Helping Patients Make Informed Choices: A Randomized Trial of a Decision Aid for Adjuvant Chemotherapy in Lymph Node-Negative Breast Cancer


Background: In recent years, patients have indicated a desire for more information about their disease and to be involved in making decisions about their care. We developed an aid called the “Decision Board” to help clinicians inform patients with lymph node-negative breast cancer of the risks and benefits of adjuvant chemotherapy. We determined whether adding the Decision Board to the medical consultation improved patient knowledge and satisfaction compared with the medical consultation alone. Methods: Between October 1995 and March 2000, 176 women with lymph node-negative breast cancer who were candidates for adjuvant chemotherapy were randomly assigned to receive the Decision Board plus the medical consultation (83 patients) or the medical consultation alone (93 patients). One week after the consultation, patients completed a questionnaire assessing their knowledge about breast cancer and chemotherapy. Satisfaction with decision making was assessed 1 week and 3, 6, and 12 months after randomization, and differences between groups were analyzed by a repeated measures analysis of variance. All statistical tests were two-sided. Results: Patients in the Decision Board arm were better informed about breast cancer and adjuvant chemotherapy than patients in the control arm (mean knowledge score = 80.2 [on a scale of 0–100], 95% confidence interval [CI] = 77.1 to 83.3, and 71.7, 95% CI = 69.0 to 74.4, respectively; P < .001). Over the entire study period, satisfaction with decision making was higher for patients in the Decision Board arm than for patients in the control arm (P = .032). There was no statistically significant difference between the two groups in the number of patients who chose adjuvant chemotherapy (77% and 70% for patients in the Decision Board arm and those in the control arm, respectively; P = .303). Conclusion: When making decisions regarding adjuvant chemotherapy, patients with early breast cancer who had been exposed to the Decision Board had better knowledge of the disease and treatment options and greater satisfaction with their decision making than those who received the standard consultation. [J Natl Cancer Inst 2003;95:581–7]
Based on the early results, a number of Decision Boards have been developed for patients considering difficult treatment decisions in a variety of clinical situations (12–16). A nonrandomized cohort study of breast cancer patients considering radiation therapy after lumpectomy found that the Decision Board increased patient comprehension and facilitated shared decision making between physician and patient (12). Thus, we were encouraged to evaluate the Decision Board in a randomized controlled trial. The purpose of the present study was to determine whether the addition of the Decision Board to the medical consultation improved patient knowledge and satisfaction with decision making compared with the medical consultation alone for women with lymph node-negative breast cancer considering adjuvant chemotherapy.

**PATIENTS AND METHODS**

**Patient Population**

Women with histologically confirmed axillary node-negative breast cancer who had undergone primary surgery (modified radical mastectomy or lumpectomy plus axillary dissection) and who were attending their first consultation with a medical oncologist regarding adjuvant systemic therapy were eligible for the study. Patients were excluded from the study for the following reasons: not a candidate for chemotherapy on the basis of current clinical practice guidelines or because of older age (>65 years) and serious comorbidity (e.g., cardiovascular or renal disease); inability to speak or read English fluently; mental incompetence that would preclude taking part in the process of shared decision making; a previous diagnosis of breast cancer; or a previous consultation regarding adjuvant systemic therapy for breast cancer.

Women were recruited to the study from October 1995 through March 2000. At the start of the study, local clinical guidelines recommended chemotherapy for lymph node-negative women with estrogen receptor (ER)-negative tumors. Chemotherapy was not recommended for patients with tumors less than 1 cm in diameter or ER-positive tumors, for which tamoxifen alone was usually offered (17). During the course of the study, the results of the National Surgical Adjuvant Breast and Bowel Project-B20 trial were published, indicating a benefit of adjuvant chemotherapy for lymph node-negative women with ER-positive breast cancer who also received tamoxifen (18). On the basis of these data, local clinical guidelines were updated to include offering such patients chemotherapy in addition to tamoxifen. Consequently, patients with ER-positive tumors became eligible for the study in July 1998.

Written informed consent was obtained from all eligible patients before they were assigned to the intervention or control group. The institutional review boards of each participating center approved the study protocol. Participating centers were the Cancer Care Ontario Regional Cancer Centres in the cities of Hamilton, Toronto, Windsor, and Thunder Bay; the Credit Valley Hospital, Mississauga, Ontario; and the Marin General Hospital, Marin County, California.

