

Decision Aids and Breast Cancer: Do They Influence Choice for Surgery and Knowledge of Treatment Options?

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ABSTRACT

Purpose

To describe the effect of decision aids on the choice for surgery and knowledge of surgical therapy among women with early-stage breast cancer.

Methods

A systematic review was conducted between years 1966 to 2006 of all studies designed to assess the effect of decision aids on surgical therapy. MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health (CINAHL), the Cochrane Network, HAPI databases, and bibliographies were searched. Of the 123 studies screened, 11 studies met criteria. Meta-analyses were performed to assess the pooled relative risk for surgical choice and the pooled mean difference in patient knowledge.

Results

Results from randomized controlled trials indicated that women who used a decision aid were 25% more likely to choose breast-conserving surgery over mastectomy (risk ratio, 1.25; 95% CI, 1.11 to 1.40). Decision aids significantly increased patient knowledge by 24% ($P = .024$). The data also suggested that decision aids decreased decisional conflict and increased satisfaction with the decision-making process. Decision aids were well received by surgeons and patients, facilitated patients' desire for shared decision making, and were feasible to implement into practice.

Conclusion

Decision aids are important adjuncts for counseling women with early-stage breast cancer. Their use increases the likelihood that women will choose breast-conserving surgery, and enhances patient knowledge of treatment options.

J Clin Oncol 25:1067-1073. © 2007 by American Society of Clinical Oncology

INTRODUCTION

Breast cancer is the most commonly diagnosed malignancy in women, and nearly all will face surgery as a component of their treatment. For early-stage breast cancer, multiple randomized trials have demonstrated equivalent survival between breast-conserving surgery (BCS) and mastectomy for early-stage breast cancer. In 1991, the National Cancer Institute advocated BCS as the preferred surgical treatment for early breast cancer.¹⁻⁴ However, wide variation in the receipt of BCS persists, raising concern that women with breast cancer may not adequately participate in their decision for surgery.^{5,6}

Prior research has revealed that only 50% of women with early breast cancer participate in the decision for surgery to the extent that they desire.⁷ Although the mechanisms underlying this finding are not entirely known, patients may feel ill-equipped to participate due to lack of informa-

tion, or are intimidated by the decision process when faced with a cancer diagnosis. Decision aids have been advocated to promote patient involvement in the decision-making process for treatment options by streamlining and standardizing communication between the patient and provider.⁸ These tools are designed to help patients make informed choices by detailing the outcomes of specific health care alternatives. The majority of patients use some type of informational material when making health care choices, such as educational audiotapes, videotapes, and text materials obtained from health care providers, and more 80% use health pamphlets or brochures.⁹⁻¹¹ In general, health literacy is correlated with improved patient outcomes, and patients with inadequate knowledge of their disease states are more likely to be hospitalized and have poorer disease-management capabilities.¹²⁻¹⁵ Thus, decision aids have an important role in the treatment process for women with early-stage breast cancer. However,

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Submitted August 1, 2006; accepted December 12, 2006.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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0732-183X/07/2509-1067/\$20.00

DOI: 10.1200/JCO.2006.08.5472

the extent to which decision aids influence the surgical choice and patient knowledge of treatment options is not known.

Our purpose was to perform a systematic review and meta-analysis of the published literature regarding the use of surgical decision aids among women with early-stage breast cancer. Our specific study objectives were to comprehensively review the literature regarding decision aids for the surgical treatment of early breast cancer, and estimate summary effects of decision aids on the type of breast cancer surgery chosen and patient knowledge of breast cancer treatment.

METHODS

Literature Search

To identify potentially relevant studies, we searched the MEDLINE, EMBASE, CINAHL, the Cochrane Network, and HAPI databases from January 1966 through July 1, 2006. We explored the following medical subject heading terms: patient decision making, computer assisted patient decision making; therapy, computer assisted decision support systems, decision aid, health education, patient education, patient satisfaction, patient participation, physician-patient relations, clinical trial, patient information, and medical information. We then combined these medical subject heading terms with the terms breast neoplasms, breast cancer, and surgery. We included articles published in any language, and manually reviewed the reference lists from potentially relevant papers in an effort to identify any additional studies that may have been missed with our electronic database search. The end date of the search was July 1, 2006. The search was conducted by one author (J.W.), and repeated independently by a research librarian.

