Published in final edited form as:
JAMA Intern Med. 2014 June 1; 174(6): 954–961. doi:10.1001/jamainternmed.2014.981.

Consequences of False-Positive Screening Mammograms

Anna N. A. Tosteson, ScD[1], **Dennis G. Fryback, PhD**[2], **Cristina S. Hammond, MPH**[1], **Lucy G. Hanna, MS**[3], **Margaret R. Grove, MS**[1], **Mary Brown**[4], **Qianfei Wang, MS**[1], **Karen Lindfors, MD**[5], and **Etta D. Pisano, MD**[6]

[1]The Dartmouth Institute for Health Policy and Clinical Practice and Norris Cotton Cancer Center, Geisel School of Medicine at Dartmouth, Hanover, NH

[2]University of Wisconsin at Madison, Madison, WI

[3]Center for Statistical Science, Brown University School of Medicine, Providence, RI

[4]University of North Carolina at Chapel Hill, Chapel Hill, NC

[5]University of California at Davis, Davis, CA

[6]Medical University of South Carolina, Charleston, SC

Abstract

Importance—False-positive mammograms, a common occurrence in breast cancer screening programs, represent a potential screening harm that is currently being evaluated by the United States Preventive Services Task Force.

Objective—To measure the impact of false-positive mammograms on quality of life by measuring personal anxiety, health utility and future screening attitudes.

Design—Longitudinal Digital Mammographic Imaging Screening Trial (DMIST) quality-of-life sub-study telephone survey shortly after screening and one year later.

Address Correspondence and reprint requests to: Anna N. A. Tosteson, ScD James J. Carroll Professor The Dartmouth Institute for Health Policy and Clinical Practice Geisel School of Medicine at Dartmouth One Medical Center Drive (HB7505) Lebanon, NH 03756 Phone: 603-653- 3568 FAX: 603-653-3554 anna.n.a.tosteson@dartmouth.edu; tamara.s.morgan@dartmouth.edu. anna.n.a.tosteson@dartmouth.edu dfryback@wisc.edu cristina.hammond@redcross.org lhanna@stat.brown.edu margaret.r.grove@dartmouth.edu marylee.brown@ppdi.com qianfei.wang@dartmouth.edu Karen.lindfors@ucdmc.ucdavis.edu pisanoe@musc.edu

Author Contributions: Author contributions to the manuscript (ms) are summarized as follows:

Tosteson	study design, analysis, interpretation & drafting of results, ms review, final submission
Fryback	study design, interpretation and drafting of results, ms review
Hammond	study design, data collection, ms review
Hanna	analysis and interpretation of findings, ms review
Grove	analysis and interpretation of findings, ms review
Brown	data collection, ms review
Wang	analysis and interpretation of findings, ms review
Lindfors	interpretation and drafting of results, ms review
Pisano	study design, interpretation and drafting of results, ms review

Setting—Twenty-two DMIST sites

Participants—Randomly-selected DMIST participants with positive and negative mammograms.

Exposure(s) for observational studies—Mammogram requiring follow-up testing or referral without a cancer diagnosis.

Main Outcome(s) and Measure(s)—The Spielberger State-Trait Anxiety Index short-form (STAI-6) and the EuroQol EQ-5D with United States scoring. Attitudes toward future screening measured by women's self-report of future intention to undergo mammography screening and willingness to travel and stay overnight to receive a hypothetical new mammogram that would detect as many cancers with half the false-positives.

Results—Among 1,450 eligible women invited to participate, 1,226 women (85%) were enrolled with follow-up interviews obtained for 1,028 (84%). Anxiety was significantly higher for women with false-positive mammograms (STAI-6:35.2 vs. 32.7), but health utility did not differ and there were no significant differences between groups at one year. Future screening intentions differed by group (26% vs. 14% more likely in false-positive vs. negative); willingness to travel and stay overnight did not (11% vs. 10% in false-positive vs. negative). Future screening intention was significantly increased among women with false-positive mammograms (OR: 2.12; 95%CI:1.54, 2.93), younger age (OR:2.78; 95%CI:1.5,5.0) and poorer health (OR: 1.63; 95%CI:1.09, 2.43). Women's anticipated high-level anxiety regarding future false-positives was associated with willingness to travel overnight (OR: 1.94; 95%CI:1.28, 2.95).

Conclusions and Relevance—False-positive mammograms were associated with increased short-term anxiety, but no long-term anxiety and no measurable health utility decrement. False-positive mammograms increased women's intention to undergo future breast cancer screening and did not increase women's stated willingness to travel to avoid a false-positive mammogram. Our finding of time-limited harm following false-positive screening mammograms is relevant for healthcare providers who counsel women on mammography screening and for screening guideline development groups.