**Intervention**

The Decision Board (Fig. 1) is a visual aid that presents written and graphical information from clinical trials to patients regarding their treatment options. It contains detailed information tailored to the individual on a patient’s treatment choices (chemotherapy or no chemotherapy); outcomes (recurrence or not); probability of outcomes and their meaning; and quality of life associated with treatment choice and outcome. The instrument (Fig. 1) is approximately 24 inches by 18 inches and is divided into three sections, each with a subtitle: Treatment Choice, Chance of Outcome, or Outcome. The treatment choices and outcomes are described by detailed information cards, and the probabilities of recurrence are described by color-coded probability wheels. Probabilities for recurrence with or without chemotherapy are tailored to the patient’s risk on the basis of tumor size and histologic tumor grade. The Decision Board is presented to the patient by a physician or nurse in a step-by-step fashion. Initially, the instrument is empty. The patient and health professional read each information card and then attach it to the board. At the end of the discussion, all the information cards have been attached to the board. The patient is encouraged to ask

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**Fig. 1.** Schematic depiction of the Decision Board. The information cards associated with each section of the Board are not shown. Treatment details and potential toxicities of the treatment or short-term potential reduction in quality of life (e.g., hair loss, stomach upset, emotions) are described using probabilistic language in the chemotherapy information card. The potential long-term benefits of treatment are captured by both the description and explanation of the meaning of the reduction in the probability of recurrence with the probability wheels and a detailed description of the “cancer comes back” event with that information card. The increased chance of remaining “cancer free” with treatment is also described with the probability wheels and that information card to avoid a framing bias. The probabilities shown are examples.
questions during and after the presentation. Further details on the design, development, and preliminary evaluation of the Decision Board are described elsewhere (10).

The original Decision Board presented a patient with an estimate of her risk of cancer recurrence at 5 years, with or without chemotherapy (10). Risk groups for recurrence were categorized on the basis of the prognostic factors of tumor size and histologic grade (19) identified in the Ontario Clinical Oncology Group (OCOG) trial, which evaluated the role of breast irradiation in lymph node-negative breast cancer (20). Before the current study began, the OCOG trial dataset was reviewed and updated to a median follow-up of 7 years (21). The analysis confirmed the two original prognostic factors (i.e., tumor size and histologic grade), and four risk groups were identified: low-risk, less than 1 cm in size; moderate-risk, 1–2 cm in size and grade I or II; high-risk, more than 2 cm in size or grade III; and very-high-risk, more than 2 cm in size and grade III. The low-risk group was not eligible for this study because these women were not candidates for chemotherapy. The actuarial estimates of the cumulative risk of recurrence at 7 years without chemotherapy for the three remaining risk groups in the study were rounded off to 25% for the moderate-risk group, 35% for the high-risk group, and 50% for the very-high-risk group. Using an estimate of a 30% relative reduction in risk of recurrence due to polychemotherapy based on the Early Breast Cancer Trialist’s Collaborative Group overview (22), we calculated the 7-year cumulative risk of recurrence for each group by applying this risk reduction as a hazard rate reduction under the assumption of proportional hazards and rounding the estimates to the nearest five percent.

When patients with ER-positive tumors became eligible for the current study, the Decision Board was modified to include a version for these patients. This modified version included an introductory card that presented information regarding baseline risk of recurrence and decreased risk of recurrence achieved with tamoxifen. The instrument then described the additional potential benefits and risks associated with chemotherapy in a manner similar to that of the instrument for patients with ER-negative breast cancer.

**Study Design**

Following a history and physical examination, patients were declared eligible for the study and were invited to participate in the trial. Consenting patients were randomly assigned to receive the medical consultation alone, i.e., presentation and discussion of information on treatment alternatives, or the medical consultation plus the Decision Board. Patients were stratified by medical oncologist/primary care nurse team before randomization, which was performed at a central location. Of the 22 oncologists who participated in the study, eight were female and 14 were male (median oncologist age = 50 years, range = 40–67 years).

