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ORIGINAL ARTICLE – BREAST ONCOLOGY

A Randomized Controlled Trial Evaluating the Impact of Pre-Consultation Information on Patients' Perception of Information Conveyed and Satisfaction with the Decision-Making Process

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ABSTRACT

Background. Patient participation in treatment decision-making is a health care priority. This study hypothesized that providing a decision aid before surgical consultation would better prepare patients for decision-making. The objective was to examine the impact of a decision aid versus high-quality websites on patients' perceptions of information conveyed during surgical consultation and satisfaction with the decision process.

Methods. Patients with stages 0 to 3 breast cancer were randomized. Surveys assessed perceptions of information conveyed, being asked surgical preference, and satisfaction with the decision process. Multivariable logistic regression assessed associations between outcomes and randomization arm, patient factors, and surgeon. Change in Pseudo-R^2 assessed the comparative effect of these factors on perceptions of the information conveyed.

Results. The median patient age was 59 years. Most of the patients (98%) were white, and 62% were college educated (n = 201). The findings showed no association between randomization arm and perceptions of information conveyed, being asked surgical preference, or satisfaction with the decision process. Most of the patients reported discussing both breast-conserving therapy and mastectomy (69%) and being asked their surgical preference (65%). The surgeon seen was more important than the randomization arm or the patient factors in predicting patients' perceptions of information conveyed (explained 64-69% of the variation), and 63% of the patients were satisfied with the decision process.

Conclusion. Use of a decision aid compared with high-quality websites did not increase patients' perceptions of information conveyed or satisfaction with the decision process. Although the surgeon seen influenced aspects of the patient experience, the surgeon was not associated with satisfaction. Understanding the factors driving low satisfaction is critical because this is increasingly used as a marker of health care quality.

Patients' participation in health care decision-making is a crucial component of high-quality care. By actively participating in decision-making, patients are able to voice and align their personal preferences with available treatment options. This leads to improved satisfaction with the decision process.[1]

Patient satisfaction with treatment decision-making is important to both providers and hospitals due to an increased emphasis on the patient experience as a measure of health care quality. For example, institutional surveys query patients regarding their involvement in decision-making and consideration of their opinion in the selection of treatment options.[2] Importantly, these types of quality measures also have been linked to reimbursement.[3]

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Consequently, patient participation and satisfaction with treatment decision-making has become a priority area in health care.

Optimizing the patient experience around treatment decision-making is particularly important in breast cancer surgery because although differences in cancer outcomes between the surgical options of breast-conserving therapy (BCT) and mastectomy are minimal,[4-6] wide variation exists in patients' surgical preferences.

A key component of optimizing patients' experiences in treatment decision-making is ensuring that patients are informed of their surgical options, and provided the opportunity to engage with their surgeon in decision-making. However, prior studies have found that many breast cancer patients do not feel they have enough information to participate actively in treatment decisions.[7,8] Patients often rely on their surgeon for information, although surgeons may not present patients with all the treatment options or may not discuss all the options equally.[7] Additionally, patients report that they are infrequently asked their preference for type of surgery.[7] These observations led to a call for increased patient participation in decision-making, with the goal of enhancing patient satisfaction.[7]

Patient decision aids are one possible solution to the observed gaps in the surgical decision-making process, supporting both patients and their surgeons. These tools have been shown to increase patient knowledge and decrease decisional conflict by encouraging patients to consider the decision in the context of their values and preference.[8] We therefore hypothesized that the provision of a decision aid before the surgical consultation would better prepare patients to participate in decision-making by providing them information about the decision to be made and emphasizing that their participation in the decision is expected and important. We anticipated that this would increase the likelihood that patients would report discussing both the pros and cons of BCT and mastectomy with their surgeon, lead to increased patient participation in the decision-making process, and result in improved patient satisfaction. This study aimed to examine the impact of a web-based decision aid versus high-quality websites on patients' perceptions of information conveyed during the surgical consultation and their satisfaction with the decision-making process.

