Mammography Decision Aid Reduces Decisional Conflict for Women in Their Forties Considering Screening

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Abstract

Background: Clinical guidelines recommend a personalized approach to mammography screening for women in their forties; however, methods to do so are lacking. An evidence-based mammography screening decision aid was developed as an electronic mobile application and evaluated in a before–after study.

Methods: The decision aid (Mammopad) included modules on breast cancer, mammography, risk assessment, and priority setting about screening. Women aged 40–49 years who were patients of rural primary care clinics, had no major risk factors for breast cancer, and no mammography during the previous year were invited to use the decision aid. Twenty women participated in pretesting of the decision aid and 75 additional women completed the before–after study. The primary outcome was decisional conflict measured before and after using Mammopad. Secondary outcomes included decision self-efficacy and intention to begin or continue mammography screening. Differences comparing measures before versus after use were determined using Wilcoxon signed rank tests.

Results: After using Mammopad, women reported reduced decisional conflict based on mean Decisional Conflict Scale scores overall (46.33 versus 8.33; $Z = -7.225$; $p < 0.001$) and on all subscales ($p < 0.001$). Women also reported increased mean Decision Self-Efficacy Scale scores (79.67 versus 95.73; $Z = 6.816$, $p < 0.001$). Although 19% of women changed their screening intentions, this was not statistically significant.

Conclusions: Women reported less conflict about their decisions for mammography screening, and felt more confident to make decisions after using Mammopad. This approach may help guide women through the decision making process to determine personalized screening choices that are appropriate for them.

Introduction

CLINICAL GUIDELINES RECOMMEND a personalized approach to mammography screening for women in their forties that considers potential benefits and harms and includes shared decision making.^{1,2} However, appropriate screening decisions can be difficult to make when women lack information about mammography, have uncertainty about the benefits and harms of screening, and are unable to access individualized breast cancer risk assessment resources.

For women in their forties with risk factors associated with high or moderate risks for breast cancer, screening decisions may be relatively straightforward. These risk factors include having a previous biopsy indicating breast cancer or a high-

risk lesion, such as atypical ductal hyperplasia; deleterious BRCA gene mutations or other genetic syndromes associated with breast cancer; high radiation exposure to the chest before age 30; and extensive family history of breast cancer.^{3–6} However, for women with lower degrees of risk,⁷ benefits and harms of screening are less clear, and decision making may be conflicted.^{8–10}

Decisional conflict has not been fully addressed by existing patient decision aids designed for average-risk women. Decisional conflict was not measured in a randomized controlled trial of a mammography screening decision aid for 40-year-old women, although those using the decision aid reported improved knowledge and reduced screening intentions.¹¹ A decision aid to determine whether to continue mammography

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screening for women age 75 and older improved knowledge and reduced screening intentions but had no effect on decisional conflict.¹² In addition, while both of these studies excluded breast cancer survivors as participants, neither determined individual breast cancer risks by incorporating risk assessment in the decision aid, missing opportunities for personalized decision making.^{11,12}

Decision aids are most useful when there is no clear option based on evidence and each option has benefits and harms that patients must consider when making their decisions.¹³ However, in order to be effective, decision aids and supporting resources must be accessible to users at the point in time when they are making decisions. Providing a patient-centered approach to decision making could enhance the use of decision aids. Mobile technology may offer an effective method of providing information about personal risk and aid in mammography screening decisions. Clinic and patient adoption of mobile technology is increasing, including electronic health applications for patients, use of text messaging and questionnaires linked to electronic health records.^{14–16} Consumer interest in using mobile technology for health is demonstrated by increased use of smartphones to acquire health-related information (17% to 31% from 2010 to 2012).¹⁷

To address these needs, we developed an evidence-based patient decision aid, an electronic mobile application called Mammopad, to assess breast cancer risk and help average-risk women in their forties decide when to begin mammography screening. The decision aid was evaluated in a group of women from rural primary care clinics in a before–after study that evaluated each woman’s decision-making process, as measured by decisional conflict and decision self-efficacy, and intention to begin or continue mammography screening.

