but a comprehensive review of the modern literature on this subject. The ASBrS Research Committee developed a consensus document which was reviewed and approved by the ASBrS Board of Directors.

Summary of Data Reviewed:

Mammographic screening guidelines have remained a high profile medical topic with increased scrutiny since the 2009 guidelines were released by the United States Preventive Services Task Force (USPSTF). These guidelines recommended biennial screening for women age 50-74, a shared decision making process for screening women age 40-49 and insufficient evidence to support screening women over the age of 75. ^[1] Recently the American Cancer Society (ACS) has published their new guidelines for mammographic screening and several changes from the USPSTF and prior ACS recommendations are notable. The 2015 ACS guidelines recommend annual screening for women age 45-54, a shared decision making process for women to elect screening in ages 40-44 and biennial screening for women over the age of 55. Women are advised in the new ACS recommendations to continue screening as long as they have an estimated 10 year life expectancy. ^[2]

In 2002 The USPSTF performed a meta-analysis for the eight large prospective mammography trials designed to assess the effectiveness of mammography in reducing breast cancer mortality but only included data from seven trials. In their estimation all the trials had limitations but they excluded the Edinburgh study from the analysis. They cited serious imbalance between control and screened group since the investigators did not control for socio economic factors and the control group had a dramatically higher all-cause mortality rate due to higher co-morbidities. ^[1] They concluded that mammography reduced breast cancer mortality among women 40 to 74 years of age with a greater benefit in women greater than 50. In 2009 this group updated their analysis to include data from the AGE trial from the United Kingdom that randomized women ages 39 to 41 to annual screening mammography until age 48. ^[3] Once again The Task Force found a 15% reduction in breast cancer mortality in favor of screening with an even greater

benefit for women over 60. In addition, they reported that for women ages 40-49 the false positive rate was the highest with the highest rate of additional imaging and unnecessary biopsies.^[4] For these reasons they changed their recommendations to consider starting mammographic screening at age 50.

There have been many analyses examining the same data with different conclusions depending on the critiques of each of the studies. Some investigators have dismissed many of the randomized prospective studies due to study flaws. In a 2011 Cochrane review, the investigators rated the quality of the 8 eligible trials; only 3 were found to have adequate randomization. Interestingly, the trials with adequate randomization did not find any effect of screening mammograms on breast cancer deaths after 10 years (relative risk [RR] 1.02, 95% confidence interval [CI] 0.95–1.10)^[5] However, there have been other pooled estimates from all the trials and all age groups that have shown that mammographic screening provides a 20% breast cancer mortality reduction which is highly statistically significant. ^{[6][7]}. Furthermore, systematic review of multiple incidence based mortality and case-control observational studies have demonstrated an even bigger benefit. The estimated breast cancer mortality reductions ranged from 1% to 9% per year in studies reporting an annual percentage change, and from 28% to 36% in those comparing post- and prescreening periods

The new ACS screening guidelines were developed through an interdisciplinary evaluation of a systematic review of the literature as well as supplemental evaluation of mammography registry data. In this review, the ACS acknowledges that the definition of average risk was broad and excluded only those women with a known prior breast cancer, a suspected or known genetic mutation or prior chest radiotherapy. The ACS guidelines acknowledge that there is an intermediate risk group that may require a different screening approach but currently a risk based screening approach for this group is not yet available. Important in the ACS guidelines was consideration of mortality, life expectancy, false positive findings, over diagnosis and quality adjusted life expectancy.^[2]

Special Screening Populations

Older women

None of the randomized prospective trials included women older than 74 years of age; therefore, the US preventative task force has not recommended screening mammography in this age group. ^[4] The ACS however recommends screening as long as women have a life expectancy of 10 years. Twenty six percent of breast cancer deaths are in women over the age of 75 and yet 50% of women over age 80 are expected to live another 10 years. In this group, individualized decisions for mammography are recommended by the ACS. ^[2] There are three observational studies in the literature showing a benefit in this population provided that the women do not have severe co-morbidities. Two studies found a survival benefit for screening women with mild co-morbidities and no benefit for women with severe co-morbidities. ^[10] Mammographic screening in an older compared to a younger population would be expected to have a lower rate of false positives and unnecessary biopsies but higher risk for over- diagnosis. Over treatment may be more of a problem in women with at least a five year life expectancy. ^[12]

Younger women

For women under 39 there is no data supporting routine screening in this group. Mammography is less accurate in pre-menopausal women age under 45 either for screening or symptoms. ^[13] The USPSTF did not recommend screening women under the age of 39. The American Cancer Society does not recommend screening prior to age 40 for women of average lifetime risk of breast cancer.