METHODS

The details of this randomized controlled trial (Clinicaltrials.gov: NCT03116035) have been described previously.[9] This report addresses secondary objectives, specifically the impact of a decision aid on patient-perceived communication with their breast cancer surgeon. The University of Wisconsin Institutional Review Board approved the study protocol, and all participants provided informed consent.

Patient Eligibility for Trial Participation

Female patients 18 years old or older who were receiving a surgical consultation for a new diagnosis of stages 0 to 3 breast cancer were eligible. Patients were enrolled from both an academic site and a community site (April 2014 to June 2016). Patients seeking a second opinion, those with their diagnosis determined by excisional biopsy, and those who had recurrent cancer were ineligible for this study because we were interested in a patient's first interaction with a surgeon. We also excluded patients lacking capacity for decision-making, those without an email address (required for administration of the intervention), and those unable to read or comprehend health information in English.

Eligible patients were invited to participate in the study via telephone, either when their diagnosis was conveyed to them or when they scheduled their surgery clinic appointment. At that time, oral consent was obtained.

Intervention

Eligible patients were randomized in a 1:1 fashion using a randomization list generated by the study statistician at the beginning of the study. Before the consultation, patients were emailed either standard, high-quality websites[10] or a decision aid. The included standard websites were those developed and supported by the following nonprofit organizations: breastcancer.org, the American Cancer Society (www.cancer.org/cancer/breastcancer/index), and the National Cancer Institute (www.cancer.gov/cancertopics/types/breast).

The decision aid was developed collaboratively by the Informed Medical Decisions Foundation and Health Dialog (Foundation for Informed Medical Decision Making and Health Dialog). This decision aid consisted of didactic information about invasive and noninvasive cancers, as well as reconstruction options. Also included were video clinical vignettes to encourage incorporation of personal values and preferences in decision-making.

Data Collection

An overview of data collection is presented in Fig. 1. The patients completed a paper survey (Survey 1-PRE-CONSULT) immediately before the surgical consultation. Follow-up surveys were sent by email after the surgical consultation (Survey 2-POST-CONSULT), and after

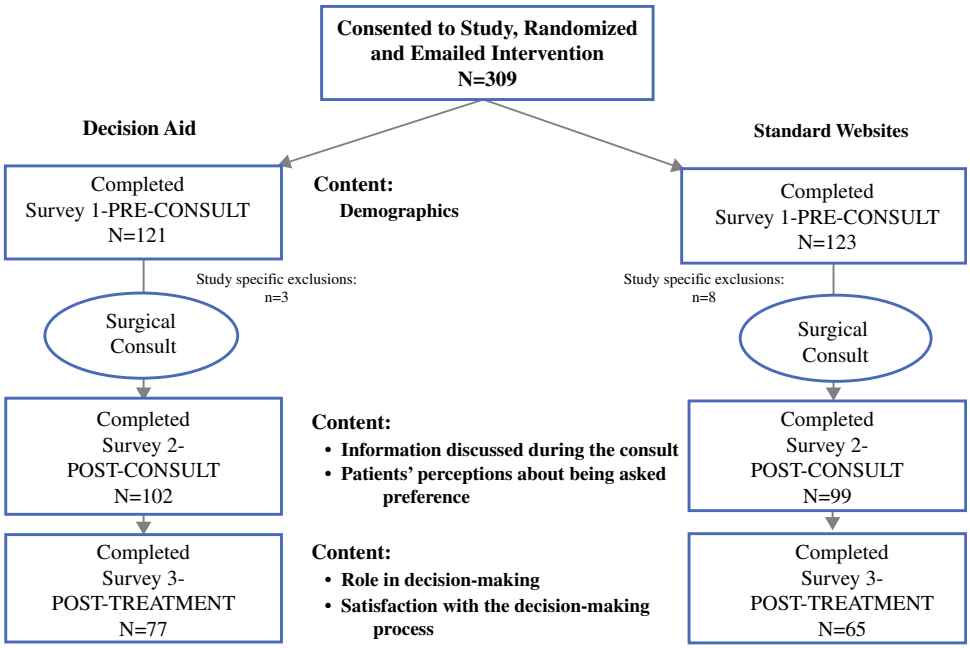

FIG. 1 Overview of study flow. Figure describes survey content relevant to this study analysis