Keywords

Mammogram; screening; false positive; quality of life; harm

A substantial proportion of women who undergo routine screening mammography over a 10-year period will experience a false-positive mammogram, requiring additional work-up to rule out breast cancer.[1-3] False-positive mammograms leading to benign unnecessary biopsies compared with the number of cancers detected contributed to the 2009 changes in the U.S. Preventive Services Task Force (USPSTF) breast cancer screening guidelines.[4] Instead of recommending routine screening among 40-49 year old women, the USPSTF recommends that women in their 40s discuss the pros and cons of mammography screening with their healthcare providers before deciding whether to initiate screening. This recommendation acknowledges that individual women's preferences regarding the balance of screening benefits vs. harms, which include false-positive mammograms, may differ. As

the USPSTF re-evaluates the evidence for breast cancer screening, the harms of screening are among the questions to be addressed in their systematic evidence review. [4]

While there is a growing literature on how women view false-positive screening mammograms, [3,5-23] few studies have attempted to assess the impact of false-positive results on generic measures which allow comparison to a broad range of health outcomes. To include such a harm in a societal cost-effectiveness analysis, the impact of false-positive screening mammograms on generic health utility, using a scale where 0 represents being dead and 1 represents perfect health, is needed to compute cost-effectiveness results which can be compared to other health care interventions. [24] These facts, combined with early digital mammography screening studies, [25-29] which suggested that digital mammography may yield fewer false-positive exams than screen-film mammography, led to inclusion of a quality-of-life (QoL) sub-study in the American College of Radiology Imaging Network Digital Mammographic Imaging Screening Trial (DMIST). [30] The QoL sub-study was designed to characterize the personal anxiety, disutility and personal time costs associated with work-up of positive screening mammograms. Personal time costs of mammography screening outcomes in DMIST were reported and used in the DMIST cost-effectiveness analysis. [31] In this paper, we report DMIST QoL sub-study results that characterize the impact of false-positive screening mammograms on personal anxiety, health utility, and attitudes toward future screening.

METHODS

Digital Mammographic Imaging Screening Trial (DMIST)

DMIST was funded by the National Cancer Institute and conducted by ACRIN as described in detail elsewhere.[30] In brief, DMIST's primary aim was to compare the diagnostic accuracy of digital mammography relative to screen-film mammography. [32,33] Secondary aims included an economic evaluation of digital mammography[31] and an assessment of the impact of false-positive screening mammograms on quality of life.

To be eligible for DMIST, women had to present for screening, agree to undergo a follow-up mammogram, and consent to study participation. Women were excluded if they had a focal dominant lump or bloody or clear nipple discharge, a history of breast cancer treated with lumpectomy, breast implants, or believed they might be pregnant. Eligible women received both digital and screen-film mammograms, which were read independently by different radiologists.

DMIST QoL Sub-study Participants

The sub-study was conducted by telephone survey and included two groups of women: (1) a random sample of DMIST participants with a positive screening mammogram, defined as any mammogram where additional work-up or consultation was recommended; and (2) a sample of women with a negative screening mammogram. To ensure a comparable number of participants with positive and negative mammograms from each site, for each woman selected with a positive screening mammogram, a woman from the same institution who had a negative screening mammogram and who was of similar age (within 5 years) was also

selected for participation. Women diagnosed with breast cancer at any time during DMIST were ineligible and were excluded.

Measures

Anxiety—The Spielberger State-Trait Anxiety Inventory (STAI) is a widely used measure of general anxiety that includes both a state scale and a trait scale.[34] In the present study we are interested in state anxiety--anxiety of the moment as experienced by the person. To measure this we used a validated 6 question short-form of the STAI state scale (STAI-6), which yields a score between 20 (least anxious) and 80 (most anxious). [35]

Health Utility—To characterize general health-related quality of life we used the validated EuroQol EQ-5D instrument which consists of 5 questions, one each about mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[36] Each question has three possible responses categorizing degree of problem with the particular aspect of health ranging from 1 (no problem) to 3 (extreme problem). The 5 questions and 3 response categories are used to define 245 distinct health states. Scoring using U.S. preference weights assigns health state values ranging from −0.11(worst health for those with extreme problems in all five areas) to 1.0 (best health for state for those with no problem in any area). [37]

A current health rating scale (RS) asked “On a scale from 0 to 100 where 0 represents death or the worst health you can imagine and 100 represents perfect health or the best health you can imagine, how would you rate your health during the past 4 weeks?”

Breast-related Resource Use—At follow-up, women were asked “since your mammogram approximately 12 months ago (date provided), have you received medical care for any breast-related concerns?” Women who answered affirmatively were read a list of tests, procedures and health provider visits that some women undergo after a mammogram and were asked which they had undergone.

Future Screening Attitudes—Women were asked to think about “how your breast-related care in the past year may change your future use of screening mammography” and to choose the statement that best represented their feelings at the time of the follow-up survey. Response choices were: “I am less likely than a year ago to undergo screening mammography in the future”; “My use of screening mammography will not change”; “I am more likely than a year ago to undergo screening mammography in the future.”

Two questions asked women their opinion about new types of mammograms that may be developed in the future. A willingness-to-pay-to-avoid approach was used to assess how women valued false-positive screening mammograms. This was implemented by asking about the duration of travel women would be willing to undertake to gain access to a hypothetical new type of mammography that would produce fewer false-positive exams while detecting just as many cancers. This survey item was developed for the present study and was modeled on the waiting-time tradeoff developed to value transient health states encountered in radiological cost-effectiveness analyses, [38] with travel serving as a metaphor for lost time.

Women were also asked to imagine they could choose between two new types of mammograms that are just as accurate as those today. One type resulted in fewer false-positive mammograms while the other type resulted in less breast compression. (See appendix for details). Development of the travel and new mammogram type survey items was informed by focus groups of women who had experienced false-positive screening mammograms.

