Single-Arm Longitudinal Study to Evaluate a Decision Aid for Women Offered Neoadjuvant Systemic Therapy for Operable Breast Cancer

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Abstract

Background: Neoadjuvant systemic therapy (NAST) is an increasingly used treatment option for women with large operable or highly proliferative breast cancer. With equivalent survival outcomes between NAST and up-front surgery, the situation-specific preference-sensitive nature of the decision makes it suitable for a decision aid (DA). This study aimed to develop and evaluate a DA for this population. **Methods:** A DA booklet was developed according to international standards, including information about adjuvant and neoadjuvant treatment, outcome probabilities, and a values clarification exercise. Eligible women, considered by investigators as candidates for NAST, were enrolled in a multi-institutional, single-arm, longitudinal study. Patient-reported outcome measure questionnaires were completed pre- and post-DA, between chemotherapy and surgery, and at 12 months. Outcomes were feasibility (percentage of eligible patients accessing the DA); acceptability to patients (percentage who would recommend it to others) and clinicians (percentage who would use the DA in routine practice); and decision-related outcomes. **Results:** From 77 eligible women, 59 were enrolled, of whom 47 (79.7%; 95% CI, 69.4–89.9) reported having read the DA; 51 completed the first post-DA questionnaire. Of these 51, 41 participants (80.4%; 95% CI, 69.5–91.3) found the DA useful for their decision about NAST. Of 18 responding investigators, 16 (88.9%; 95% CI, 74.4–103.4) indicated they would continue to use the DA in routine practice. Post-DA, decisional conflict decreased significantly ($P < .01$); anxiety and distress decreased significantly; and 86.3% (95% CI, 73.7–94.3) achieved at least as much decisional control as they desired. **Conclusions:** This DA was feasible and acceptable to patients and clinicians, and improvement in decision-related outcomes was demonstrated when used in combination with clinical consultations. This DA could safely be implemented into routine practice for women considering NAST for operable breast cancer.

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Patient-centered care is a key component of high-quality healthcare.^{1,2} The process of shared decision-making supports patient-centered care by actively involving the patient and their healthcare providers in choosing the best treatment option.³ One strategy to implement shared decision-making is the patient decision aid (DA), which is an evidence-based, structured tool to support deliberation between patients, clinicians, and others when there is more than one treatment option.^{4,5}

For women with large or highly proliferative operable breast cancer, the decision about whether to receive neoadjuvant systemic therapy (NAST) is guided by preferences that may lead to individual patients with similar clinical circumstances choosing different options. DAs have been shown to help guide patients in such preference-sensitive situations and improve decision-related outcomes, including reducing decisional conflict, increasing patient knowledge, increasing their involvement in decision-making, and improving their understanding of risks associated with the options.⁶ Several DAs have been developed to address values-sensitive patient decisions for early-stage breast cancer⁷; however, none was available for women considering NAST for operable breast cancer. This treatment option involves a complex interplay of preferences,⁸ presented in the context of a distress-inducing diagnosis of cancer. Despite this distress and decisional complexity, previous work has shown that patients benefit from being involved in decisions about management of early-stage breast cancer.⁹

An increasing proportion of patients with operable breast cancer are being treated with NAST.¹⁰ Advantages include downstaging from mastectomy to lumpectomy and downstaging the axilla^{11,12}; better oncologic clearance, allowing for consideration of immediate breast reconstruction in women still requiring mastectomy; improved prognostication based on response¹³; time to plan surgery¹⁴; and participation in a neoadjuvant or postneoadjuvant clinical trial.¹⁵ Disadvantages for some patients include fear of disease progression on chemotherapy,¹⁶ and the psychological impact of leaving a tumor in place rather than its immediate surgical removal and of an adverse prognosis if the tumor does not respond to chemotherapy. Importantly, disease-free and overall survival outcomes are equivalent, whether NAST or

surgery is the first treatment modality for operable disease.¹⁷

Involving patients in the decision about NAST can be challenging due to the complexity and perceived urgency of the decision. This study aimed to develop a DA for women with operable breast cancer who had been offered NAST, and to test the feasibility and acceptability of that DA in clinical practice.