treatment completion (Survey 3-POST-TREATMENT). The median time from initial surgical consult to completion of Survey 2-POST-CONSULT was 7 days (range, 0–367 days). The median time from the initial surgical consultation to Survey 3-POST-TREATMENT was 614 days (range, 232–1063 days).

A relatively small proportion of patients (13.4%) in the cohort underwent neoadjuvant chemotherapy. These patients showed an increase in the median time between Survey 1-PRE-CONSULT and Survey 2-POST-CONSULT (19 days; range, 0–126 vs 5.5 days; range, 0–367). This difference, although statistically significant ($p = 0.02$), was thought too small given the overall data range to result in enough bias to alter conclusions.

Chart review was performed to abstract tumor characteristics, surgery type, and ZIP code+4 for determination of the Area Deprivation Index (ADI).[11] The ADI, an existing composite measure of neighborhood socioeconomic disadvantage based on an individual patient's ZIP code+4, was used as a surrogate for socioeconomic status.[11,12]

Cohort Selection

In the overall randomized controlled trial (RCT), 377 patients were eligible for inclusion, with 309 consenting to participate and 244 completing Survey 1-PRE-CONSULT (Fig. 1).[9] The patients who did not respond to the question about education level ($n = 9$) were excluded from this secondary analysis. Additionally, two surgeons saw only one patient each. Because this precluded an assessment of surgeon-level differences, these patients ($n = 233$) were excluded from the analytic data set.

In this analysis of secondary outcomes, patients were included if they completed the Survey 2-POST-CONSULT ($n = 201$; response rate, 86%). In addition, 142 patients completed Survey 3-POST-TREATMENT (response rate, 61%).

Measures and Variables

Figure 1 presents an overview of survey content relevant to this analysis. The Survey 2-POST-CONSULT was based on the Breast Cancer Surgery Decision Quality Instrument.[13] This instrument elicited patients' perceptions of whether they were asked their preference for surgery and about information conveyed during the consultation. Questions about the information conveyed were phrased as "How much did you and your health care provider talk about. . . ." The Likert scale responses to these questions were categorized into a binary variable (a lot/some/a little vs not at all).

The Survey 3-POST-TREATMENT included the Control Preferences Scale.[14] Responses were categorized as indicating a shared role in decision-making if patients reported making the decision alone, making it with consideration of surgeon's opinion, or making a joint decision with the surgeon. The survey also included the Satisfaction With the Decision-Making Process scale.[1] The responses on this 4-question scale (range of scores, 0–4) were averaged to provide a composite score. The scores then were dichotomized, with a score of 3 or higher considered as indicating satisfaction.

The patients with stage 2 and those with stage 3 cancer were combined into one category in the analytic data set due to the low number of stage 3 patients ($n = 3$). The patients with high school and those with some college education also were combined into a single category. The patients were grouped into quartiles based on their ADI using national cut-points.[11,12]

Data Analysis

Summary statistics were generated by randomization arms. Chi squared tests compared patients' perceptions of being asked their surgical preference by randomization arm, patient factors (age, education, stage), and surgeon seen. Patients' perception of the information conveyed during the consultation was summarized by describing the proportion of patients that reported discussing specific topics. Chi square tests compared patients' perceptions of information conveyed by randomization arm.