Telephone Interview Schedule—Telephone interviews were conducted shortly after the baseline mammogram and approximately one year later. At both times, the interview included the STAI -6, EQ-5D and the current health rating scale.

The baseline interview was intended to occur after notification of the need for further work-up and before work-up completion—during what we define as the "active work-up window." This was not always possible. Based on follow-up data on the date of subsequent breast-related medical care, we categorized baseline interviews as occurring during or after the active work-up window. Women interviewed after the active work-up window were considered to have had "resolved" false-positive mammograms at the time of the baseline interview. We hypothesized that, compared to women with negative screening mammograms, anxiety would be highest and quality of life lowest for women with positive screening exams who were interviewed in the active work-up window (i.e., before the false-positive mammogram was resolved). We further hypothesized that elevated anxiety and reduced health utility associated with a false-positive mammogram would be transient such that at follow-up there would be no differences between those with positive and negative screening mammograms.

At the second interview, additional information on breast-related resource utilization and attitudes toward future screening mammography was collected.

Statistical Analysis

Characteristics of participants were summarized using means and proportions, with comparisons between women with positive versus negative mammograms made using t-tests and chi-squared tests. To assess the impact of the positive mammogram on anxiety and health utility, the change between baseline and follow-up scores were compared between those with positive and negative mammograms. In logistic regression analyses, we explored factors associated with women's self-report of their increased likelihood to undergo future breast cancer screening and with the odds of being willing to travel overnight to avoid a false-positive exam. Variables considered included age, breast cancer risk, baseline mammogram positivity, need for biopsy, anticipated anxiety regarding future false positive mammograms, race/ethnicity and institution.

RESULTS

Among 1,450 eligible women invited to participate, 1,226 women (85%) from 22 institutions were enrolled in the QoL sub-study and follow-up interviews were obtained for 1,028 participants (84%). Women with false positive mammograms tended to be younger, but did not differ on any other characteristics (Table 1).

At baseline, there were significant differences in anxiety between women with positive and negative exams, but no statistically significant differences in EQ-5D or current health RS (Table 2). At follow-up, a significant decline in anxiety was noted (mean STAI-6 difference - 1.53, 95%CI: −2.70, −0.35) among women with positive mammograms (Table 2). Women with negative mammograms were found to have a modest, but significant, decline in RS at follow-up (RS mean difference, −1.22, 95%CI: −2.34,−0.10).

Use of breast-related care reported one-year following the initial screening exam differed by positivity status for all categories except clinical breast exam (Table 3). Biopsy procedures were used in 15% of women with a false-positive mammogram compared with 1% of women with negative mammograms. Among women with a false-positive exam, anxiety was reported as moderate or higher by 51% and as extreme by 5%.

Women's plans to undergo mammography within the next two years did not differ by screening outcome, but significantly more women who experienced a false-positive mammogram characterized themselves as "more likely" to undergo future breast cancer screening (26%) than women who had a negative mammogram (14%) (Table 4). However, there were no differences noted in women's attitudes toward the anticipated anxiety they would feel if they were to experience a positive mammogram in the future. A majority of women in each group (62% of negative and 64% of false positive groups) felt they would experience anxiety that was moderate or worse if a false positive mammogram were to occur in the future; and a substantial proportion anticipated feeling high anxiety (27% characterizing anticipated anxiety as "a lot" or "extreme" in each group).

Women's experience of a false-positive mammogram compared to women who had negative mammograms did not influence their willingness to travel to avoid a false-positive mammogram in the future, with the vast majority of women in both groups being willing to travel up to 4 hours to avoid a false-positive mammogram. A small minority in each group was willing to travel and stay overnight to avoid a false positive mammogram (11% of negative and 10% of false positive groups). When women were asked to choose between a new type of mammography that would either avoid breast compression or avoid false-positive mammograms, the vast majority (81%) chose the technology with fewer false positives.

When correlates of future breast cancer screening intention were examined, we found that women with a false-positive baseline mammogram, lower quartile health utility, or age under 65years were more likely to report they would undergo future screening (Table 5). In multivariable analyses, a false-positive mammogram more than doubled women's stated intention to utilize future screening (OR, 2.17, 95%CI: 1.57, 3.01). Willingness to travel and stay overnight to avoid a false-positive mammogram did not vary by positivity but was associated with women's reports of anticipated anxiety if they were to experience a false-positive mammogram in the future (Table 5).

DISCUSSION

The DMIST QoL sub-study provides evidence that women with a false-positive mammogram initially experienced a significant increase in anxiety, and that these effects were transient and were not measurable using the EQ-5D questionnaire or current health rating scale. A small proportion of women were willing to travel and stay overnight to undergo screening with a hypothetical modality that would have fewer false-positive findings, but this willingness was not influenced by experience of a false-positive mammogram. Instead, willingness to travel was associated with women's anticipated feelings of anxiety surrounding a future false-positive mammogram. Women who anticipated feeling more than moderate anxiety were nearly twice as likely to report a willingness to travel and stay overnight relative to women who anticipated feeling lesser anxiety. Our results regarding the transient anxiety associated with false positive mammograms may provide useful information for clinicians who counsel individual women regarding the decision of whether to initiate breast cancer screening and for policy-makers assessing the clinical effectiveness of mammography screening.