Methods

Design, Patients, and Setting

This was a prospective, single-arm, multicenter, longitudinal study. This study received approval from a recognized ethics committee, and all participants provided informed consent prior to any study processes. A detailed description of study methods and DA development has been published previously.¹⁸ Participants were Australian women aged ≥ 18 years with a diagnosis of operable invasive breast cancer, and were candidates for NAST of ≥ 3 months. Exclusion criteria were insufficient English language to complete study questionnaires; inflammatory, metastatic, or inoperable breast cancer; or inability to access the internet and email to complete study requirements.

A DA was developed for this study based on literature review, patient interviews,¹⁹ a clinician survey,²⁰ and the International Patient Decision Aid Standards (IPDAS) Collaboration guidelines ([see supplemental eAppendix 1 for the IPDAS checklist, available online with this article at JNCCN.org](#)).⁴ A stakeholder group reviewed the DA, including medical oncologists, surgeons, a psychologist, breast care nurse, consumers, and a breast cancer advocacy group representative. The DA is a 26-page booklet available online or in print. It contains a description of options for adjuvant and neoadjuvant therapy, with advantages and disadvantages, outcome probabilities (pathologic complete response, downstaging, progression on neoadjuvant therapy), graphical and pictorial information, and a values clarification exercise. It is designed for flexibility of use, whether to be read cover-to-cover, or only sections of interest. The Flesch-Kincaid reading level is year 10, despite consumer input and substantial effort to simplify the language. A full copy of the DA is available at <https://www.breastcancertrials.org.au/file/44/Neoadjuvant-Patient-Decision-Aid>.²¹

Participants were recruited by their breast surgeon or medical oncologist, completed the baseline

questionnaire (assessment 1), and then accessed the DA for on-screen or hard copy review (see [supplemental eFigure 1](#) for study schema). The DA was intended to be given to patients by their surgeon at the time of referral to a medical oncologist, for review prior to that appointment. After the follow-up visit in which a decision was made about undergoing NAST or surgery first, patients received a follow-up questionnaire (assessment 2). Assessment 3 was between completion of systemic therapy and before surgery (or after surgery and before chemotherapy if surgery was first), and the final questionnaire (assessment 4) was given 12 months after registration. All questionnaires were completed online.

Outcomes

Co-primary outcomes comprised feasibility of DA use and acceptability to patients and clinicians. Feasibility was defined as the percentage of eligible patients who accessed the DA after being offered participation in the study, which we hypothesized would be >50%. Patient acceptability was defined as the percentage of participants who would recommend the DA to others in their situation, hypothesized to be >50%. Investigator acceptability was defined as the percentage of investigators who would use the DA in routine practice, hypothesized to be >50%. Acceptability and feasibility margins were prospectively defined based on the estimated proportion of patients and investigators required to warrant routine implementation of the DA.

Patient-reported outcome questionnaires were completed by participants at each time point ([supplemental eTable 1](#)) and were described in detail previously.¹⁸ Measures were Decisional Conflict Scale²²; Information and Involvement Preferences²³; Decision-Making Preference Questionnaire²⁴; 6-item State-Trait Anxiety Inventory²⁵; Distress Thermometer²⁶; Fear of Progression Questionnaire-Short Form²⁷; Fear of Cancer Recurrence Inventory²⁸; custom knowledge questionnaire; Decision Regret Scale²⁹; Satisfaction with Decision Scale³⁰; and DA feedback.³¹ Investigators were also asked to complete a feedback questionnaire.

Analysis

Recruitment of 50 participants was planned so that a primary outcome score of ≥67% would provide 80% power with a one-sided α of 5% to reject a true rate

of ≤50%. To provide sufficient numbers for secondary outcome analysis, recruitment was planned to continue until 50 participants had completed assessment 2. We summarized demographic, tumor, and treatment data by mean and standard deviation for continuous data, and by number and frequency for categorical data. Primary outcomes were analysed using tests of proportions and presented with 95% CIs. Those who did not complete assessment 2 were assumed to have not read the DA. Differences in Decisional Conflict Subscale and Information and Involvement Preferences (detail) were assessed using paired *t* tests. Change in Information and Involvement Preferences (information type) from baseline was tested using McNemar's test. Linear mixed models were used to examine changes in distress and anxiety, with fixed effects for final treatment choice and time (modeled as a categorical variable) and a subject-level random intercept term. Fear of progression, fear of cancer recurrence, and decisional regret are reported using summary statistics and paired *t* tests. Agreement in decision control and treatment choice (preferred vs achieved at assessment 2) is presented using the κ statistic, with scores defined as poor (<0), slight (0–0.20), fair (0.21–0.40), moderate (0.41–0.60), substantial (0.61–0.80), and almost perfect (0.81–0.99).³² Change in decisional control is presented using the Bowker test, collapsing categories into shared (collaborative, guided by either patient, doctor, or both equally) versus not shared (only patient or doctor made the final decision). An exploratory analysis of outcomes at assessment 2 was conducted according to whether the participant had read the DA. A *P* value of <0.05 was considered significant for all analyses. Analyses were computed using Stata/IC 13.1 (StataCorp LP).