Multivariable logistic regression was used to assess the association between patients' perception of information conveyed and randomization arm, patient factors, and surgeon. To determine the comparative effect of randomization arm, patient factors, and surgeon on patients' perception of information conveyed, the change in logistic regression Pseudo-R^2 was used.[15] The difference in the Pseudo-R^2 value for the full model and three separate models with removal of randomization arm, patient factors, and then surgeon was measured. The percentage change in Pseudo-R^2 value was calculated by dividing the difference of each separate model by the Pseudo-R^2 value for the full model.

The proportion of patients reporting an active role in decision-making and satisfaction with the decision process was summarized. The association between satisfaction with the decision process and patient factors, randomization arm, and surgeon was assessed using a multivariable logistic regression model.

RESULTS

Demographic information is presented in Table 1. Overall, the patient population was white (97–98%), educated (62% with a college education), and affluent (54–55% within the highest socioeconomic quartile). The randomization arms did not differ significantly with regard to patient demographics or clinic type.

Patient Perceptions of Being Asked Their Preference

Most of the patients (65%) reported being asked their preference for surgery type. No significant difference in terms of randomization arm or patient factors was found ($p > 0.07$). Whether the patients perceived being asked their preference varied by the surgeon seen ($p < 0.0001$) (Fig. 2).

Information Conveyed During the Consultation

The majority of patients (69%) reported hearing about both BCT and mastectomy as options for them (Fig. 3). The vast majority of the patients reported discussing BCT (94%) as well as reasons for BCT (94%). A lower proportion reported discussing mastectomy as an option for them (75%), reasons for mastectomy (83%), reasons against BCT (69%), and reasons against mastectomy (80%). No significant difference by randomization arm was found ($p > 0.21$). In the multivariable logistic regression, the surgeon seen was more important than randomization arm or patient factors in predicting patients' perception of information conveyed during the surgical consultation (Table 2).

Satisfaction with the Decision Process

Most of the patients who completed Survey 3-POST-TREATMENT (84%) reported an active role in decision-making. A lower proportion of the patients (63%) reported satisfaction with the decision-making process. In the multivariable logistic regression, a significant difference in satisfaction by education level was noted. More educated patients were more likely to report satisfaction with the decision process than those with high school or some college education (odds ratio [OR] for college graduates, 2.49; 95% confidence interval [CI] 1.06–5.85 and OR for graduate school graduates, 4.02; 95% CI 1.52–10.62; $p = 0.01$). No significant difference in satisfaction by randomization arm (OR 0.75; 95% CI 0.35–1.57), age (OR 1.02; 95% CI 0.98–1.06), or surgeon (OR range, 0.33–1.31; $p = 0.76$) was observed.

DISCUSSION

Prior studies have demonstrated that the use of a decision aid leads to improved patient–clinician communication, more active patient participation in decision-making, and increased patient satisfaction with the decision process.[8,16,17] The data support our hypothesis that receipt of a pre-consultation decision aid better prepares patients for their surgical consultation by providing information about the decision to be made and emphasizing that their participation in the decision is expected and important. However, our analysis of secondary outcomes in an RCT did not demonstrate a difference in patients'

TABLE 1 Demographics of patient cohort by randomization arm

	Standard arm (n = 99) n (%)	Decision aid (n = 102) n (%)
Median age: years (range)	58 (27–79)	61 (29–80)
Race		
White/non-Hispanic	97 (98)	99 (97)
Years of education		
High school/some college	45 (45)	31 (30)
College degree	32 (32)	39 (38)
Graduate school	22 (22)	32 (31)
Area Deprivation Index		
Quartile 1 (lowest SES)	4 (4)	1 (1)
Quartile 2	8 (8)	4 (4)
Quartile 3	27 (27)	34 (33)
Quartile 4 (highest SES)	53 (54)	56 (55)
Unknown	7 (7)	7 (7)
Stage		
0	16 (16)	20 (20)
1	53 (54)	54 (53)
2/3	30 (30)	28 (27)
Clinic type		
Community	49 (49)	38 (37)
Academic	50 (51)	64 (63)