In addition, we conducted an extensive search for unpublished work in this area using the same search terms. We searched abstracts from the following organizations: American Society of Clinical Oncology, the Society of Surgical Oncology, the Society for Medical Decision Making, Center for the Advancement of Health, Center for Health and Well-Being, Institute for Health Care Improvement, American College of Physicians, National Coalition on Health Care, and the RAND Corporation. This search yielded one additional study that matched our search criteria.

Study Selection Criteria

One investigator (J.W.) reviewed the titles and abstracts, where available, of all citations identified by the literature search. Potentially relevant studies were selected if the study evaluated a decision aid for stage I or II breast cancer treatment of BCS versus mastectomy.

Data Extraction

Eligible articles were reviewed in a duplicate, independent manner by three investigators (J.W., A.A., and M.R.). Consensus was obtained through discussion.

Statistical Analyses

All eligible controlled trials were used to calculate a pooled risk ratio (RR) and 95% CIs for the relation between the use of a decision aid and the choice of surgery (BCS *v* mastectomy). Inverse variance was used for weights. Both fixed and random-effects (DerSimonian-Laird) models were used and Cochran's Q test of heterogeneity was performed. The index of inconsistency (I^2) was also determined, which measures the proportion of inconsistency in individual studies that cannot be explained by random error. A sensitivity analysis was performed to evaluate potential differences in effect for randomized versus nonrandomized controlled trials.

For assessment of the impact of decision aids on patient knowledge, standardized mean differences (between decision aid and control groups) were pooled using inverse variance weighting for all randomized controlled trials. α was set at .05 (two tailed). All analyses were conducted using STATA software (STATA Corp, College Station, TX).

RESULTS

Our search yielded 116 articles and seven unpublished abstracts, of which 11 met the study criteria (Table 1). Three studies were randomized controlled trials (RCTs), two of which were conducted in Canada and one of which was conducted in the United States.¹⁶⁻¹⁸ One study in the Netherlands yielded three publications and was a nonrandomized trial with rotating concurrent controls over multiple 6-month time periods at three hospitals.¹⁹⁻²¹ Another nonrandomized trial conducted in Canada used historical controls.²⁷ The historical controls were a select group of patients (19% were excluded for various reasons) who underwent surgery for breast cancer during the 18-month period before the introduction of the decision aid. There were also four nonrandomized studies without control groups, two of which included newly diagnosed breast cancer patients and two of which used student proxies as cases or controls.²²⁻²⁵

An overview of the types of decision aids in each of the studies is listed in Table 2. Overall, the majority of the decision aids were conducted in an office setting, but few required direct physician involvement. Approximately half of the decision aids used photographs, and half of the decision aids were computer based. All of the decision aids included information regarding the risks and benefits of both mastectomy and BCS.

Final Treatment Decision

The effect of decision aids on the receipt of surgery (BCS or mastectomy) varied by the type of study design. Figure 1 illustrates the differences in proportions of women who chose BCS by study and treatment group for the trials (both randomized and nonrandomized) with concurrent controls. Overall usage of BCS was high; it was the preferred method of surgery in all three studies. Results from the RCTs (Fig 2) showed that women who used a decision aid were 25% more likely to choose BCS than mastectomy compared with women who did not use a decision aid (random-effects pooled RR, 1.25; 95% CI, 1.11 to 1.40). The effect was consistent across RCTs ($I^2 = 0\%$; Cochran's Q test $\chi^2 = 0.21$; $P = .651$). Results from the fixed-effects model were the same (RR, 1.25; 95% CI, 1.11 to 1.40).

For nonrandomized controlled trials, the random-effects pooled RR for the association between decision aids and type of surgery was 0.94 (95% CI, 0.72 to 1.23), and there was no difference in surgical choice by use of a decision aid. The study by Molenaar et al²¹ used concurrent controls and although the point estimate was above the null (RR = 1.09), the results were not significant. The study by Whelan et al²⁷ in 1999 used a selected subset of former patients as historical controls and found that the use of a decision aid resulted in a greater likelihood of mastectomy.