For patients assigned to the experimental arm after randomization, the medical oncologist introduced the patient to the two treatment options, i.e., adjuvant chemotherapy or no chemotherapy, and explained to the patient that information regarding the choices was to be presented by a research nurse who would use the Decision Board. After the Board had been presented, the medical oncologist returned to answer any further questions the patient may have had. The patient was given a take-home version of the Board and a pamphlet describing lymph node-negative breast cancer and treatment options routinely given to newly diagnosed patients. The patient was asked to return the following week to see the medical oncologist, who would then answer any further questions regarding the previous consultation or information received and to make a decision regarding treatment.

For patients assigned to the control arm after randomization, the medical oncologist met with the patient to discuss treatment options, i.e., adjuvant chemotherapy or no chemotherapy, in his or her usual fashion. After this discussion, the primary care nurse met with the patient to address any concerns or information needs. This procedure was consistent with usual practice and also served as a mechanism to avoid any attention effect associated with administration of the Decision Board to patients in the experimental arm. After the meeting with the primary care nurse, the patient received the same lymph node-negative breast cancer pamphlet that was given to patients in the experimental arm. The patient was asked to return the following week (1-week visit) to see the medical oncologist, who would then answer any further questions regarding the consultation or material received and to make a decision regarding treatment.

**Outcome Measures**

The primary outcome measures for this study were patient knowledge and satisfaction with decision making. Patient knowledge was assessed using a 25-item questionnaire that covered various content areas regarding lymph node-negative breast cancer, e.g., the natural history of breast cancer, the risk of cancer recurrence and its meaning, what chemotherapy is and how it is given, and the benefits and risks associated with chemotherapy. Each item on the questionnaire consisted of a statement followed by a true/false/unsure response. The instrument was scored as the percentage of correct responses from 0–100. We had used such an approach in the past and had shown it to be valid (12,16). We also asked patients to identify their risk of recurrence with and without chemotherapy on two linear analog scales that ranged from 0% to 100%. A response was considered correct if it was within 10% (plus or minus) of that predicted for the patient on the basis of tumor size and grade.

Patient satisfaction with decision making was assessed using the effective decision-making subscale of the Decision Conflict Inventory (23). The subscale consists of four items regarding satisfaction with decision making (being informed, reflective of patients’ values, likelihood to comply, and satisfied) followed by a 5-point Likert scale from “1 = Strongly Agree” to “5 = Strongly Disagree”). A mean score was obtained for each patient.

Secondary outcomes included the level of patient anxiety, preference for role in decision making, processes of decision making, the treatment chosen, physician satisfaction with decision making, and the length of the medical consultation. Anxiety was assessed by the Spielberger State Anxiety Inventory (24), which consists of 20 items—each with a 4-point Likert response. The inventory yielded total scores ranging from 20 to 80. Patient preference for role in decision making was assessed using a scale modeled on an instrument developed by Degner et al. (6). Patients were asked to indicate whether they preferred an independent role (i.e., “to make the final decision about which treatment I receive alone or after seriously considering my doctor’s opinion”), a shared role (i.e., “that my doctor and I share the responsibility for deciding which treatment is best for me”), or a dependent role (i.e., “that my doctor makes the final decision about which treatment will be used alone or seriously considers my
opinion”). Patients were also asked whether they were offered a choice of receiving chemotherapy or not and whether their doctor made a recommendation regarding treatment. Physician satisfaction with decision making was assessed by using a modification of the scale used for patients.

Follow-Up

Before the initial consultation, information was collected by a research assistant on each patient’s demographic characteristics, level of anxiety, and preference for decision making. At the 1-week visit, after meeting with the medical oncologist, patients expressed their treatment decision, and information was collected regarding their knowledge of breast cancer and adjuvant chemotherapy, their risk of cancer recurrence with and without chemotherapy, and their preference for decision making. Patient information was also collected at 1 week and at 3, 6, and 12 months post-consultation regarding their satisfaction with decision making and anxiety level.

Medical oncologists completed a self-report immediately after the initial consultation with the patient regarding their satisfaction with the decision-making process. The duration of the patient consultation with the medical oncologist and nurse was determined on the first visit and at the 1-week visit as a measure of resource utilization.