SES socioeconomic status

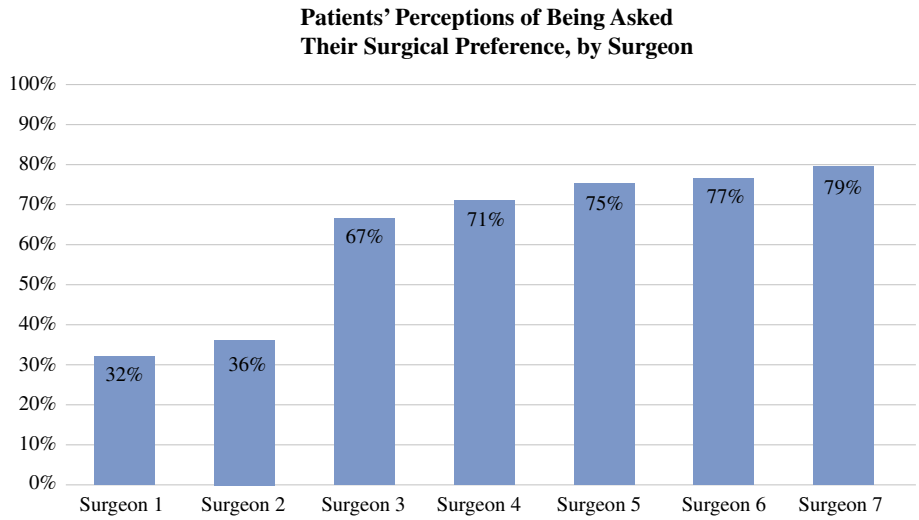

FIG. 2 Patient's perceptions of being asked their surgical preference, by surgeon

perceptions of information conveyed during the surgical consultation or satisfaction with the decision process based on whether patients received a decision aid versus high-quality websites.

A number of factors may contribute to these negative findings. One of the most noteworthy factors is that our patients reported a high level of involvement with decision-making in both randomization arms. In our study, most of the patients reported a shared role in decision-making (84%) and being asked their preference (65%). This contrasts with the findings by Lee et al.[7] in which only 48.6% of the patients reported being asked their preference. Furthermore, the patients in our study reported more balanced discussions about the surgical treatment options than was reported in the Lee et al.[7] study, with the majority of our patients discussing the reasons both for and against mastectomy and BCT.[7] The observed differences between these studies may be a reflection of our patient population, which was less diverse and more educated than in prior studies.[1,18] However, it also may reflect differences in

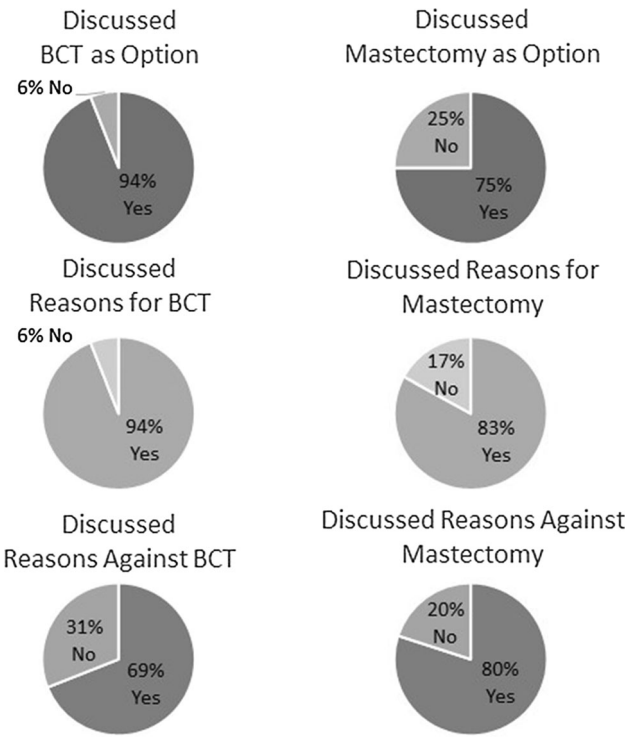

FIG. 3 Patient's perceptions of information conveyed during surgical consultation. As no differences between study arms were observed, data for overall cohort is present in the figure. *BCT* breast conserving therapy

