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Women's interest in taking tamoxifen and raloxifene for breast cancer prevention: Response to a tailored decision aid

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Abstract

Although tamoxifen can prevent primary breast cancer, few women use it as a preventive measure. A second option, raloxifene, has recently been approved. The objective of the study was to determine women's interest in tamoxifen and raloxifene after reading a decision aid describing the risks and benefits of each medication. Women with 5-year risk of breast cancer 1.66 from two large health maintenance organizations were randomized to receive a decision aid versus usual care. After reading an on-line decision aid that discussed the risks and benefits of tamoxifen and raloxifene, women completed measures of risk perception, decisional conflict, behavioral intentions and actual behavior related to tamoxifen and raloxifene. 3 months following the intervention, 8.1% of participants had looked for additional information about breast cancer prevention drugs and 1.8% had talked to their doctor about tamoxifen and/or raloxifene. The majority, 54.7%, had decided to not take either drug, 0.5% had started raloxifene, and none had started tamoxifen. Participants were not particularly worried about taking tamoxifen or raloxifene and did not perceive significant benefits from taking these drugs. Over 50% did not perceive a change in their risk of getting breast cancer if they took tamoxifen or raloxifene. After reading a DA about tamoxifen and raloxifene, few women were interested in taking either breast cancer prevention drug.

Keywords

decision aids; patient education; tamoxifen; raloxifene; breast cancer prevention

Introduction

Tamoxifen has been available for the prevention of primary breast cancer for over 10 years, yet most women eligible for chemoprevention have chosen not to take it.[1-3] In 2008, only .08% of women aged 40-79 had taken tamoxifen to prevent a primary diagnosis of breast cancer.[4] This reluctance persists even after women receive educational interventions about tamoxifen's risks and benefits.[5-8] Most women perceive that the risks of tamoxifen exceed its benefits.[5, 6, 9, 10] Furthermore, many women lack confidence that taking tamoxifen will reduce their breast cancer risk.[5, 11] Finally, some women are reluctant to take tamoxifen because of negative associations raised by its traditional use to treat cancer. [12] [13]

In 2006, the results of the STAR trial (Study of Tamoxifen And Raloxifene) showed that raloxifene was equivalent to tamoxifen for reducing the risk of invasive breast cancer in post menopausal women.[12] Additionally, those who took tamoxifen had a nonstatistically significant lower risk of noninvasive breast cancer diagnosis. With the availability of this second option, it is possible that women will become more interested in chemoprevention. First, raloxifene carries a decreased incidence of some side effects (thromboembolic events, cataracts).[12] Second, women might be more willing to take raloxifene, a drug initially approved to reduce the risk of osteoporosis, than tamoxifen, a drug initially approved to treat cancer.

Yet, the availability of raloxifene might not increase interest. . Research has shown that people often have difficulty making decisions when the available choices are similar. When people are torn between multiple options, they often choose the status quo.[14] Therefore, the need to choose between raloxifene and tamoxifen may lead women to avoid the decision and continue on their present course of not using chemoprevention.

To date, we do not know of any formal decision aid (DA) studies that have assessed women's interest in chemoprevention since the STAR trial. Therefore, we conducted a randomized controlled trial of a tailored, web-based breast cancer chemoprevention DA—the *Guide to Decide*— which informed women about the risks and benefits of tamoxifen and raloxifene.

Methods

Recruitment

Participants were recruited from Henry Ford Health System (Detroit, MI) and Group Health i (Seattle, WA). After obtaining IRB approval, we used electronic medical data to determine women's preliminary 5-year risk of breast cancer and the presence of contraindications to tamoxifen or raloxifene. Eligible women received invitation letters with a description of the study, the website address, and a username and password. Interested women logged in and were screened for eligibility. To be eligible, women had to be aged 40-74 (the ages approved for chemoprevention), have a 5-year risk >1.66% (the recommended minimum risk level used in the P-1 study[15]), and be post-menopausal (raloxifene has only been studied in post-menopausal women[12]). Exclusion criteria included history of breast cancer or chemoprevention, contraindications to tamoxifen or raloxifene, participation in the STAR trial, terminal illness, or currently pregnant/nursing.