Materials and Methods

Population and setting

The study population included women age 40–49 years with no known risk factors associated with high or moderate risks for breast cancer and no mammography during the previous year. Women were recruited from three member clinics in the Oregon Rural Practice-Based Research Network (ORPRN) near Salem, Oregon between February 2014 and July 2014. ORPRN research coordinators, who have offices in rural Oregon, facilitate the research studies in primary care clinics. Eligible women were identified by electronic medical chart review, contacted by mail, and followed with up to three phone calls using an internal review board–approved phone script to determine eligibility and familiarity with English. Mammopad was only available in English, and required that women be comfortable listening or reading English.

Age-eligible women who were active patients in participating clinics were then assessed for breast cancer risk based on the Breast Cancer Genetics Referral Screening Tool (B-RST).^{18–20} Risk was assessed during the recruitment call, and again, for verification, with the decision aid at the time of enrollment. Women were not eligible for the study if they reported a personal history of breast or ovarian cancer, high doses of radiation to the chest between the age of 10 and 30, a personal or family history of BRCA mutations, or extensive family history of breast and ovarian cancer as detailed in the

B-RST.^{18–20} Women who identified one or more of these risk factors were encouraged to talk with their clinical providers about an appropriate screening plan. Women who had prior breast biopsies were also excluded, because diagnostic results could not be verified. Women who reported current breast symptoms were excluded and encouraged to contact their clinical providers for follow-up.

All women who pretested the decision aid or enrolled in the study provided informed consent and were given a gift card for time and travel. The study was approved by the Oregon Health & Science University Internal Review Board. The authors have no competing financial interests.

Mammopad development

In a pilot study, we designed and implemented a mammography decision aid as a web-based application²¹ using the International Patient Decision Aids Standards.²² We conducted interviews with users and clinical experts who evaluated it for face validity, patient comprehension, and ease of use. Based on feedback, we redesigned the decision aid as a mobile application for use on an iPad Mini (second generation, 2013) with eighth-grade reading level content.

The decision aid was further refined based on feedback after four evaluation rounds involving 15 women representing the target population (3–5 women per round). During these sessions, women talked aloud as they used the decision aid and participated in semistructured interviews to determine their understanding of graphics, content, and navigation. Women were specifically asked to describe in their own words what each graphic meant to them (Fig. 1).

In the first round of interviews, the women also participated in a priority-setting activity to identify the important benefits (e.g., catching cancer early) and harms (e.g., extra tests and worry from false alarms) for deciding when to begin mammography screening. Care was taken to use plain language in describing benefits and harms and we avoided use of complex medical terms (e.g., false positive test). From this activity, we also identified the most important harms and benefits to include in the decision aid.

As a final step, the decision aid was pretested by 20 women meeting inclusion criteria for the research study.

Description of Mammopad

The purpose of the Mammopad decision aid is to help users gain deeper insights into their priorities for screening and prepare them to discuss mammography screening with their health care providers, not to direct them toward or away from screening.

The Mammopad decision aid includes a breast cancer risk assessment component with the same questions from the B-RST instrument that were used to determine eligibility for the study. The risk questions have “yes” or “no” responses with appropriate skip logic. In the study, women indicating the presence of risk factors or current breast symptoms were informed that they were not eligible for the study and provided with appropriate messages approved by the clinics. For example, women reporting current breast symptoms were encouraged to contact their providers.

The decision aid contains separate modules providing information about breast cancer and mammography and a priority setting activity (Supplementary Appendix S1;

FIG. 1. Mammography graphic from the Mammopad decision aid (sample screenshot).

Supplementary Data are available online at www.liebertpub.com/jwh). Modules are available as an audio recording in addition to the screen images. The breast cancer information module describes uncertainty about who gets breast cancer and its progression (i.e., aggressive vs. other types) and risk factors. Breast cancer risk is described through text and pictographs based on previous work.²¹ Information is also provided about disagreements among experts about screening women in their forties, and the role of shared decision making in determining whether screening is appropriate for individual women. The mammography information module describes mammography, the screening experience, and the yield of screening. In this module, users learn how many women would be expected to have normal and abnormal results, additional imaging and biopsies, and cancer diagnoses.