In multivariate analyses conducted by two studies, significant predictors of patient's surgical choice were the surgeon's recommendation and patient's concerns regarding breast loss and tumor recurrence, not receipt of a decision aid.^{16,21} Among the studies that did not use a control group, the majority of patients reported they would opt for BCS.²²

Patient Knowledge

The majority of studies included in this review analyzed the effect of decision aids on patient knowledge of treatment options. Of these, three studies used the Breast Cancer Information Test to assess patient knowledge.^{18,23,24,28} Two studies used an instrument developed by the authors to assess patient knowledge. Street et al¹⁷ assessed patient

Table 1. Studies Regarding the Use of Decision Aids Among Women With Breast Cancer Facing a Decision Between BCS and Mastectomy

Trial Type	Reference	Population	Intervention	Primary Outcomes
Randomized controlled trials	Whelan et al, 2004 ¹⁶	201 newly diagnosed stage I and II breast cancer patients	Hand-held decision board v no intervention	Final treatment decision,* patient knowledge,† decisional conflict,† satisfaction with decision making,† patient anxiety, patient depression
	Goel et al, 2001 ¹⁸	180 newly diagnosed stage I and II breast cancer patients	Audiotape workbook v a trifold pamphlet	Patient knowledge, decisional conflict, decisional regret, patient anxiety
	Street et al, 1995 ¹⁷	60 newly diagnosed stage I and II breast cancer patients	Interactive, multimedia program v brochure	Final treatment decision, patient knowledge,† patient optimism,† patient involvement in decision
Nonrandomized trials with concurrent controls	Molenaar et al, 2004 ²¹ Molenaar et al, 2001 ¹⁹ Molenaar et al, 2001 ²⁰	180 newly diagnosed stage I and II breast cancer patients	Interactive, multimedia CDROM v no intervention	Final treatment decision, decisional conflict,† patient satisfaction,† quality of life†
Nonrandomized trials with historical controls	Whelan et al, 1999 ²⁸	175 newly diagnosed stage I and II breast cancer patients	Hand-held decision board v no intervention (historical control)	Final treatment decision‡; for cases only: patient knowledge, patient satisfaction, patient and surgeon acceptance of intervention
Nonrandomized noncontrolled trials	Sawka et al, 1998 ²⁵	28 newly diagnosed stage I and II breast cancer patients	Audiotape workbook	Patient knowledge, qualitative responses to intervention, decisional conflict, satisfaction with the decision aid, patient anxiety
	Sepucha et al, 2006 ²⁶	43 newly diagnosed breast cancer patients	Video-based decision aid	Patient knowledge
Other trials using nonpatient populations	Chapman et al, 1995 ²⁴	82 students acting as advisors to a hypothetical patient	Videotape v booklet	Participant knowledge,† participant preferences†
	Vodermaier et al, 2004 ²³	35 treated breast cancer patients and 36 nursing students	Informational pamphlets and hand-held decision boards	Participant decision preference, participant satisfaction with the decision aid

Abbreviation: BCS, breast-conserving surgery.
*Statistically significant difference ($P < .05$) between treatment arms, favoring breast conserving surgery.
†Statistically significant difference between women who received a decision aid, and women who did not.
‡Statistically significant difference ($P < .05$) between treatment arms, favoring mastectomy.

knowledge of breast cancer treatment using an 11-item multiple choice test developed by the authors. Whelan et al¹⁶ used a 44-item survey regarding breast cancer, surgical therapy, and adverse events.

Five studies reported a significant increase in knowledge after use of the decision aid.^{16,17,22,24,27} Only one study found no significant difference in knowledge by receipt of a decision aid.¹⁸ Areas in which patients gained the most knowledge included understanding postoperative survival, radiation therapy, and recurrence after BCS. In addition, patients with lower baseline knowledge scores had the most pronounced increase in knowledge in several of the studies.

Three RCTs reported mean knowledge scores in both the decision aid and control groups (Fig 3). The pooled estimate for the

difference in mean knowledge scores was 0.24 in both fixed- and random-effects models (95% CI, 0.03 to 0.45), indicating that there was a significant increase in average knowledge scores by 24% in patients who received a decision aid compared with controls. Cochran's Q test for heterogeneity was not significant ($P = .571$), with $I^2 = 0\%$.