Randomization to intervention and control groups

Figure 1 shows the randomization procedure and the experience of subjects in each arm. After completing eligibility and baseline questions, participants were randomly assigned to one of three arms: Intervention, Time 1 control, or 3-month control. Participants in the

intervention group immediately received a DA, completed post-test questionnaires, and then completed a 3-month follow-up survey. Participants in the Time 1 control group completed similar questionnaires, but did not receive a copy of the DA until they completed the 3-month follow-up survey. The inclusion of this control group allowed us to examine the immediate effects of our DA. We were also interested in longer-term effects of our DA, and were concerned that questioning participants about chemoprevention might provoke Time 1 controls to seek additional information between the baseline and 3-month survey. Therefore, the 3-month control group neither received a DA nor answered any of the questions about chemoprevention at the time of enrollment, but answered chemoprevention questions at the 3-month follow up.

Description of the DA

The DA described breast cancer in general and then provided women with their 5-year risk of breast cancer tailored to each woman based on her Gail Model score[15]). Next, the DA described how chemoprevention works and the clinical trials that tested each drug.[16] Each woman then received tailored (age- and race-based) information on the impact of tamoxifen and raloxifene on the rates of the benefits (breast cancer, bone fractures) and side effects (endometrial cancer; blood clotting problems such as stroke, pulmonary embolism, deep vein thrombosis; cataracts; hormone symptoms; sexual problems). For all benefits and risks, baseline data and the change in risk were displayed. The DA was written at approximately an 8th grade reading level. Following completion of the DA, participants completed a “decision guide” which asked numerous questions about the risks and benefits of tamoxifen and raloxifene. An example pdf of the DA can be found at <http://www.cbdsr.org/files/downloads/ChemopreventionDecisionAid.pdf>.

Measures

Perceptions of benefits—Participants reported how likely they were to get breast cancer if they: 1) did not take a chemoprevention drug, 2) took tamoxifen, and 3) took raloxifene (0-10 point scale where 0=not likely at all, 10=extremely likely).

Perceptions of risks—Participants indicated on a 0=not at all to 5=extremely scale: 1) how worried they would be about getting any of the side effects 2) how common they think the side effects are), and 3) the likelihood they would experience a side effect within the next 5 years

Finally, we asked participants “How good of a choice is taking tamoxifen as a way to reduce your chance of getting breast cancer?” (1=For me it is not a good choice at all to 5=For me it is an extremely good choice).

Behavioral Intentions at Time 1

Behavioral intent was measured after receiving the DA for intervention participants and at the beginning of the survey for the Time 1 control participants (3-month control participants did not receive these questions). The 3 questions were: 1) “How likely are you to look for more information about breast cancer prevention drugs (for example, use the Internet, call the numbers listed on the website, etc.)?”, 2) “How likely are you to talk to your doctor about breast cancer prevention drugs?”, and 3) “Given what you know right now, how likely do you think you are to take a breast cancer prevention drug in the next year?” (1=not at all likely to 5=extremely likely).

Behavior at 3 months

Actual behavior was measured in all 3 groups in the 3-month follow-up survey with the following questions: 1) “In the past 3 months, have you looked for information about breast cancer prevention drugs (for example, searched the Internet, called the numbers listed in the resources section in *Guide to Decide*, etc)?”, 2) “In the past 3-months, did you talk to a doctor about taking breast cancer prevention drugs to prevent breast cancer?”, 3) “Have you made a decision about whether or not to take a breast cancer prevention drug as a way to prevent breast cancer?”. The response options for the first 2 questions were yes/no, while the response options for the final question were 1) have not made a decision whether or not to take a breast cancer prevention drug, 2) decided to not take either tamoxifen or raloxifene, 3) decided to take tamoxifen, and 4) decided to take raloxifene.

Decisional Conflict

Decisional conflict was measured using O’Connor et al.’s Decisional Conflict Scale.[17]

Personality measures

The following personality scales were administered: Numeracy,[18, 19] need for cognition (subset),[20] personal need for structure,[21] and breast cancer anxiety questions.