Statistical Analysis

The trial was designed to enroll approximately 85 patients per group to have the power to detect an effect size of 0.5 in patient satisfaction with a type 1 error of 0.05 and a type 2 error of 0.10. Among the two groups, patient comprehension at the 1-week visit was compared using the Student’s t test. The proportion of patients who correctly identified their risk of recurrence and other proportions were compared using the chi-square test. Scores for patient satisfaction with decision making were reversed, so that the highest level of satisfaction would be reflected in the highest score (i.e., a reversed Likert scale in which 5 is the highest score). Satisfaction and anxiety scores were compared by repeated measures analysis of variance (SAS, version 8.2; SAS Institute, Cary, NC). All statistical tests were two-sided.

RESULTS

Patient Population

One hundred seventy-six women were recruited to this study and randomly assigned to the medical consultation plus the Decision Board arm (83 women) or to the medical consultation alone arm (93 women). One patient who was randomly assigned to the Decision Board arm was subsequently determined by her physician not to be a candidate for chemotherapy and was excluded from the analysis. The analysis, therefore, includes only 175 patients. Age, marital status, educational level, employment status, preference for role in decision making at baseline, anxiety level at baseline, and tumor characteristics were similar between the two treatment groups (Table 1).

Primary Outcome Measures—Patient Knowledge and Satisfaction

At 1 week post-consultation, patients in the Decision Board arm had a mean knowledge score of 80.2 (95% CI = 77.1 to 83.3), whereas patients in the control arm had a mean score of 77.1 to 80.4 (95% CI = 74.4 to 84.1) (P = .056). Patients in the Decision Board arm were also more likely than patients in the control arm to correctly identify their individual risk of recurrence without chemotherapy (Decision Board arm, 49 of 82 [60%] versus control arm, 31 of 92 [34%]; P < .001) or with chemotherapy (Decision Board arm, 44 of 82 [54%] versus control arm, 36 of 92 [39%]; P = .056).

Patient satisfaction with decision making 1 week and 3, 6, and 12 months post-randomization is presented in Fig. 2. Patients in the Decision Board arm had statistically significantly higher mean scores than controls over the study period (P = .032).

Secondary Outcome Measures

Patient anxiety was high at the time of the consultation, as shown in Table 1, and remained high 1 week later (mean score for patients in Decision Board arm = 45.6, 95% CI = 42.7 to 48.5, and for patients in the control arm = 47.4, 95% CI = 44.6 to 50.2). Patient anxiety relative to these levels appeared to decrease at 3, 6, and 12 months for patients in the Decision Board arm (mean scores = 36.0, 38.2, and 39.2, respectively) and for patients in the control arm (mean scores = 37.8, 38.2, and 40.2, respectively). No statistically significant difference was observed between the groups (P = .78).

Before the consultation, 66 of 80 (83%) patients in the Decision Board arm and 77 of 91 (85%) patients in the control arm preferred an independent or shared role in decision making. At 1 week after the consultation, 74 of 80 (93%) patients in the Decision Board arm and 79 of 91 (87%) patients in the control

| Table 1. Characteristics of patients enrolled in the randomized trial of a decision aid |
|-----------------------------------------------|---------------|---------------|
| Characteristics                                      | Decision Board | Control        |
| No. of patients with preference for role in decision making (%)† | 21 (26)       | 30 (32)       |
| No. of patients with grade 3 tumors*                | 37 (45)       | 38 (41)       |
| No. of patients with tumors >2 cm                   | 42 (51)       | 45 (50)       |
| No. employed full-time or part-time (%)              | 43 (52)       | 47 (51)       |
| No. of patients who correctly identified their risk of cancer recurrence (%) | 45 (56)       | 47 (52)       |
| Mean age, y                                         | 51.0          | 51.8          |
| No. married (%)                                     | 64 (78)       | 66 (71)       |
| No. with post-secondary education (%)                | 38 (46)       | 43 (47)       |
| No. with grade 3 tumors†                             | 43.4 (40.5 to 46.3) |
| Mean patient anxiety score (95% CI)‡                | 46.6 (44.0 to 49.2) |