Results

Between June 2015 and September 2016, 77 eligible women were offered participation and consented to demographic details being recorded (Figure 1). A total of 59 completed the online consent and the first questionnaire, and accessed the DA (Table 1).

Feasibility and Acceptability of the DA

The DA was feasible, with 59 of 77 eligible patients accessing it (76.6%; 95% CI, 67.2–86.1; *P*<.0001). Of those 59 participants, 47 read all or part of the

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Figure 1. CONSORT diagram.

Abbreviations: DA, decision aid; DOMINO, Decision-Making About Neoadjuvant Therapy for Breast Cancer study; NAST, neoadjuvant systemic therapy.

*At the data cutoff date, 20 participants had not yet reached their 4th questionnaire.

DA (79.7%; 95% CI, 69.4–89.9; $P < .0001$). No significant differences were seen in baseline demographics or outcome measure scores between those

who read the DA and those who did not. The DA was acceptable to 41 of 51 participants who completed assessment 2, and they indicated that they would recommend the DA to others in their situation (82.4%; 95% CI, 69.5–91.3; $P < .0001$); 9 (18%) were neutral. The DA was acceptable to 16 of 18 site investigators (88.9%; 95% CI, 74.4–103.4; $P < .001$) for routine use.

Patient-Reported Outcomes

Overall, 51 of 59 participants (86.4%) chose NAST. Agreement was good between desired (post-DA) and actual treatment (κ , 0.6; 95% CI, 0.290–0.911). At baseline, 18 participants were unsure about whether to proceed with NAST or surgery as their first treatment, 6 of whom proceeded with surgery and 12 underwent NAST. Decisional conflict decreased in total and in all subscales (informed, values clarity, support, uncertain, effective) after use of the DA in combination with clinical consultation (all P values $< .002$; Figure 2). The post-DA score was < 25 in all except the “uncertain” subscale. Patient-reported outcome measure scores are presented in Table 2.

No differences were seen in baseline demographics or assessment 1 outcome scores between those who read the DA and those who did not. At assessment 2, those who read the DA had no difference in decisional conflict, anxiety, distress, or decision control preferences. Those who read the DA had a higher mean knowledge score.

Most patients preferred, and achieved, a shared approach in their decision about NAST (Table 3);

Variable	n (%)
Number	59
Mean age, y (SD)	52 (8.9)
Marital status	
Married/De facto	48 (81.4)
Single	11 (18.6)
Highest education level	
Postgraduate	17 (28.8)
Undergraduate	13 (22.0)
Vocational	13 (22.0)
High school	15 (25.4)
Missing	1 (1.7)
Private health insurance	
Yes	51 (86.4)
No	8 (13.6)
Health professional	
Yes	10 (17.0)
No	49 (83.0)
English as first language	
Yes	56 (94.9)
No	3 (5.1)

Figure 2. Decisional Conflict Subscales pre- and post-decision aid (DA). Horizontal reference lines at scores of 25 and 37.5. $P < .002$ for all pre/post-DA comparisons. Boxes represent the interquartile range (25th to 75th); whisker length is 1.5 times the interquartile range above and below the box. Dots represent values outside the whiskers.