While there is concern that the health and psychological burden of false-positive mammograms may not be justified when weighed relative to the few additional breast cancers that routine screening would confer among younger women, we found only a transient impact of a false-positive mammogram on anxiety. Our finding differs from recent reports of longer-term impact of false-positive mammograms on specific psychological outcomes.[21-23] However, it is important to note that the ongoing harms reported in the literature are related primarily to breast-cancer specific outcomes rather than general psychological measures such as the general anxiety measure used in our study. Whether one should expect harms that are only measurable when framed in terms of a specific disease to affect a general anxiety or health-utility measure is an open question. An important feature of the two generic measures, STAI-6 and EQ-5D, used in our study is the ability to compare potential harms associated with breast cancer screening to those associated with a broad range of other health care practices.

In addition to the transient impact on anxiety, we also provide evidence that women are motivated to avoid false-positive mammograms. It is notable that a large proportion of women were willing to travel up to 4 hours to receive a hypothetical new type of mammogram that would be just as good at finding cancer, but would result in fewer false-positive mammograms. Further supporting women's interest in avoiding false-positive mammograms is the fact that when given the choice between two new types of mammograms—one with reduced false positives and one with reduce breast compression—that the majority of women in our study chose the type with fewer false positives.

Our study also characterized the anxiety and discomfort imposed by the health care visits and procedures used to resolve positive screening mammograms. Although anxiety and discomfort were significantly higher among women with false-positive mammograms compared to women with negative mammograms, these findings appeared to have no impact on women's plans to have a mammogram in the next 2 years—something that 94% of women intended to do. In contrast, women's intention to use breast cancer screening in the

future (i.e., self-characterization as being more likely to undergo future breast cancer screening) was increased by 2-fold among women who experienced a false-positive mammogram. The reasons for this are unclear, but a meta-analysis of observed screening practices following a positive mammogram has similarly concluded that women in the U.S. who experience a false-positive mammogram are significantly more likely to participate in future mammography screening.[11]

QoL sub-study results were used to estimate previously reported economic time costs associated with follow-up of screening mammograms and were incorporated into the cost-effectiveness analysis of digital mammography.[31] In this paper, we have provided further information on use of follow-up tests. Not surprisingly, some women with negative screening mammograms reported use of breast-related medical services within the year following their screening mammogram (e.g., additional imaging in 5% and breast biopsy in 1%), but use of such services were associated with lower levels of anxiety and less discomfort than was reported among women with false-positive mammograms.

The DMIST cost-effectiveness analysis did not adjust for a quality of life/health utility loss when estimating quality-adjusted life years (QALYs) for women with false-positive screening exams, a decision supported by our results showing no measurable impact with EQ-5D. [31] Nonetheless, it is important to recognize that measures such as the EQ-5D, which are appropriate for use in societal cost-effectiveness studies, are of limited value in clinical settings where individual women must consider how they value potential screening outcomes when weighing the benefits and harms of breast cancer screening. In this context, it is noteworthy that there were no differences reported in DMIST between women with false-positive mammograms and those with negative mammograms concerning the amount of anxiety they said they would anticipate feeling if they were to encounter a positive screening mammogram in the future. However, 27% of women reported that they would feel more than a moderate amount of anxiety/concern (i.e., a lot of anxiety/concern or extreme anxiety/concern) if such a screening outcome were to occur. Thus, it seems prudent for women and their healthcare providers to consider the potential outcomes of screening when coming to a decision on the best course of action for each individual woman. In addition, studies to improve breast screening practices by finding approaches that reduce such anxiety are also warranted.

Several limitations to our study deserve comment. First, we intended to interview women during the active work-up window but this was not always achieved. As a result, many women were interviewed after work-up was completed. Nonetheless, we were able to document heightened anxiety associated with false-positive mammograms. We did not document any impact on overall health utility using the EQ-5D preference-based measure that is appropriate for use in estimating QALYs. This may be due to limitations in the EQ-5D descriptive system, which combines the rating of anxiety and depression together at only 3 levels: 1) I am not anxious or depressed; 2) I am moderately anxious or depressed; and 3) I am extremely anxious or depressed; due to general insensitivity of EQ-5D to small changes in health of healthy people; or it may suggest a relatively low anxiety effect for false-positive mammograms. In addition, the majority of participants rated their health at the

ceiling of the EQ-5D descriptive system at baseline in both the false-positive (n=272/494, 55%) and negative groups (n=293/531, 55%) groups.