Analyses

We used ANOVAs to test for differences between intervention subjects and the appropriate control groups’ risk perceptions, decisional conflict, behavioral intentions, and 3-month behavior. Comparisons between the intervention group and the control groups differed by when questions were asked. Time 1 control group was the comparison group for all Time 1 measures. For analyses resulting from the 3-month follow-up survey, the 3 month control group was the comparison group.

While our ANOVA analyses used all variables as originally coded, our descriptive tables collapsed participants’ intentions to engage in chemoprevention behavior and their actual behavior into two categories: unlikely to or did not engage in chemoprevention behavior (responses: 1-3) versus likely to engage or did engage in chemoprevention behavior (responses: 4 or 5).

Bivariate correlations were used to assess the relationship between personality characteristics and each outcome variable.

Results

Participants

Of the 14,048 women who received an invitation, 2340 (17%) came to the website. Of these, 1299 (59%) were eligible and 1197 (92% of those eligible) consented to participate. Ultimately, 1039 participants (87% of those consented) completed the post-test. 712 participants returned to complete the 3-month survey (68.5% of those completing the post test). Due to a computer error, 27 control subjects received a DA at Time 1, rather than at the 3-month follow up, and thus their data were excluded in the analyses below. The DA and the post-test took an average of 49 minutes to complete (range=15-173; 78 subjects who took 3 hours were excluded from the timing analysis, but were included in all analyses described below).

Table 1 describes participants’ demographic characteristics.

Behavioral Intentions

After reading the DA, 24.4% of the intervention group indicated that they were likely to look for more information about breast cancer prevention drugs, 22.4% indicated they were likely to talk to their doctor about these drugs, and 5.7% indicated they were likely to take a chemoprevention drug. These intentions were mostly similar to participants in the Time 1 control group who were not exposed to the DA (Figure 2). Of the Time 1 control group participants, 44.4% responded they were likely to look for more information, 24.4% indicated they were likely to talk to their doctor, and 3.2% indicated they were likely to take a chemoprevention drug. With the exception of their interest in looking for more information ($F=34.86$, $p<0.001$), the Time 1 control and intervention groups did not differ significantly in their behavioral intentions ($p's>0.20$).

When asked “How good of a choice is taking a breast cancer prevention drug as a way to reduce your chance of getting breast cancer?”, only 7.3% of intervention participants and 3.1% of Time 1 control group participants indicated it was a good choice.

Actual Behavior

Three months following post test, all participants were sent a follow-up survey. In the preceding 3 months, 8.1% of intervention subjects had looked at additional information about breast cancer prevention drugs and 1.8% had talked to their doctor (Figure 3). Of the participants in the 3-month control group, 3.0% had looked for information about tamoxifen or raloxifene (which was marginally less than those in the intervention group, $F=3.17$, $p=0.076$) and no one had talked to their physician about tamoxifen or raloxifene.

With regard to deciding whether to take a breast cancer prevention drug, 44.8% of intervention participants had yet to make a decision, 54.7% had decided to not take a prevention drug, 0.5% ($N=2$) had chosen to take raloxifene, and no women had decided to take tamoxifen (Figure 4). Intervention participants differed in their decision making compared to the 3-month control subjects ($F=20.76$, $p<0.001$). More controls reported not having made a decision about beginning chemoprevention (70.0%) and none had decided to begin either drug.

Perceptions of the risks and benefits

Given that few women engaged in any behaviors related to tamoxifen/raloxifene (or had any intentions to), it is important to understand the cause of this reluctance. Women's concerns regarding the side effects of the drugs could have driven women away from taking either drug. However, as Table 2 shows, intervention subjects only expressed moderate concerns about the risks of either drug, fewer concerns, even, than for those who did not receive the DA (Time 1 control group).