The priority setting module guides users through identifying the benefits and harms of screening that are most important to them. This module is based on several decision-making theories derived from descriptive analyses about how people use information to make difficult decisions.²³ The decision aid drew heavily from the decisional conflict theory,²³ which recognizes the competing gains and losses with each option. To address this underlying conflict, users set priorities among benefits (peace of mind; catching cancer early) and harms (extra tests and worry from false alarms; overdiagnosis) of breast cancer screening. In this module, users also identify their concerns about mammography and questions for their medical providers. The decision aid then provides a customized report summarizing the user's screening priorities and intentions for screening, concerns, and questions (Supplementary Appendix S2).

Clinic protocol

A research coordinator met participating women in quiet locations at the clinics with the Mammopad decision aid. After the woman completed the decision aid, a customized report was automatically emailed to the research coordinator as well as the woman if desired. Women were encouraged to share their reports at their next clinic visits, and, in collaboration with the clinics, appointments were made available to women for this purpose.

Questions and outcome measures

Before using Mammopad, women answered baseline questions about race, education level, income, health insurance, history of mammography, and prior false-positive mammography results. The main outcome measures, decisional conflict, decision self-efficacy, and intention for screening, were asked before and after using Mammopad (Supplementary Appendix S3). At the end of the session, women also answered questions about the decision aid itself.

Questions were tailored from the low literacy version of the Decisional Conflict Scale to be specific to mammography screening (e.g., "Do you know your options on when to start having mammograms on a regular basis?").^{24,25} Responses to these questions were used to determine scores for overall conflict as well as conflict subscales. This validated and reliable tool predicts that users with greater decisional conflict are more likely to delay decisions and are less knowledgeable about their decisions.^{24,25} We tested the hypothesis that women would report lower decisional conflict after using Mammopad for both the total scale and across the subscales.

Women also answered questions from the low literacy version of the Decision Self-Efficacy Scale²⁶ to measure their ability to make decisions or participate in shared decision making before and after using Mammopad. Scores relating to making decisions about when to begin screening ranged from 0 (not at all confident) to 100 (very confident).

The women also answered questions about their intention to start or continue mammography while in their forties (yes, no, unsure). At the end of the session, women evaluated how well Mammopad prepared them for shared decision making using the Preparation for Decision Making Scale.²⁷ Finally, women indicated how much new information they learned from Mammopad on a scale from 1 (lowest) to 10 (highest).

Sample size determination

Decisional conflict was the primary outcome in this study. The sample size was based on our pilot study evaluating an earlier version of the decision aid using a convenience sample of 51 women, most of whom were already engaged in mammography screening.²¹ In the pilot study, the women reported reduced decisional conflict after using the aid when

compared with baseline. Because this study enrolled women considering screening, we conservatively estimated that 75 participants would be necessary to detect differences between before and after measures.

Statistical analysis

Baseline characteristics of participants were analyzed descriptively. For the Decisional Conflict Scale and subscales, Decision Self-Efficacy Scale, and Preparation for Decision Making Scale, we calculated Cronbach- α scores to evaluate reliability. For suitably reliable scales and subscales, and for responses to the question of intent to have a mammogram before age 50, we conducted Wilcoxon ranked-sum tests to determine whether there were significant changes between initial and subsequent responses. The Bonferroni correction for multiple comparisons was applied to the significance criterion for the Decisional Conflict Scale. All statistical analyses were completed using IBM SPSS Statistics 22 (IBM Corporation). Changes in individual scores were graphed using a bee swarm plot.²⁸

Results

Of the 390 women identified in medical charts as potentially eligible for the study, 208 were ineligible, 61 declined before eligibility could be confirmed, and 10 more declined after found eligible (Fig. 2). Of the 111 remaining eligible women, 16 were not enrolled (for scheduling reasons or no internet), 20 participated as pretesters, and 75 were enrolled in the study. With the exception of a low participation rate by Latinas, the women in this study were similar to the rural areas in which they resided.²⁹ Enrolled women were slightly

older than women who declined (mean age 45.0 versus 43.9, $p=0.014$). The participants spent up to 30 minutes completing the research survey and using Mammopad.

Of the 75 enrolled women, 32% had no previous mammography and 72% intended to continue or begin mammography before age 50 (Table 1). Eighty-nine percent of women knew someone personally (family, friend, acquaintance) with breast cancer. Despite this experience, 53% of the women reported that they were not worried about getting breast cancer.