Second, the attitudes of DMIST volunteers may not be representative of the general population of women eligible for breast cancer screening. One might expect that DMIST participants' enthusiasm for screening may be higher than in a general population, a conjecture supported by the fact that 94% of women reported their intention to undergo breast cancer screening with mammography again within two years. However, attitudes toward cancer screening in the US have generally been documented as highly favorable. [39]

We conclude that false-positive mammograms are associated with a measurable, small and transient impact on personal anxiety and that further research should address opportunities for reducing this anxiety. While the impact of false-positive mammograms on health utility for estimating QALYs is not measurable using the current EQ-5D instrument, it is clear that women, regardless of whether or not they experienced a false-positive, are willing to invest the time necessary for travel to avoid future false-positive mammograms. The fact that women's anticipated anxiety about future false-positive mammograms was a correlate of willingness to travel and stay overnight to avoid a false-positive mammogram, but that the actual experience of a false positive was not, further highlights opportunities for educating women about screening outcomes. While health utilities were not measurably affected, the experience of a false-positive mammogram did increase women's intentions to undergo breast cancer screening in the future. Ongoing studies of breast cancer screening processes of care through NCI's PROSPR (Population-based Screening Optimizing Screening through Personalized Regimens) initiative may further elucidate the frequency and sequelae of false positive screening mammograms. Meanwhile, our report on women's experience of false-positive mammograms may provide useful information for those counseling women regarding the decision to undergo mammography screening and for screening guideline development groups.

Acknowledgments

Author Financial Disclosures and Reports of Conflicts of Interest: Drs. Tosteson, Fryback and Lindfors have no financial disclosures or conflicts of interest to report. Ms.'s Hammond, Hanna, Grove, Brown and Wang have no financial disclosures or conflicts of interest to report. Dr. Pisano reports the following: 1) Grants or grants pending with: Alan Penn & Associates; Koning Corp.; DHHS; Konica Minolta; Zumatek, Inc.; NSF; 2) Patents planned/ pending or issued: Assigned to UNC-Chapel Hill, Brookhaven Science Associates, and the University of Saskatchewan, and to NextRay, Inc.; 3) Dr. Pisano is also a co-founder and board member of NextRay, Inc.

Source(s) of Funding/Sponsor's Role: This study was supported by grants from the National Cancer Institute (U01CA80098, U01CA80098-S1, U01CA79778, U0179778-S1, RC2/UC2CA148259 and U54CA163307).

The sponsor had no role in any of the following: design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Previous Presentation of Information in Manuscript: *None*.

Acknowledgement of contributions that don't rise to the level of authorship: *None*.

Appendix: Follow-up interview used to assess attitudes toward future screening

Interviewer Instructions are italicized. Read the next set of questions that ask about your plans for and feelings about future breast-related care.

1. Please think about how your breast-related care in the past year may change your future use of screening mammography. Which statement best represents how you feel today?

- ☐ I am less likely than a year ago to undergo screening mammography in the future.
- ☐ My use of screening mammography will not change
- ☐ I am more likely than a year ago to undergo screening mammography in the future.
- ☐ Refuse/don't know

2. Are you planning on having a screening mammogram within the next 2 years?

☐ Yes ☐ No ☐ Don't know/haven't decided yet

3. After a screening mammogram, additional tests and procedures are sometimes needed because the mammogram mistakenly indicates that breast cancer may be present when it is not. These are known as "false positive mammograms." How much anxiety/concern would you have if additional tests or procedures were required after your next screening mammogram?

- ☐ No anxiety/concern
- ☐ A little anxiety/concern
- ☐ Moderate anxiety/concern
- ☐ A lot of anxiety/concern
- ☐ Extreme anxiety/concern
- ☐ Refuse/don't know

READ: The last 2 questions ask your opinion about new types of mammograms that may be developed in the future.

4. Imagine there is a new type of mammogram that is just as good at finding breast cancer as standard mammograms are today. This new mammogram results in fewer false positives (i.e., only one-half as many women who don't have breast cancer will have to have additional testing after a mammogram), but this mammogram is not available where you usually go for your mammogram. If you wish to receive the new mammogram, you must plan for additional travel time to go to another medical center where they have this new type of mammogram.

Would you choose to have the new mammogram instead of a standard screening mammogram if you had to travel for:

[start at 30 minutes; stop once woman answers "No" then go to question #5]

a… 30 minutes more?	☐ Yes	☐ No
b… 60 minutes more?	☐ Yes	☐ No
c… 90 minutes more?	☐ Yes	☐ No
d… 2 hours more?	☐ Yes	☐ No
e… 4 hours more ?	☐ Yes	☐ No
f… 8 hours more?	☐ Yes	☐ No
g….had to stay overnight away from home?	☐ Yes	☐ No

5. Imagine that there are two new types of mammograms. Both are as accurate as mammograms we have today. Imagine you have to choose between the two new types of mammograms. One type of mammogram results in fewer false positives (i.e., fewer women who do not have breast cancer will have to have additional testing), the other type of mammogram requires less breast compression but has the same number of false positives as today's methods. Which would you choose to have?

☐ I would choose the mammogram that results in fewer false positives.

☐ I would choose the mammogram that requires less breast compression.