In addition, participants who received the DA did not perceive significant benefits from taking these drugs, no different, in fact, than the control group ($p>0.50$). Only 44.7% of intervention participants believed that their risk of breast cancer would decrease if they took tamoxifen, whereas 51.5% perceived no change in their risk.¹ Similarly, 42.9% perceived that raloxifene would decrease their risk of breast cancer whereas 55.4% perceived that it would not. Among Time 1 control group participants, 30.8% perceived a reduction in their risk from taking tamoxifen and 30.8% perceived a reduction in their risk if they were to take raloxifene.

Decisional Conflict

Intervention participants demonstrated significantly greater decisional conflict compared to Time 1 controls overall ($F=360.44$, $p<0.001$) and for each of the subscales (F 's ranged from 169.53 to 454.14, all p 's <0.001).

Role of personality characteristics

Intervention women's pretest breast cancer related anxiety predicted their intentions to get more information about chemoprevention ($r=0.22$, $p<0.001$), to talk to their doctor ($r=0.19$, $p<0.001$), and to take either tamoxifen or raloxifene ($r=0.20$, $p<0.001$). Furthermore, it predicted whether they actually looked for more information ($r=-0.11$, $p<0.05$) and their actual decision ($r=-0.14$, $p<0.01$). Other personality measures did not predict behavioral intentions or actual behavior (all p 's $>.05$).

Pretest breast cancer anxiety, numeracy, need for cognition, personal need for structure each predicted answers to risk perception questions that focused on the probability of experiencing side effects (Table 3). Breast cancer anxiety also predicted women's beliefs about whether tamoxifen was a good choice for them ($r=.22$, $p<0.001$).

Discussion

In this randomized trial—the first test of breast cancer chemoprevention DA since the STAR trial—we discovered that women who received a tailored DA that described the risks and benefits of tamoxifen and raloxifene had very little interest in taking either drug. Immediately after reviewing the DA, only 6% of women said they were likely to take tamoxifen or raloxifene, and three months later, less than 1% had begun taking either drug.

Although previous studies have shown that women's perceptions of the risks of tamoxifen are a significant factor in their reluctance to utilize chemoprevention, [5, 6, 9, 10],^[8] our study showed only moderate concern regarding the medications' side effects. Furthermore, participants who viewed our DA had fewer concerns about the side effects than did those who did not receive the DA.

Instead, women seem to be reluctant to take chemoprevention drugs because they perceive that the drugs do not substantially lower their risk of breast cancer. Our results show that even after learning that their relative risk will decrease by 50% if they took either drug, less than half of women perceive that they will experience *any* decrease in their own breast cancer risk. Women's perceptions of the low benefit of taking tamoxifen or raloxifene may have also been influenced by the fact that for the majority of the women their 5-year risk was 3% or lower. Thus, their risk of breast cancer might have felt very low, especially compared to their risk of side effects. Additionally, women's risk of breast cancer may have felt low given that they are accustomed to hearing the average woman's lifetime risk of 13%. Compared to 13%, 3% may seem like a very small risk, particularly if one fails to notice the different time intervals (i.e., 5-year risk vs. lifetime risk). Combined, these factors may have led women to view their risk of breast cancer as so low that they do not need a preventive medication that is accompanied by significant side effects.

We should note that our goal in the design of our DA was not to convince women to take chemoprevention. Rather, we designed the *Guide to Decide* to present information in a neutral manner so that participants could decide, for themselves or with their doctors, whether chemoprevention was a good option.

Our study has several limitations. First, our sample consisted mostly of White women. Low recruitment of African American women has plagued other studies[5-7] including the

NSABP P-1 trial of tamoxifen [16] and the STAR trial.[12] A second limitation was the use of an online DA. While web-based DAs can ultimately increase intervention reach, this modality limits participation to those with Internet access. Third, our sample included only women with health care coverage. These limitations led to a relatively educated sample and a low response rate. In fact, we believe that among the primary reasons for our low response rate was lack of Internet access or lack of comfort with using the Internet (potentially reducing the participation of lower income or lower educated individuals). Other reasons for our low response rate may include lack of interest in the topic or lack of time to complete a study that was 30-60 minutes long. Thus, our findings may not be generalizable to women of other racial and ethnic groups or less educated or economically-disadvantaged women. That said, we would expect our sample to be biased in favor of women who are more likely to consider using chemoprevention, since they were an insured population with pharmacy benefits.

