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Intervention

Results from a randomized trial of a web-based, tailored decision aid for women at high risk for breast cancer

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ABSTRACT

Objective: To assess the impact of Guide to Decide (GtD), a web-based, personally-tailored decision aid designed to inform women's decisions about prophylactic tamoxifen and raloxifene use.
Methods: Postmenopausal women, age 46–74, with BCRAT 5-year risk ≥1.66% and no prior history of breast cancer were randomized to one of three study arms:intervention ($n = 690$), Time 1 control ($n = 160$), or 3-month control ($n = 162$). Intervention participants viewed GtD prior to completing a post-test and 3 month follow-up assessment. Controls did not. We assessed the impact of GtD on women's decisional conflict levels and treatment decision behavior at post-test and at 3 months, respectively.
Results: Intervention participants had significantly lower decisional conflict levels at post-test ($p < 0.001$) and significantly higher odds of making a decision about whether or not to take prophylactic tamoxifen or raloxifene at 3-month follow-up ($p < 0.001$) compared to control participants.
Conclusion: GtD lowered decisional conflict and helped women at high risk of breast cancer decide whether to take prophylactic tamoxifen or raloxifene to reduce their cancer risk.
Practice implications: Web-based, tailored decision aids should be used more routinely to facilitate informed medical decisions, reduce patients' decisional conflict, and empower patients to choose the treatment strategy that best reflects their own values.

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1. Introduction

Recent evidence suggests that approximately 15% of women aged 30–84 in the United States (US), more than 11.5 million women, may be at high risk of breast cancer [1], based on the National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT) 5-year absolute risk estimate [2,3]. For women who meet the high risk threshold of BCRAT 5-year risk ≥1.66% and are between the ages 40 and 74, the American Society of Clinical Oncology and National Comprehensive Cancer Network recommend that patients consider prophylactic treatment with tamoxifen or raloxifene to reduce the risk of invasive breast cancer in the future, although the latter is only recommended for postmenopausal women [4,5]. However, the decision to use prophylactic chemoprevention can be overwhelming to women, especially since there is not a clear right or wrong decision. The best decision for each woman must take into account the balance of potential

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risks and benefits, as well as one's own values and preferences. Thus, it is considered a preference-sensitive decision [6].

Decision aids are designed to help individuals make specific and deliberate choices about their care by providing accurate, balanced information on the options and outcomes to prepare individuals for decision making [7]. Ideally, the decision aid should also help individuals clarify their own values and better inform their personal choices [8]. Decision aids have been shown to increase individuals' knowledge of their options, provide evidence-based information about a health condition and the associated uncertainties, help patients recognize the value-sensitive nature of decisions, guide patients to consider which benefits and harms are most important to them, increase individuals' comfort with their personal choice, improve patient-provider communication about options, provide guidance in the steps of decision making and communication of their values, and enable patients to be active, informed participants [7,9].

The purpose of this study was to assess the impact of Guide to Decide (GtD) a web-based, personally tailored decision aid developed to inform women at high risk of breast cancer about the risks and benefits of prophylactic tamoxifen and raloxifene use [10]. The International Patient Decision Aid Standards (IPDAS) Collaboration suggests that the primary measure for evaluating patient decision aids should be decision quality, defined as the extent to which a patient's decision is informed and based on personal values. Furthermore, IPDAS recommended the need to assess patients' recognition that a decision needs to be made, appreciation of one's goals and values, and the importance of values in the decision [11]. Subsequently, to assess these key concepts of the patient decision making process, we aimed to evaluate the impact of the Guide to Decide on decisional conflict and treatment decision behavior (primary outcomes), and the association between these outcomes with patient satisfaction with the decision aid and preparation for decision making (secondary outcomes).

We hypothesized that the odds of having made a decision about whether or not to take prophylactic tamoxifen or raloxifene, at 3-month follow-up, would be higher among women who received the GtD; additionally, that women who received the GtD would report higher levels of post-test decisional conflict, since it is likely that these women would be unaware of their increased risk of developing breast cancer or the chemopreventive options prior to receiving the GtD. Further, we hypothesized that higher decisional conflict levels would be associated with lower patient satisfaction with the decision aid, and that higher levels of preparation for decision would be associated with higher odds of having made a decision about whether prophylactic tamoxifen or raloxifene, at 3-month follow-up.