☐ Refuse/don't know

REFERENCES

1. Elmore JG, Barton MB, Moceri VM, Polk S, Arena PJ, Fletcher SW. Ten-year risk of false positive screening mammograms and clinical breast examinations. N Engl J Med. Apr 16; 1998 338(16): 1089–1096. [PubMed: 9545356]
2. Hubbard RA, Kerlikowske K, Flowers CI, Yankaskas BC, Zhu W, Miglioretti DL. Cumulative probability of false-positive recall or biopsy recommendation after 10 years of screening mammography: A cohort study. Ann Intern Med. Oct 18; 2011 155(8):481–492. [PubMed: 22007042]
3. Schwartz LM, Woloshin S, Sox HC, Fischhoff B, Welch HG. Us women's attitudes to false positive mammography results and detection of ductal carcinoma in situ: Cross sectional survey. BMJ. Jun 17; 2000 320(7250):1635–1640. [PubMed: 10856064]
4. US Preventive Services Task Force. [Accessed November 17, 2013] Draft research plan: Screening for breast cancer. 2013. http://www.uspreventiveservicestaskforce.org/draftresplan2.htm
5. Aro AR, Pilvikki Absetz S, van Elderen TM, van der Ploeg E, van der Kamp LJ. False-positive findings in mammography screening induces short-term distress - breast cancer-specific concern prevails longer. Eur J Cancer. Jun; 2000 36(9):1089–1097. [PubMed: 10854941]
6. Barton MB, Moore S, Polk S, Shtatland E, Elmore JG, Fletcher SW. Increased patient concern after false-positive mammograms: Clinician documentation and subsequent ambulatory visits. J Gen Intern Med. Mar; 2001 16(3):150–156. [PubMed: 11318909]
7. Barton MB, Morley DS, Moore S, et al. Decreasing women's anxieties after abnormal mammograms: A controlled trial. Journal of the National Cancer Institute. 2004; 96(7):529–538. [PubMed: 15069115]
8. Brett J, Austoker J. Women who are recalled for further investigation for breast screening: Psychological consequences 3 years after recall and factors affecting re-attendance. J Public Health Med. Dec; 2001 23(4):292–300. [PubMed: 11873891]
9. Brett J, Austoker J, Ong G. Do women who undergo further investigation for breast screening suffer adverse psychological consequences? A multi-centre follow-up study comparing different breast screening result groups five months after their last breast screening appointment. J Public Health Med. Dec; 1998 20(4):396–403. [PubMed: 9923945]
10. Brett J, Bankhead C, Henderson B, Watson E, Austoker J. The psychological impact of mammographic screening. A systematic review. Psychooncology. Nov; 2005 14(11):917–938. [PubMed: 15786514]
11. Brewer NT, Salz T, Lillie SE. Systematic review: The long-term effects of false-positive mammograms. Ann Intern Med. Apr 3; 2007 146(7):502–510. [PubMed: 17404352]
12. Brodersen J, Thorsen H, Cockburn J. The adequacy of measurement of short and long-term consequences of false-positive screening mammography. J Med Screen. 2004; 11(1):39–44. [PubMed: 15006113]
13. Burman ML, Taplin SH, Herta DF, Elmore JG. Effect of false-positive mammograms on interval breast cancer screening in a health maintenance organization. Ann Intern Med. Jul 6; 1999 131(1): 1–6. [PubMed: 10391809]

14. Castells X, Molins E, Macia F. Cumulative false positive recall rate and association with participant related factors in a population based breast cancer screening programme. J Epidemiol Community Health. Apr; 2006 60(4):316–321. [PubMed: 16537348]
15. Christiansen CL, Wang F, Barton MB, et al. Predicting the cumulative risk of false-positive mammograms. J Natl Cancer Inst. Oct 18; 2000 92(20):1657–1666. [PubMed: 11036111]
16. Currence BV, Pisano ED, Earp JA, et al. Does biopsy, aspiration or six-month follow-up of a false-positive mammogram reduce future screening or have large psychosocial effects? Acad Radiol. Nov; 2003 10(11):1257–1266. [PubMed: 14626300]
17. Sickles EA. False positive rate of screening mammography. N Engl J Med. Aug 20; 1998 339(8): 561–562. author reply 563. [PubMed: 9714622]
18. Sickles EA. Successful methods to reduce false-positive mammography interpretations. Radiol Clin North Am. Jul; 2000 38(4):693–700. [PubMed: 10943271]
19. Tobias IS, Baum M. False positive findings of mammography will have psychological consequences. BMJ. May 11.1996 312(7040):1227. [PubMed: 8634581]
20. Woloshin S, Schwartz LM. The benefits and harms of mammography screening: Understanding the trade-offs. JAMA. Jan 13; 2010 303(2):164–165. [PubMed: 20068211]
21. Brodersen J, Siersma VD. Long-term psychosocial consequences of false-positive screening mammography. Ann Fam Med. Mar-Apr;2013 11(2):106–115. [PubMed: 23508596]
22. Bond M, Pavey T, Welch K, et al. Systematic review of the psychological consequences of false-positive screening mammograms. Health Technol Assess. Mar; 2013 17(13):1–170. v–vi. [PubMed: 23540978]
23. Salz T, Richman AR, Brewer NT. Meta-analyses of the effect of false-positive mammograms on generic and specific psychosocial outcomes. Psychooncology. Oct; 2010 19(10):1026–1034. [PubMed: 20882572]
24. Gold, M.; Siegel, J.; Russell, L., et al., editors. Cost-effectiveness in health and medicine. Oxford University Press; New York, New York: 1996.
25. Cole EB, Pisano ED, Kistner EO, et al. Diagnostic accuracy of digital mammography in patients with dense breasts who underwent problem-solving mammography: Effects of image processing and lesion type. Radiology. Jan; 2003 226(1):153–160. [PubMed: 12511684]
26. Hendrick, RE.; Lewin, JM.; D'Orsi, C. Non-inferiority study of ffdm in an enriched diagnostic cohort: Comparison with screen-film mammography in 625 women. In: Yaffe, M., editor. International workshopon digital mammography 2000: 5th international workshop on digital mammography. Medical Physics; Madison, WI: 2001. p. 475-481.et a
27. Lewin JM, D'Orsi CJ, Hendrick RE, et al. Clinical comparison of full-field digital mammography and screen-film mammography for detection of breast cancer. AJR Am J Roentgenol. Sep; 2002 179(3):671–677. [PubMed: 12185042]
28. Skaane P, Skjennald A. Screen-film mammography versus full-field digital mammography with soft-copy reading: Randomized trial in a population-based screening program--the oslo ii study. Radiology. Jul; 2004 232(1):197–204. [PubMed: 15155893]
29. Skaane P, Young K, Skjennald A. Population-based mammography screening: Comparison of screen-film and full-field digital mammography with soft-copy reading--oslo i study. Radiology. Dec; 2003 229(3):877–884. [PubMed: 14576447]
30. Pisano ED, Gatsonis CA, Yaffe MJ, et al. American college of radiology imaging network digital mammographic imaging screening trial: Objectives and methodology. Radiology. Aug; 2005 236(2):404–412. [PubMed: 15961755]
31. Tosteson AN, Stout NK, Fryback DG, et al. Cost-effectiveness of digital mammography breast cancer screening. Ann Intern Med. Jan 1; 2008 148(1):1–10. [PubMed: 18166758]
32. Pisano ED, Gatsonis C, Hendrick E, et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. N Engl J Med. Oct 27; 2005 353(17):1773–1783. [PubMed: 16169887]
33. Pisano ED, Hendrick RE, Yaffe MJ, et al. Diagnostic accuracy of digital versus film mammography: Exploratory analysis of selected population subgroups in dmist. Radiology. Feb; 2008 246(2):376–383. [PubMed: 18227537]