While the above limitations limit the external validity of our study, the inclusion of control groups significantly strengthen the internal validity. Inclusion of the Time 1 control group allows for a test of our DA compared to not receiving any information about tamoxifen and raloxifene. Furthermore, inclusion of the 3 month control group allows for an untarnished control for participants behavior over the 3 month time period.

The results of this study show clearly that many women at moderately higher risk of developing a first breast cancer nevertheless have little interest in chemoprevention, even after exposure to a tailored DA. Moreover, the inclusion of raloxifene in our DA, following completion of the STAR trial, did not lead to greater interest in chemoprevention. Adding “the bone drug,” in other words, did not lead informed women to seek out prescriptions from their physicians.

Given the robust literature that has shown that women have significant concerns regarding the use of tamoxifen[22], and numerous studies demonstrating that that they do not believe that the benefits outweigh the risks of chemoprevention,^{1,4} it appears that women will not be interested in breast cancer chemoprevention until they perceive a significant change in the risks or benefits of such drugs.

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Figure 1.
Randomization and participant experience

Figure 2.
Percent of participants intending to engage in chemoprevention behavior

Figure 3.
Percent of participants performing chemoprevention behavior (3-month follow-up)

Figure 4.
Decision about taking breast cancer prevention drugs (3-month follow-up)

Table 1

Demographic characteristics of sample

Age
Mean: 61.74 (SD = 5.30)
Range = 46-74 *
Race
White: 97.5%
Black: 0.4%
Asian: 1.7%
Hispanic: .4%
Education
High school diploma or GED: 7.3%
Some college/trade school: 26.2
Bachelor's degree or higher: 66.6%
Gail score
Mean: 2.67 (SD = 1.31)
Range: 1.7-19.1

* Age range was constrained by eligibility requirements of study.

Table 2

Perceptions of the risks involved with taking tamoxifen and raloxifene.

	Intervention Participants M (SD)	Time 1 Control Participants M (SD)	Statistical comparison between groups
How worried about getting side effect (if do not take a drug)	2.25 (0.97)	2.70 (1.54)	F = 23.76 p <0.001
How worried about getting side effect (if take tamoxifen)	3.15 (1.20)	3.87 (1.52)	F = 41.23 p <0.001
How worried about getting side effect (if take raloxifene)	2.95 (1.18)	3.92 (1.51)	F = 75.22 p <0.001
How common side effects are if take tamoxifen	3.12 (1.26)	4.67 (1.59)	F = 151.43 p <0.001
How common side effects are if take raloxifene	2.98 (1.31)	4.75 (1.58)	F = 197.28 p <0.001
How likely subject is to experience side effect if take tamoxifen	3.61 (1.31)	4.41 (1.40)	F = 52.68 p <0.001
How likely subject is to experience side effect if take raloxifene	3.39 (1.35)	4.43 (1.42)	F = 81.22 p <0.001

All questions use a response scale ranging from 1 (low endorsement) to 5 (high endorsement)

Table 3

Personality characteristics as predictors of risk perception

	Worry about side effects if do not take chemo-prevention R	Worry about side effects if take Tamoxifen R	Worry about side effects if take Raloxifene R	Likelihood of experiencing side effect if take tamoxifen R	Likelihood of experience side effect if take raloxifene R	How common is side effect if take tamoxifen R	How common is side effect if take raloxifene R
Breast cancer anxiety	.29 ***	.18 ***	.15 ***	.10 **	.08 *	.07	.07
Numeracy	-.02	.03	.01	-.12 **	-.13 ***	-.17 ***	-.16 ***
Need for cognition	.04	.05	.02	-.12 **	-.12 **	-.15 ***	.15 ***
Personal need for structure	.08	.16 ***	.11 **	.09 *	.07	.09 *	.10 **

*
P< 0.05**
P<0.01***
P .001