2. Methods

2.1. Study design and intervention

Information about the study design, recruitment, study population and intervention has been previously described in detail [10]. In brief, upon obtaining IRB approval from the University of Michigan and the two recruiting sites, women at high risk of breast cancer (based on the National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT) 5-year risk $\geq$1.66%) were recruited from Group Health Cooperative (Seattle, WA) and the Henry Ford Health System (Detroit, MI) between August 2007 and March 2008. All women who were identified as meeting this BCRAT 5-year risk threshold, based on automated medical records at Group Health Cooperative and Henry Ford Health System, were mailed a study invitation letter, explaining that the study aimed to educate women about breast cancer chemoprevention, test an Internet-based information tool, and understand the best way to communicate breast cancer risk to women. Further, the invitation letter directed women how to log into the study website using a unique username and password to learn more about the study, be screened for eligibility, and enroll. Women were eligible if they were age 40–74, postmenopausal, not pregnant or nursing, had a BCRAT 5-year risk $\geq$1.66%, no prior history of breast cancer or chemoprevention, no contraindications for tamoxifen or raloxifene use, no terminal illness, and did not participate in the Study of Tamoxifen and Raloxifene (STAR) trial [12]. Eligible women provided consent via an online consent form.

Upon completing the eligibility and baseline questions, eligible participants were randomized to one of three study arms: intervention (n = 690), Time 1 control (n = 160), or 3-month control (n = 162). A block-randomized design was employed, using an automated algorithm, to ensure balanced distribution of participant characteristics across the three groups. Blocking was based on data collection site (Seattle vs. Detroit), race (White vs. Non-White), age ($<$60 vs. $\geq$60), and subjective numeracy (low vs. high). Intervention participants received the personalized GtD decision aid at baseline, followed immediately by a post-test survey and then a 3-month follow-up survey. Time 1 control participants completed the same 'post-test' questionnaire at baseline as the intervention group (excluding items assessing satisfaction with the decision aid) and the 3-month follow-up survey. After completion of the last survey, they received access to their tailored GtD decision aid. Participants in the 3-month control group completed an abbreviated 'post-test' survey (personality measures only) followed by the 3-month follow-up survey and access to the decision aid. The latter control group was used to address threats to internal validity, due to our concern that participants in the Time 1 control group would search the Internet for information about tamoxifen and raloxifene after answering questions about these drugs in the post-test survey, potentially impacting their answers at the 3-month follow up. Inclusion of the 3-month control arm allowed us to have a control group truly blinded to the concept of chemoprevention and to which we could compare the intervention group at 3 months.

Following completion of the post-test intervention, women were mailed a $10 gift card to a store of their choice (i.e. Starbucks, Target, and a local grocery store). To encourage completion of the 3-month follow-up surveys, participants were randomized to receive either a $2 or $5 bill as pre-incentive, included with a reminder letter to complete the online survey. Women who failed to complete the survey within about a week were sent a series of three emails over the following week asking them to log in and complete the brief assessment.

The GtD was designed from a more practice-based framework, trying to understand risk communication. The GtD was based on previous work looking at deficiencies with decision aids in prostate cancer and attempts to address those areas that were lacking when trying to assess issues in presenting risks and benefits [13]. Within the GtD, participants received information about breast cancer (in general), their individual absolute risk of developing breast cancer (BCRAT 5-year risk score) and information on the risks and benefits of tamoxifen and raloxifene. Information on the risks of both drugs was tailored to each woman's age and race/ethnicity, while the benefits of the drugs were tailored based on the BCRAT risk score. This study assessed the Guide to Decide (GtD) version 2, which was based largely on the GtD version 1 that provided information on tamoxifen only. That decision aid had undergone focus group testing, 1-on-1 cognitive interviews, and went through a randomized controlled trial. GtD2 then added information on raloxifene, added communication factors, and pilot tested using cognitive interviews. All content was written in English at an 8th grade reading level, equivalent to that of a 13-year old in the US