34. Spielberger, CD.; Gorsuch, RL.; Lushene, R.; Vagg, PR.; J acobs, GA. Manual for the state-trait anxiety inventory. Consulting Psyhologists Press; Palo Alto, CA: 1983.

35. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the spielberger state-trait anxiety inventory (stai). Br J Clin Psychol. Sep; 1992 31(Pt 3):301–306. [PubMed: 1393159]

36. Kind, P. The euroqol instrument: An index of health-related quality of life. In: Spilker, B., editor. Quality of life and pharmacoeconomics in clinical trials. 2nd ed. Lippincott-Raven; Philadelphia, PA: 1996.

37. Shaw JW, Johnson JA, Coons SJ. Us valuation of the eq-5d health states: Development and testing of the d1 valuation model. Med Care. Mar; 2005 43(3):203–220. [PubMed: 15725977]

38. Swan JS, Fryback DG, Lawrence WF, Sainfort F, Hagenauer ME, Heisey DM. A time-tradeoff method for cost-effectiveness models applied to radiology. Med Decis Making. Jan-Mar;2000 20(1):79–88. [PubMed: 10638540]

39. Schwartz LM, Woloshin S, Fowler FJ Jr. Welch HG. Enthusiasm for cancer screening in the united states. JAMA. Jan 7; 2004 291(1):71–78. [PubMed: 14709578]

Table 1

Participant characteristics both overall and by screening mammogram outcome.

Characteristic	Overall N=1028	Negative N=534	False Positive N=494
Age			
<50 years	424 (41)	206 (39)	218 (44)[1]
50-64 years	462(45)	260 (49)	202 (41)
65+ years	142(14)	68 (13)	74 (15)
Lifetime Breast Cancer Risk			
<5%	160 (16)	76 (14)	84 (17)
5-9.9%	501 (49)	269 (50)	232 (47)
10%+	367 (36)	189 (35)	178 (36)
Race			
White	843 (82)	444 (83)	399 (81)
Black	127 (12)	59 (11)	68 (14)
Hispanic/Latina	37 (4)	20 (4)	17 (3)
Other	21(2)	11 (2)	10 (2)
Health Rating			
Excellent	337 (33)	189 (35)	148 (30)
Very Good	444 (43)	220 (41)	224 (45)
Good	194 (19)	103 (19)	91 (18)
Fair	42 (4)	16 (3)	26 (5)
Poor	10 (1)	5 (1)	5 (1)

[1] $p<0.05$

Table 2

Mean quality of life measures and standard deviations (SD) at baseline and follow-up and mean differences between follow-up and baseline measures.

	Baseline			Follow-up			Difference			P-value
	N[1]	Mean	(SD)	N[1]	Mean	(SD)	N[1]	Mean	(SD)	
STAI Y-6										
Negative	533	33	12	531	33	12	530	0.40	11.32	0.42
False Positive*	488	35	13	487	34	13	482	−1.53	13.14	0.01*
FP Unresolved+	259	36	12	256	34	13	256	−1.52	13.60	0.10
FP Resolved	229	35	13	231	33	12	226	−1.53	12.64	0.17
EQ-5D										
Negative	531	0.90	0.13	527	0.90	0.13	524	−0.007	0.12	0.17
False Positive	494	0.90	0.13	492	0.90	0.14	492	0.001	0.13	0.13
FP Unresolved+	259	0.90	0.13	258	0.90	0.15	258	−0.004	0.13	0.66
FP Resolved	235	0.91	0.13	234	0.91	0.14	234	0.007	0.13	0.42
Rating Scale**										
Negative	533	86	13	533	85	14	532	−1.22	13.13	0.03*
False Positive	493	84	15	494	84	15	493	−0.25	14.22	0.69
FP Unresolved+	259	85	15	259	83	17	259	−1.55	15.11	0.07
FP Resolved	234	84	15	235	85	13	234	1.18	13.05	0.07

[1] Number of women contributing to mean at each timepoint.