study methodology. Our study prospectively enrolled patients and elicited information conveyed a median of 6 days after the consultation. In contrast, Lee et al.[7] conducted a cross-sectional, mailed survey of patients a median of 30.8 months (924 days) after the consultation.[7] This large interval between diagnosis and survey completion may have allowed for recall bias, with patients having stronger recollections of conversations pertaining to the type of surgery they received.

It also is important to consider that neither of our randomization arms reflected the true usual care within our breast program at the time of the study. The patients in both study arms were sent materials before the consultation, with an emphasis on the value of reviewing this information before the surgical consultation. As such, the outcomes reported by both arms of our study may be higher than what may have otherwise been seen, further contributing to our negative findings.

One noteworthy observation from our study is the important role that surgeons play in influencing the patient experience. We observed variations in patient-reported experiences by surgeon with regard to whether patients perceived that they were asked their preference for surgery type and what information was conveyed. Two prospective studies published in 2004 identified the surgeon's recommendations as one of the most significant predictors of a patient's final surgical choice.[18,19] *What* specific information is conveyed as well as *how* that information is shared likely influences patients' perceptions and ultimate decision-making. Based on these observations, future research will explore patient–surgeon communication through analysis of audio-recorded consultations.

Importantly, our findings showed that although the specific surgeon was strongly associated with aspects of the patient experience, the surgeon did not influence whether patients were satisfied with the decision process. Overall, only 63% of the patients in our study were satisfied. The relatively low satisfaction rate may reflect the complex decision process associated with breast cancer surgery, together with the emotions related to a new cancer diagnosis. This represents a critical area for additional research given the increasing importance of patient experience as a measure of health care quality.

A few limitations of our study should be considered. First, the timing of Survey 3-POST-TREATMENT may have introduced potential recall bias. Although this survey was removed in time from the surgical consultation, the survey primarily assessed patients' reported role in decision-making and their satisfaction with the decision process. The delay allowed for the stress and uncertainty of the patient's diagnosis, treatment, and prognosis to dissipate. As such, we believe that this delay was unlikely to influence reported outcomes. Second, we are aware that not

TABLE 2 Effect of randomization arm, patient factors, and surgeon on the proportion of variance in patients' perceptions of information conveyed during consultation

Information conveyed	% Change in Pseudo-R^2		
	Randomization arm (%)	Patient factors (%)	Surgeon (%)
Mastectomy as option	0.2	38.5	65.8
Reasons for mastectomy	0.3	45.5	64.9
Reasons against mastectomy	2.2	40.6	63.5
Reasons against BCT	4.0	31.1	68.9

Information discussed was categorized as binary variables (a lot/some/a little vs not at all). The percentage change in Pseudo-R^2 value was calculated by dividing the difference of each separate model by the Pseudo-R^2 value for the full model

BCT breast-conserving surgery

all patients (only about 85%) viewed the standard websites or decision aid before surgical consultation.[20] We performed an intention-to-treat analysis to minimize this possible bias. Finally, the population of patients in our breast center is largely white, educated, and more affluent. Ongoing work within our group will explore the use of decision aids in more racially and economically diverse patient populations.

CONCLUSIONS

In this study, the use of a decision aid compared with high-quality websites did not significantly increase patients' perceptions of information conveyed during the surgical consultation or their satisfaction with the decision process. Although the surgeon seen influenced aspects of the patient experience, the surgeon was not related to patient satisfaction with the decision process. Understanding the factors driving the low rates of satisfaction observed in our study represents a critical area for future research given the emphasis on patient satisfaction as a marker of quality of health care and reimbursement.

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DISCLOSURES There are no conflicts of interest.

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