* Tumor grade was determined as per Bloom and Richardson (19).
† Patient preference for a role in decision making was assessed using a scale modeled on an instrument developed by Degner et al. (6). An independent role was defined as one in which the patient makes the final decision about which treatment to receive alone or after seriously considering the physician’s opinion; a shared role was defined as one in which the patient and the physician share the responsibility of deciding which treatment is best for the patient; a dependent role was defined as one in which the physician makes the final decision about which treatment the patient will receive or does so after seriously considering the patient’s opinion.
‡ Patient anxiety was assessed by the Spielberger State Anxiety Inventory (24). Scores can range from 20 to 80. CI = confidence interval.
arm preferred an independent or shared role in decision making. The increase in the number of patients who preferred a more active role in decision making was more evident for those in the Decision Board arm (8 of 80 [10%]) than for those in the control arm (2 of 91 [2%], \( P = .033 \)).

Most patients, 79 of 82 (96%) patients in the Decision Board arm and 85 of 92 (92%) patients in the control arm, perceived that they were offered a choice about treatment. The difference between groups was not statistically significant (\( P = .34 \)). Fewer patients in the Decision Board arm (40 of 82 [49%]) than patients in the control arm (56 of 89 [62%]) \( P = .063 \) received a formal recommendation from their doctor about which treatment to choose. More patients in the Decision Board arm (63 of 82 [77%]) chose chemotherapy than did those in the control arm (65 of 93 [70%]), but the difference between groups was not statistically significant (\( P = .303 \)).

Physician satisfaction with decision making was similar between groups; mean satisfaction was 4.37 (95% CI = 4.16 to 4.58) for those in the Decision Board arm and 4.35 (95% CI = 4.19 to 4.51) for the control arm \( P = .89 \). Mean time for consultation (i.e., time spent by medical oncologist and nurse) was assessed for 50 patients in the Decision Board arm and 55 patients in the control arm. The duration of the initial consultation (47.5 minutes versus 39.9 minutes; \( P = .26 \)), of the second visit at 1 week (20.8 minutes versus 25.8 minutes; \( P = .52 \)), and total duration (time for initial consultation plus that for the second visit) (68.3 minutes versus 65.7 minutes; \( P = .53 \)) did not differ statistically significantly between groups.

**Discussion**

The Decision Board was developed to improve information transfer between the physician and patient to support patients in the decision-making process during the medical consultation. Here, we evaluated two relevant outcomes—patient knowledge and satisfaction with decision making—in a randomized trial involving the Decision Board. Our results demonstrate that the patients in the Decision Board arm had improved knowledge about breast cancer and chemotherapy and increased understanding about individual risk of cancer recurrence with or without chemotherapy compared with patients in the control arm. Previous interventions have had variable results on informing patients about risk (25).

Patient satisfaction with decision making was also improved for those in the Decision Board arm. Satisfaction was measured at several intervals (1 week and 3, 6, and 12 months) after the initial consultation. Patients who chose chemotherapy (the majority) often started their treatment 1 week after the initial consultation. The improvement in patient satisfaction was most evident at 6 months after the consultation, suggesting that high anxiety and symptoms associated with chemotherapy treatment may have limited our ability to detect an improvement early on.

One of the goals of a decision aid is to improve a patient’s decision making by engaging patients in the decision process and ensuring that the decision reflects their personal values (26). Patients in the Decision Board arm were more likely than patients in the control arm to change their preference to a more active role in decision making, suggesting that the instrument, directly and/or indirectly, by improving knowledge, empowered patients in decision making. This empowerment is also suggested by the observation that patients in the Decision Board arm were less likely than those in the control arm to need or receive a formal recommendation regarding treatment from their physician.

In this study, no difference was detected in the choice of whether to receive adjuvant chemotherapy between groups. The majority of patients chose adjuvant chemotherapy. This made it more difficult to detect an effect of the intervention on treatment choice and probably reflects the desire of most cancer patients to prevent recurrence of their disease despite the side effects of chemotherapy (27).

Concerns have been raised about the potential negative impact of using a decision aid to provide cancer patients with explicit information about their disease and prognosis and the time required for such discussions (28). We found no grounds for such concerns because in our study, discussions involving the Decision Board did not increase patient anxiety nor did they significantly increase the time of the consultation. Physicians also reported high satisfaction with decision making when the Decision Board was used.