* p-value<0.05

+ FP Unresolved means that the baseline interview was conducted before the outcome of the positive mammogram was known (i.e., women did not yet know they did not have breast cancer); FP Resolved means that the baseline interview was conducted after workup of the positive mammogram was completed (i.e., women knew they did not have cancer).

** Current health was rated on a scale from 0 (worst) to 100 (best).

Table 3

Nature of breast-related care and reported experience one-year following baseline mammogram by screening mammogram outcome.

	Negative N=534 (%)	False Positive N=494 (%)
Additional Imaging		
Any additional imaging**	24 (5)	327 (66)
Additional mammogram**	20 (4)	280 (57)
Ultrasound**	7 (1)	141 (29)
Breast MRI	3 (1)	6 (1)
Clinical Exam Visits		
Any clinical exam visit	283 (44)	273 (55)
Clinical breast exam	282 (53)	267 (54)
Surgical consult**	6 (1)	36 (7)
Other clinical exam visit	6 (1)	5 (1)
Any Biopsy **		
Biopsy or Needle Aspiration	6 (1)	72 (15)
Anxiety Level associated with additional care,+		
No anxiety/concern	138 (48)	66 (17)
A little anxiety/concern	104 (36)	128 (33)
Moderate anxiety/concern	32 (11)	107 (27)
A lot of anxiety/concern	10 (4)	74 (19)
Extreme anxiety/concern	3 (1)	18 (5)
Discomfort Level associated with additional care,+		
No Discomfort	159 (56)	102 (26)
A little discomfort	83(29)	152(39)
Moderate discomfort	33(12)	90 (23)
A lot of discomfort	8 (3)	31 (8)
Extreme discomfort	3 (1)	17 (4)

** $p<0.001$ for comparison between negative and false positive groups.

+ Note that data were obtained for these items from 287/534 (53%) women with negative mammograms and 393/494 (80%) women with a false-positive mammogram and comparisons are based on a chi-squared test of association between response categories and positivity with $p<0.001$.

Table 4

Attitudes toward future mammography use and willingness to travel to avoid a false-positive mammogram by screening mammogram outcome.

	Negative **N=534 (%)**	***False Positive*** **N=494 (%)**
Intention to Have Mammography in Next 2 years		
Yes	499 (94)	462 (94)
No	31 (6)	25 (5)
Don't know/refuse	2 (0)	5 (1)
Intention to Use Future Screening **		
Less likely	5 (1)	11 (2)
Unchanged	449 (84)	355 (72)
More likely	76 (14)	127 (26)
Choice of New Mammogram		
Fewer false positives	432 (81)	407 (82)
Less breast compression	94 (18)	77 (16)
Anxiety if Future False Positive		
No anxiety/concern	35 (7)	33 (7)
A little anxiety/concern	170 (32)	165 (33)
Moderate anxiety/concern	185 (35)	156 (32)
A lot of anxiety/concern	120 (23)	104 (21)
Extreme anxiety/concern	22 (4)	31 (6)
Willingness to Travel to Avoid False Positive		
Less than 30 minutes	87 (16)	63 (13)
Up to 4 hours	355 (67)	349 (71)
Up to overnight stay	30 (6)	30 (6)
Overnight	56 (11)	49 (10)

** <0.0001

Table 5

Correlates of greater intention to use future screening and willingness to travel and stay overnight to avoid a false-positive (FP) mammogram. Values above 1 indicate greater intention to use/willingness to travel.

	Univariate Odds Ratio (95% CI)	Multivariate Odds Ratio (95% CI)
Intention to Use Future Breast Cancer Screening		
FP screening mammogram	2.07 (1.51, 2.84)	2.12 (1.54, 2.93)
Age younger than 65	2.44 (1.39, 4.35)	2.78 (1.56, 5.00)
EQ-5D baseline (good[1] vs. perfect[2])	1.00 (0.69, 1.46)	1.04 (0.71, 1.52)
EQ-5D baseline (lower quartile[3] vs. perfect)	1.52 (1.03, 2.24)	1.63 (1.09, 2.43)
Willingness to Travel and Stay Overnight to Avoid a False-Positive Mammogram		
FP screening mammogram	0.93 (0.62, 1.40)	0.93 (0.62, 1.40)
Anticipated high anxiety[4] if future FP	1.94 (1.28, 2.94)	1.94 (1.28, 2.95)

[1] EQ-5D value below 1.0 and above 0.8271.

[2] EQ-5D value of 1.0;

[3] EQ-5D score<0.8271.

[4] Self-report of “a lot” or “extreme” anxiety/concern.