Digital breast tomosynthesis: A major limitation in the detection of breast cancer on routine mammography is overlapping tissue. Digital breast tomosynthesis is a modification of digital mammography that allows for the acquisition of three-dimensional (3D) thin section data of the breast. Approximately 10-15 1 mm thickness slices are acquired through each breast and reconstructed using algorithms similar to those used with computed tomography (CT)^[14]. A tomogram reduces the visualization of overlapping structures by blurring tissue above and below the slice of interest. Both conventional two-dimensional (2D) mammography and 3D images can be acquired on the same tomosynthesis unit. Digital breast tomosynthesis was approved for the same clinical uses as conventional 2D mammography in February 2011.

Currently, a variety of imaging protocols exist for digital breast tomosynthesis. Most centers are opting to do both conventional 2D mammography in addition to 3D tomosynthesis for screening; however newer technology will soon permit the performance of just the 3D imaging with ability to create a 2D image. Many centers are offering breast tomosynthesis to patients with dense breasts or those at higher risk for breast cancer.

Multiple large screening trials are currently underway comparing the utility of screening patients with 2D + 3D tomosynthesis to 2D conventional mammography alone. Recent data from the Screening with Tomosynthesis OR standard Mammography (STORM) study demonstrated a 17.1% reduction in false positive recalls and a 33.9% increase in the cancer detection rate by adding 3D tomosynthesis to screening ^{[14] [15]}. Another study reported similar results, with a 15% decrease in false positives and a 27% increase in the cancer detection rate ^[16]. Of note, another study found that the increased sensitivity of tomosynthesis was largest for invasive cancers where 15-22% of cases were invasive versus 3% being in situ ^[17]. Neither the USPSTF or ACS guidelines provide specific recommendations for type of mammogram but recognize that all prior randomized trials used film screen mammography.

Breast scintigraphy, thermography, ductal lavage:

Current evidence does not support the use of breast scintigraphy (e.g. sestamibi scan), thermography or ductal lavage for screening of average risk women outside of clinical trials.

ASBrS Recommendations for asymptomatic Average Risk Women

- 1. Discussion with her physician to consider screening mammography at age 40-44 based on a balanced discussion of risks and benefits
 - **a.** Most studies show a decrease in breast cancer mortality from screening starting at age 40 but in the group 40-49 there is a higher false positive rate
 - **b.** Patients should discuss screening with their physician including risk assessment to determine if they are average risk
- 2. Annual Screening for women ages 45-54 as indicated by the new ACS guidelines

- 3. Annual or Biennial screening for women 55 and older based on a shared decision making discussion regarding risk and benefits of screening timing
- 4. Biennial screening for women over the age of 75 if an estimated life expectancy is greater than 10 years
- 5. Breast tomography may be considered for screening
 - a. Early data shows promise in higher sensitivity rates and specificity rates
 - b. May_increase detection rates and decrease false positive rates especially in women with dense breast tissue
 - c. Data from large randomized clinical trials is pending

ASBrS (Brief) Recommendations for asymptomatic Intermediate Risk Women

- 1. Consider use of a risk assessment tool to determine an estimated life time risk for breast cancer
- 2. Consider use of annual screening mammography for women with greater than an estimated 15% lifetime risk for breast cancer or recommend entry into clinical trials evaluating risk based screening

<u>ASBrS (Brief) Recommendations for asymptomatic High Risk Women (20-25% or greater</u> <u>estimated lifetime risk)</u>

- 1. Discuss use a risk assessment tool to determine estimated life time risk for breast cancer and risk of a germ line mutation predisposing to breast cancer.
- 2. Discuss annual screening with both mammography and breast MRI compliant with American Cancer Society and NCCN Guidelines.^[17,18]

References

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This statement was developed by the Society's Research Committee and on October 29, 2015, was approved by the Board of Directors.