Although we were unable to blind participants in our trial for practical reasons, measures were taken to minimize bias in the design of the study and the assessment of outcomes. To avoid the potential of an attention effect associated with the nurse interview, patients in the control arm also were seen by a nurse not involved with administration of the Decision Board. When we obtained consent, we informed patients that we were studying information transfer and decision making in the physician–patient encounter but not specifically that we were evaluating a new intervention. The purpose of stating the protocol in this way was to avoid the potential for a “novelty bias,” in which patients randomly assigned to the Decision Board arm might have been more satisfied simply because they had received the intervention, and those in the control group might have been less satisfied because they had not. The Decision Board may be administered by a physician or nurse. In this study, the instrument was administered by a research nurse to avoid bias that might occur.
if the physician were to administer the instrument to patients in the experimental arm and to discuss treatments with patients in the control arm using a similar approach. Even if some contamination did occur, it likely would have decreased the observed effects.

Previous studies of decision aids have been variable in design, instruments tested, outcomes measured, and results observed. O’Connor et al. (11) conducted a systematic review of decision aids in various health conditions. Seventeen randomized trials were included, of which only two studies involved patients with cancer. A number of different instruments were studied that included written materials, computer-based programs, video programs, and audio-guided workbooks. The authors concluded that, overall, decision aids improved patient knowledge, but in the studies involving cancer patients, no statistically significant impact on patient knowledge was observed. Decision aids also did not appear to have a consistent impact on patient satisfaction.

There have been two randomized trials (29,30) of decision aids for breast cancer patients regarding options for surgery. Street et al. (29) compared an interactive video program outlining the options of mastectomy or lumpectomy with an information pamphlet. No difference was seen in patient knowledge or helpfulness. Goel et al. (30) reported the results of a randomized trial of an audio-guided workbook compared with an information pamphlet given to patients after their consultation with the surgeon. No difference was detected in patient knowledge or decisional conflict. It is unclear whether the lack of benefits observed in these studies relates to the instruments themselves, the time of application, or the situation studied. In a recently reported randomized trial of an interviewer-administered visual aid for adjuvant chemotherapy for women with early breast cancer, investigators observed improvements in patient knowledge and satisfaction (31).

Our study is the first randomized trial of the Decision Board. The use of the Decision Board is consistent with the model of shared decision making. This model recognizes that the majority of patients and physicians prefer to share in all stages of decision making, information exchange, deliberation, and the final treatment decision (32). Consequently, the instrument is administered during the medical encounter to encourage two-way communication. Administration of the Decision Board uses several known methods to improve understanding, including presenting information using simple language, both orally and visually, and using diagrams. Repetition is used judiciously and serves to engage patients and reinforce the message. The Decision Board is easy to use and, as new information becomes available, easy to modify. Indeed, we modified the Board to reflect the broadened eligibility criteria during our study. In our study, the reduction of recurrence with chemotherapy described with the Decision Board was determined by using the same relative benefit applied to all patients irrespective of their baseline risk. A more recent computer-based version of the Decision Board (33) applies different relative benefits of chemotherapy depending on age, which is consistent with the most recent report of the Early Breast Cancer Trialist’s Collaborative Group Overview (34) and other developed decision tools (35,36).

In Western society, increasing attention is being focused on improving the quality of health care delivered. The Institute of Medicine has defined quality care as providing patients with appropriate services in a technically competent manner with good communication and shared decision making (37). Improved communication and involvement of patients in health care decision making is expected to lead to a number of important outcomes, including better health care decisions incorporating patients’ values, increased patient satisfaction, adherence to therapy, and improved emotional and physical well-being (38). Although decision aids may improve physician–patient communication and decision making, few positive studies have been performed with cancer patients. Our results demonstrate that the Decision Board in addition to medical consultation improves both patient knowledge and satisfaction with decision making for women with lymph node-negative breast cancer deciding on adjuvant chemotherapy. This study was done in participating centers by experienced physicians and nurses with an interest in information exchange and shared decision making. It is possible that the Decision Board may provide even greater benefits in other settings. We recommend that physicians consider such an instrument when presenting treatment options of adjuvant systemic therapy to women with early-stage breast cancer.

REFERENCES


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