Decisional Conflict and Satisfaction

Several studies assessed the effect of decision aids on patient satisfaction and conflict with their decision for surgery, using the decisional conflict scale. This 16-item instrument is designed to determine how informed patients feel regarding their choices, the associated benefits and risks, the clarity of their values, support

Table 2. Description of Decision Aids Included in Systematic Review

Reference	Description of Decision Aids											
	Media Type				Treatment Options		Included Elements				Length (minutes)	
	Paper	Visual	Audiotape	Computer (audiovisual)	Risks	Benefits	Photographs	Reconstruction	Direct Physician Involvement?	Location		
Whelan et al ^{16,22}	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Office	21
Goel et al ^{18,25}	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Home	26
Street et al ¹⁷	No	Yes	No	Yes	Yes	Yes	No	No	No	No	Office	30-45
Molenaar et al ¹⁹⁻²¹	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Office	70
Chapman et al ²⁴	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Office	Not given
Vodermaier et al ²³	Yes	Yes	No	No	Yes	Yes	No	No	No	No	Office	Not given

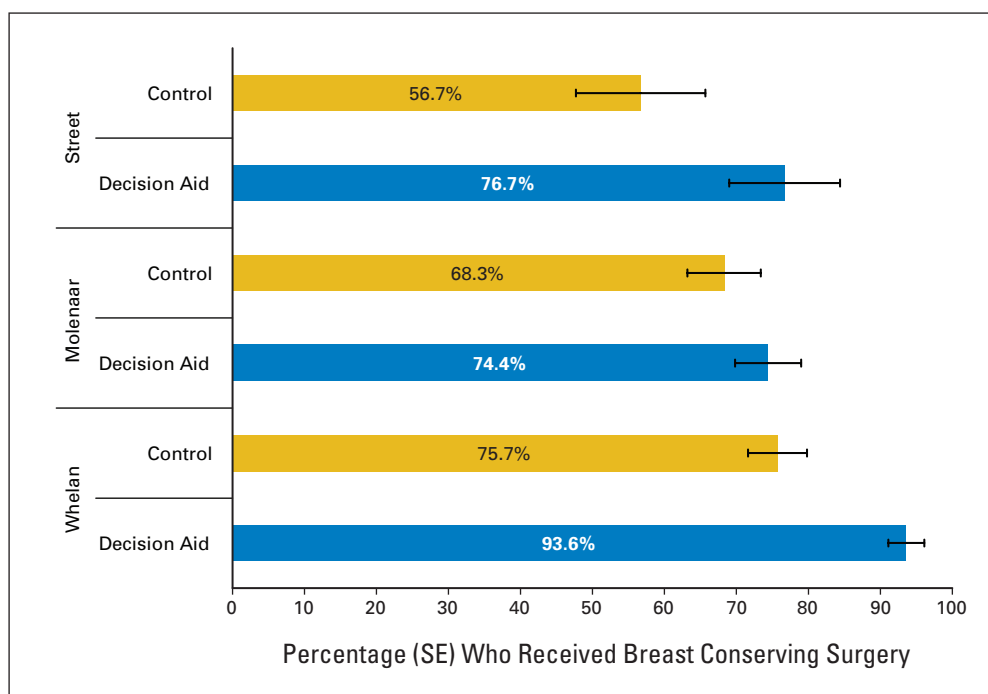


Fig 1. Proportion of women who received breast-conserving surgery by study and intervention group for all trials with concurrent controls.^{16,17,21}

during the decision-making process, and level of uncertainty.²⁶ Molenaar et al¹⁹ used an additional scale developed by the authors to assess patient satisfaction.

Overall, decision aids reduced decisional conflict and increased patients' satisfaction with their decisions.^{16,18,19,24} Women who initially preferred a mastectomy or who were unsure of their preference experienced the most pronounced decline in decisional conflict after receiving the decision aid. In addition, patients who received a decision aid were more likely to perceive they were offered a clear choice between the two options by their surgeon, and were more likely to prefer the treatment they chose.¹⁶

Convenience and Ease of Use

Decision aids were well received by patients in all studies. More than half (62%) reported that the decision aid assisted them

in communicating with their surgeon, and almost all women (98%) reported that they would recommend the decision aid for other patients going through the same experience.²⁷ Furthermore, the majority of the patients found the information to be sufficient, and few patients reported there was an inadequate amount of information.²⁰