Outcomes

Comparisons of before and after decisional conflict scores indicated statistically significant reductions in overall decisional conflict ($Z=-7.225$; $p<0.001$); and in all decisional conflict subscales including feeling uncertain ($Z=-5.971$; $p<0.001$), feeling unclear about values related to screening ($Z=-6.457$; $p<0.001$), and feeling uninformed and unsupported ($Z=-7.067$; $p<0.001$) (Table 2). However, reliability was lower than expected on two subscales (feeling uninformed, Cronbach- $\alpha=0.621$; feeling unsupported, Cronbach- $\alpha=0.554$). When these two subscales were combined based on a prior factor analysis,³⁰ the resulting Cronbach- α levels were improved (total decisional conflict, Cronbach- $\alpha=0.839$; feeling uncertain, Cronbach- $\alpha=0.884$; feeling unclear about values, Cronbach- $\alpha=0.728$); and feeling uninformed and unsupported, Cronbach- $\alpha=0.720$).

Women also reported improved decision self-efficacy after using the Mammopad decision aid (79.67 vs. 95.73; $Z=6.816$, $p<0.001$). The Decision Self-Efficacy Scale demonstrated acceptable internal reliability (Cronbach- $\alpha=0.857$). Women

TABLE 1. CHARACTERISTICS OF 75 PARTICIPANTS

<i>Characteristic</i>	<i>Number (%)</i>
Race*	
American Indian or Alaska Native	2 (2.7)
Asian	3 (4.0)
Black or African American	0 (0.0)
Native Hawaiian or other Pacific Islander	1 (1.3)
White	72 (96.0)
Declined to respond	1 (1.3)
Ethnicity	
Hispanic or Latino	3 (4.0)
Not Hispanic or Latino	72 (96.0)
Education level	
Some high school	1 (1.3)
High school diploma or GED	20 (26.7)
Some college	20 (26.7)
Associate's degree or technical certificate	16 (21.3)
Bachelor's degree	14 (18.7)
Masters, PhD, or MD	4 (5.3)
Health insurance	
Uninsured	10 (13.3)
Medicare/Medicaid	17 (22.7)
Private Insurance	48 (64.0)
Intention to get mammogram or continue in 40s	
Yes	54 (72.0)
No	10 (13.3)
Unsure	11 (14.7)
Prior mammogram	
No mammogram	24 (32.0)
1–2 years	20 (26.7)
2–3 years	17 (22.7)
More than 3 years	13 (17.3)
Unsure about timing/missing	1 (1.3)
Required additional imaging (<i>n</i> =51)	
Yes	8 (15.7)
No	43 (84.3)
Breast exam with check-up	
Yes	59 (78.7)
No	16 (21.3)
How do you feel about your risk of breast cancer?	
Not worried	40 (53.3)
A little worried	15 (20.0)
Very worried	1 (1.3)
Undecided	19 (25.3)
Do you know someone with breast cancer?	
Yes	67 (89.3)
No	8 (10.7)

*Four women reported more than one race.

with the lowest initial decision self-efficacy scores demonstrated the largest increases (Fig. 3). Most women reported that they intended to have a mammogram before age 50, both before and after using Mammopad, and there was no significant change over time ($Z = 1.543$, $p = 0.123$).

Women rated how much information they learned from the Mammopad decision aid on a scale from 1 (lowest) to 10 (highest), with a median response of 7 (interquartile range of 3). The Preparation for Decision Making Scale, which ranges from 0 to 100, indicated that the women felt the decision aid prepared them to make a shared decision with clinical providers (mean 73.2, standard deviation 18.1). This scale was highly reliable in our sample (Cronbach- $\alpha = 0.904$).

Discussion

This is the first study to develop and evaluate a mammography screening decision aid that includes a validated personal risk assessment instrument to help average-risk women in their forties decide whether to screen for breast cancer. While women with above-average risk status were ineligible to use the decision aid part of Mammopad in the study, they were able to identify their risk factors and consider personalized screening alternatives with their health care providers. The dual purposes of risk assessment and decision aid have proven useful to the clinical practices participating in the study to efficiently identify women who may particularly benefit from screening. The participating clinics asked to be notified of women at increased risk so they could follow-up with appropriate screening, and are now working toward implementing Mammopad as a standard practice for all age-appropriate women.