Table 2. Patient-Reported Outcome Scores

Measure	Assessment 1 (n=59)	Assessment 2 (n=51)	Assessment 3 (n=51)	Assessment 4 (n=29) ^a	P Value
Total decisional conflict, mean (SD)	33.4/100 (19.3)	21.0 (14.1)	–	–	<.001 ^b
Information detail preference, mean (SD)	8.5/10 (2.16)	8.6/10 (2.02)	–	–	.73 ^b
Information type					.69 ^c
All information, good and bad	76.3%	72.6%	–	–	
Additional information only if it is good news	5.1%	3.9%	–	–	
Only information needed to care for myself	18.6%	23.5%	–	–	
Anxiety, mean (SD)	55.4/100 (15.0)	49.4/100 (14.1)	40.1/100 (13.0)	36.1/100 (12.2)	<.001 ^d
Distress, mean (SD)	5.9/10 (2.9)	5.0/10 (2.5)	3.2/10 (2.5)	2.2/10 (2.5)	<.02 ^d
Fear of cancer progression, mean (SD)	–	33.4/60 (7.2)	29.9/60 (7.2)	–	<.001 ^b
Fear of cancer recurrence, mean (SD)	–	–	58.9/168 (25.0)	57.5/168 (22.9)	.359 ^b
Satisfaction with decision, mean (SD)	–	–	25.5/30 (3.6)	–	.005 ^e
Decisional regret, mean (SD)	–	–	16.4/100 (20.0)	10.0/100 (15.4)	.0176 ^b
Knowledge, mean (SD)	–	76% (12.5)	–	–	<.001 ^e
Feedback, mean (SD)	–	74% (8.4)	–	–	<.001 ^e

^aAt the data cutoff, 20 patients had yet to complete their 4th questionnaire.

^bPaired *t* test.

^cMcNemar's test.

^dLinear mixed model.

^eP value comparison with prespecified hypothesis.

86% (44/51) achieved at least as much decisional control as they desired. No significant changes were observed between pre-DA preferred decisional control and actual perceived decisional control ($P=.50$). Fair agreement was observed between preferred and achieved decisional control at assessment 2 (κ , 0.32; 95% CI, 0.16–0.49). Fear of Cancer Recurrence scores were low in 76.5% of participants, moderate in 19.6%, and severe in 3.9% at assessment 2. At assessment 3, scores were low in 88.2% and moderate in the remainder.

Investigator-Reported Outcomes

Of 24 participating investigators, 18 (75%; 7/11 medical oncologists and 11/13 surgeons) completed the investigator questionnaire, and 16 (88.9%) indicated that they would use the DA in routine practice; 16 also indicated that the DA appeared to make the decision easier, or no more difficult, for their patients compared with those who had not used the DA. A total of 14 investigators felt that the DA did not change patients' decisions about NAST, and the remaining 4 felt that the DA increased the likelihood of a patient choosing NAST; 12 noted no change in consultation time, and the remaining 6 noted a mean increase of 7.5 minutes.

Discussion

This study fills a gap in the breast cancer decision literature by producing a neoadjuvant DA that was not previously available.¹⁹ Findings show that a DA in this setting was acceptable to most patients and clinicians, and could feasibly be used within routine clinical workflow. Decision-related patient-reported outcome scores improved in the post-DA assessments. These findings are consistent with the literature showing that systematically developed DAs designed for patient use in healthcare decision-making effectively improve decision-related outcomes for a range of general medical treatment decisions⁶ and for breast cancer.⁷

Previous work has indicated that patients benefit from being at least as involved as they wish to be.⁹ The decision regarding NAST is complex due to the need to consider the implications of a range of individual treatment decisions in the context of distress due to a recent breast cancer diagnosis. Patients in the present study engaged in decision-making despite this inherent complexity. Using the DA did not appear to increase patient anxiety, and, with an additional consultation, appeared to resolve decisional uncertainty.

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Table 3. Decision-Making Preference Questionnaire

Level of Control	Survey 1 – Preferred (n=59)	%	Survey 2 – Preferred (n=51)	%	Survey 2 – Actual (n=51)	%
Doctor makes final decision	7	11.9	5	9.8	6	11.8
Doctor makes final decision, seriously considering my opinion	9	15.3	11	21.6	6	11.8
Shared	28	47.5	26	51.0	18	35.3
I make final decision, seriously considering my doctor's opinion	15	25.4	8	15.7	19	37.3
I make final decision	0	–	1	2.0	2	3.9

A DA should be implementable in routine practice to realize the benefits seen in this study. Although the hypothesized threshold values for feasibility and acceptability were based on estimated likelihood of routine uptake, lower (or higher) thresholds might be appropriate depending on individual clinician and patient factors. A minority of patients in this study were neutral regarding whether they would recommend the DA to others in their situation, and only one indicated that she would recommend against it. Most read part or all of the DA once they had accessed it. Reasons for not reading the DA were that they had already made their decision or that the DA was provided too late in their decision-making process. The nonrandomized analysis of outcomes according to whether the participant had read the DA is exploratory and should be interpreted as such.