Two studies used qualitative methodology to assess the use of a decision aid for the decision for surgery.^{22,24} Patients responded that photographs were useful aspects in the decision aid, and few women found them inappropriate or frightening. Areas of uncertainty included the use of adjuvant chemotherapy, long-term radiation effects, breast reconstruction, staging tests, breast cancer recurrence, and the timing of the surgical decision. However, only 69% of patients

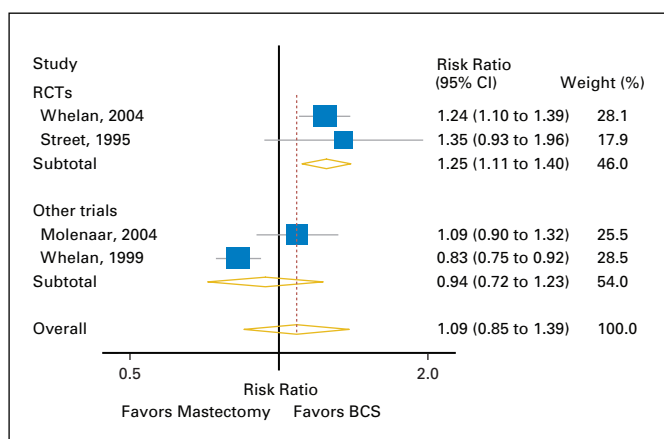


Fig 2. The effect of decision aids on the decision for breast-conserving (BCS; compared with mastectomy) among women with stage I or II breast cancer. RCT, randomized controlled trial.^{16,17,21,27}

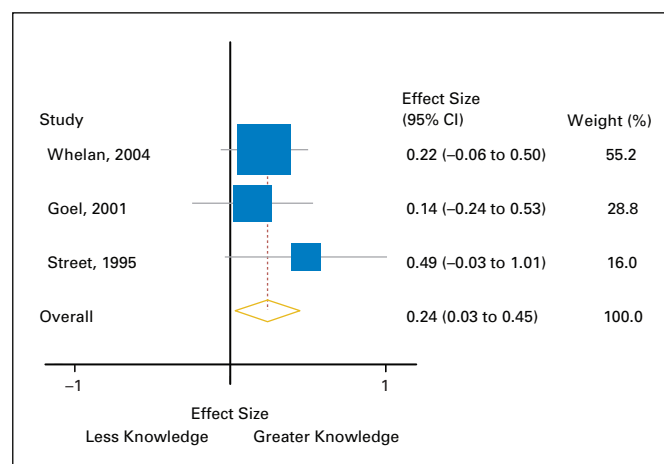


Fig 3. The effect of decision aids on patient knowledge (standardized difference in mean knowledge scores) among women with stage I or II breast cancer.¹⁶⁻¹⁸

reported they had gained all of the information necessary to participate in the therapy decision.

Surgeon Perspectives

Of the two studies that reported surgeon comments after use of decision aids, all found that decision aids were well received by physicians in practice.^{20,27} The majority of surgeons reported that the decision aid facilitated communication between the patient and surgeon, and that pictorial information was an important component of these tools. Nearly all surgeons reported decision aids are feasible to implement in practice. However, involvement of ancillary staff and requirement of additional space to view the decision aid were viewed as potential barriers to use in practice.

Quality of Life

Several studies retrieved assessed the effect of decision aids on quality-of-life outcomes. Molenaar et al¹⁹ reported that women who used the decision aid had improved general health and physical functioning, and reduced pain, as measured by the with the Medical Outcomes Study 20 scale and the European Organization for Research and Treatment of Cancer Quality of Life scale.^{30,31} Finally, the use of decision aids did not increase either anxiety or depression among patients who used these tools in three of the studies.^{16,18,24,32,33}

DISCUSSION

In this review, women with early-stage breast cancer who received counseling with a decision aid were 20% more likely to receive BCS compared with women who did not receive counseling with a decision aid. Decision aids significantly improved patient knowledge regarding treatment options, and increased patient satisfaction with the decision-making process. Finally, decision aids were well received by both surgeons and patients across all studies.