Most patients want to be informed and involved in decisions about their medical care.³¹ The decision aid was intentionally designed to educate and to support evidence-based shared decision making about mammography screening between a woman and her primary care clinician. The results indicated that women learned new information about breast cancer screening and felt less conflicted about their screening decisions after using the decision aid. Women reported more confidence in their abilities to enter shared decision making as measured by decision self-efficacy. This was particularly true of women who reported low confidence in ability to prepare for this decision, suggesting that decision aids are particularly needed for women who are the least informed and least confident to discuss their screening options.

Implementing the Mammopad decision aid as a mobile application on an iPad mini was important for providing a user-friendly experience for both patients and study coordinators. Patients could easily hold the lightweight tablets in their laps and the touch screens were easier to use than a mouse. Despite the small tablet size, the screens were still large enough for easy reading and interaction. The size of the iPad mini made them easy for study coordinators to store and transport securely while the battery life allowed them to be

TABLE 2. CHANGES BETWEEN INITIAL AND SUBSEQUENT SCORES ON THE DECISIONAL CONFLICT SCALE AND SUBSCALES

	<i>Before mean (SD)</i>	<i>After mean (SD)</i>	<i>Change*</i>	<i>Significance*</i>
Total decision conflict	46.33 (27.04)	8.33 (15.58)	$Z = -7.225$	$p < 0.001$
Uncertainty subscale	55.00 (41.71)	15.00 (31.57)	$Z = -5.971$	$p < 0.001$
Unclear values subscale	51.33 (37.19)	6.00 (18.30)	$Z = -6.457$	$p < 0.001$
Combined uninformed and unsupported subscales	43.44 (26.75)	6.89 (12.88)	$Z = -7.067$	$p < 0.001$

*Wilcoxon ranked-sum test results.
SD, standard deviation.

FIG. 3. Decision self-efficacy difference scores. The bee swarm diagram plots the distribution of women's difference scores (before–after) as a function of their before scores. Each initial score group is represented by a different color in the diagram; groups of women with the same initial and difference scores are arranged in a horizontal array centered over the corresponding initial score value on the x-axis. Color images available online at www.liebertpub.com/jwh

used throughout a clinic day. We presume we would achieve similar benefits using other small touch screen mobile devices, but probably not with smartphones since the reduced screen size would make text and graphics harder to read.

A limitation of this study is that shared decision making was measured only through the patient's perspective. Few studies have provided direct evidence of the effectiveness of screening decision aids on the actual decision making discussion between patients and providers.³² In addition, this study included a small sample of English-speaking women, most with higher than high school education, in a single rural geographical area and should be replicated in other populations. For this region of Oregon, we recruited fewer women with only high school education and also fewer Latinas, than expected. In the future, we plan to develop a Spanish version of Mammopad. We did not record the education level of the women who declined but did note the most common reasons for declining: conflict with work and lack of transportation or childcare. Future studies would need to address these barriers in order to obtain a more representative sample. While the current study provides some evidence of improved decision making with Mammopad, future studies should also compare the use of Mammopad to other types of decision making tools in a randomized trial.

Some participating clinics scanned the women's reports from Mammopad and attached them to the medical record requiring staff time. Future studies could provide a more seamless workflow, such as providing the decision aid via a patient portal prior to an upcoming visit.³³ This approach would prepare patients and providers to discuss screening options, concerns, and values and form a shared plan when they next meet.

The strengths of this study include the use of a mobile application that provides access to many users, as demonstrated among the rural women enrolled in the study. The risk assessment instrument and decision aid information were based on current evidence of effectiveness,^{2,3,7,18–20} and are consistent with current recommendations of the United States Preventive Services Task Force for mammography screening¹ and assessment for breast cancer risk.³⁴ The development of Mammopad was extensive and rigorous and involved users and experts at several points. The study used established and

validated scales to determine outcomes. Further work is needed to evaluate the effectiveness of Mammopad on provider and patient communication, decision making, and clinical outcomes in a prospective randomized controlled trial.

Conclusions

We designed and evaluated an electronic mobile application that included an individualized breast cancer risk assessment instrument and a decision aid to guide decisions about mammography screening for average-risk women in their forties. Women reported less conflict about their decisions for mammography screening and felt more confident to make decisions after using the decision aid. The decision aid was particularly effective for women who lacked self-efficacy to make screening decisions.

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Author Disclosure Statement

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