Study procedures such as the online delivery and pre-DA assessment made access to the DA more difficult than it would be in routine practice, where it would be appropriate to hand the patient a paper copy for immediate review. We suspect that others did not access the DA because it, and the study, were a burden at a time when they were dealing with the impact of their diagnosis and planning for treatment. Therefore, patient uptake in this study may underestimate real-world conditions. Broader reach might be gained if the DA were distributed by breast care nurses as well as clinicians.

At baseline, mean decisional conflict scores were high, consistent with patients delaying or feeling unsure about decision-making.²² After use of the DA and a subsequent clinical consultation, decisional conflict scores were consistent with patients implementing their treatment choice. This correlates with a significant decrease in the proportion of participants who reported being unsure about which treatment they preferred. The relative contributions of

clinical consultation versus the DA cannot be enumerated with this single-arm study design. Anxiety scores were consistent with participants being in a stressful situation, and did not decrease to population norms until assessment 4.²⁵ Lower anxiety in the neoadjuvant group might be explained by patients' expectations of receiving NAST if they were offered that treatment. Alternatively, anxious patients might have elected to undergo surgery first. Lower anxiety might also have been associated with seeing their tumor shrink and with getting a feared treatment "over and done with." A decision to have surgery upfront might also have been seen as contradicting the perceived medical recommendation in patients who had been referred for NAST.

Scores for fear of cancer progression were similar to the mean score of 60.6 (SD, 24.6) reported by historical breast cancer controls.²⁸ This suggests that these women were no more worried than the average patient with breast cancer about the impact of the tumor becoming larger or developing distant metastases while on treatment. Mean decisional regret at assessment 3 was comparable with historical patient data indicating low levels of regret related to the decision about NAST.²⁹ The strength of clinical recommendation for NAST will depend on the individual patient and tumor characteristics. Clinical equipoise was not expected regarding whether NAST or surgery was the best initial approach for individual patients, nor was the DA expected to change patients' minds. Results support this, with no significant changes in preferred treatment following use of the DA. Only 18 patients reported being unsure about their preferred treatment schedule pre-DA, which may represent clinical influence toward treatment decisions. Of those 18 patients, 6 chose surgery, whereas 2 of the 41 who were sure about their decision at baseline chose surgery. Unsure patients may choose the normative behavior

of surgery first, or the DA may influence unsure patients toward surgery. It is possible that the DA was not balanced, although most patients and clinicians perceived it to be.

This study is limited by its relatively small sample size and single-arm design, although a single-arm design was felt to provide adequate confidence in the DA's safety and acceptability. Positive end points allow broad implementation of this DA, given the large amount of existing literature on the efficacy of these tools. We cannot derive the relative contribution of the DA versus clinical consultations, independent pursuit of information, discussion with family and friends, or natural history. The study population was well educated, which may reduce the generalizability to a less educated group. The DA was written at year 10 reading level—higher than the recommended year 8 level, which is a common issue in patient information material.³³ Strengths include the evidence-based, systematic development process and the use of validated patient-reported outcome measures. The DA was used successfully in a variety of settings as part of this study, supporting its ability to be implemented in routine clinical care.

Because DA uptake is typically low,³⁴ implementation implications must be considered. A minority of investigators reported a small increase in consultation time when they used the DA, with no impact on their intention to use the DA, suggesting that they considered the benefits of the DA worth the additional consultation time. The document was intended to be reviewed in detail outside of the con-

sultation to reduce impact on consultation time. The DA is scalable through electronic distribution. The intervention will be made freely available to encourage sustained uptake.

Conclusions

A DA for women with operable breast cancer who were offered NAST was acceptable to clinicians and patients. It was feasible to integrate into patient care pathways, ideally after an appointment with a surgeon and before consultation with a medical oncologist for a final treatment decision. Improvements in decision-related outcomes were seen, without evidence of adverse effects. Implementation strategies are warranted to ensure optimal use in routine patient care.

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Chronic Lymphocytic Leukemia (CLL)

Monday, May 14, 2018 • 11:30 AM – 12:30 PM EDT

Jennifer Brown, MD, PhD, and Matthew Davids, MD, MMSc

Dana-Farber Cancer Institute

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This program has been approved for *AMA PRA Category 1 Credit™* for physicians and will award contact hours for nurses, pharmacists, and other health care professionals. NCCN will also seek approval for case manager clock hours.

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