In addition to surgery for breast cancer, decision aids have been studied for other types of health decisions. In a recent review by O'Connor et al, decision aids were most helpful for patients who were uncertain regarding their preferences for treatment.^{34,35} Consistent with our findings, decision aids increased patient knowledge of treatment options and provided patients with more realistic expectations of outcomes. Decision aids have also been studied among men diagnosed with prostate cancer. These patients reported improved discussion with physicians regarding treatment options and increased knowledge of possible adverse effects of treatment after use of a decision aid.³⁶ Finally, decision aids have been evaluated across other aspects breast cancer treatment, including the decision for radiation therapy and adjuvant chemotherapy, and the decision for surgical therapy for women with genetic predispositions to breast cancer.³⁷⁻³⁹ In these settings, decision aids were acceptable to patients, effectively elicited treatment preferences, increased patient knowledge regarding treatment options, and facilitated shared decision making between the patient and provider.

As a systematic review and meta-analysis, this study is limited by the variation in the types of decision aids used in the published reports. Although all the decision aids included information regarding the risks and benefits of both mastectomy and BCS, they varied in the type and format of delivery, and the amount of physician involvement required. Regardless of the

variation in the types of decision aids, our results demonstrate a consistent effect of decision aids on the choice of surgical procedure and patient knowledge of treatment options. Our review is also subject to publishing bias, although we attempted to identify unpublished data by review of abstracts from multiple sources. Finally, a notable limitation is the paucity of studies conducted in women from the United States on this topic. Given that the decision-making process often has socioeconomic and cultural underpinnings, it is unknown whether these results are generalizable to all racial, ethnic, and socioeconomic groups of women in the United States.

Despite these limitations, our study reveals that decision aids may increase patients' ability to make informed choices for surgery and potentially can improve the quality of care for breast cancer patients. For example, decision aids can be integrated into the informed consent process to document patient knowledge of surgical treatment. These tools may reassure surgeons that their patients are adequately informed and can highlight areas of patient uncertainty regarding surgery. Decision aids also allow women to participate more effectively in the decision for surgery by increasing their knowledge of treatment options. Women who participate in the decision for surgery at the level they desire are more likely to report that are adequately informed, and are more satisfied with treatment outcomes and the decision process.^{7,40}

Decision aids are already being incorporated into health care policy for breast cancer. For example, some states have proposed legislation requiring physicians to provide patients with decision aids during consultation. Such efforts can increase awareness of disparities in breast cancer treatment, and provide an opportunity to develop a standardized decision tool for patients with breast cancer. However, legislation alone is unlikely to change surgeon practices. For example, BCS rates increased transiently after the passage of state laws requiring physicians to disclose all surgical options for women with breast cancer. Within a year, however, BCS rates had returned to previous levels.⁴¹ Similarly, rates of breast reconstruction after mastectomy did not change after the 1999 Women's Health and Cancer Rights Act, which mandated the coverage of breast reconstruction after mastectomy for breast cancer by insurers.⁴² In addition to legislation, future research is needed to identify the optimal strategy to assimilate decision aids into standard practice.

Additional study of decision aids will inform efforts to improve the quality of care for breast cancer patients. Little is known regarding the quality of information contained in decision aids for breast cancer, and the accuracy of these tools may be highly variable. A recent study of decision aids for prostate cancer treatment revealed more than 90% of informational tools do not describe all standard treatments, only 30% include the risks and benefits of each treatment, and most do not contain enough information to meet the requirements of informed consent.⁴³ In addition, the inclusion and presentation of specific elements may influence patients' preference for treatments. For example, patients may have difficulty understanding probabilistic outcomes such as survival and local recurrence.⁴⁴ Women's perceptions of risk are highly variable, and often influenced by the display format of information.⁴⁵⁻⁴⁸ Identifying aspects of decision aids that are most salient to women facing a decision for surgery will

improve the quality of these tools, and facilitate their implementation into routine practice.

As treatment decisions increase in complexity due to the advent of new technologies and treatment options, such as neoadjuvant chemotherapy, the ability to inform and educate our patients properly becomes paramount. Decision aids will continue to be an important adjunct for counseling women with breast cancer, and can improve the quality of health care delivered to these patients.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The authors indicated no potential conflicts of interest.

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Decision Aids and Breast Cancer Surgery

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