Development and evaluation of a decision aid for patients considering first-line chemotherapy for metastatic breast cancer

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Abstract

Objective Treatment decisions in advanced breast cancer are complex, with enhanced quality of life and survival among important treatment goals. Patients with metastatic breast cancer face the decision of whether or not to have chemotherapy, and many wish to be involved in this decision. We report the development and evaluation of a decision aid (DA) designed to assist patients facing this treatment decision.

Design and sample Women with metastatic breast cancer (n = 17) and medical oncologists in Australia and Canada (n = 7) were invited to evaluate the DA.

Intervention A DA was developed for patients with hormone-resistant metastatic breast cancer considering chemotherapy. The DA presented options of supportive care, with or without chemotherapy. Potential benefits and side effects of different chemotherapy regimens, and evidence-based prognostic estimates were described, and a values clarification exercise included.

Main outcome measures Patient questionnaires evaluating information and decision involvement preferences, attitudes toward the DA and oncologist feedback regarding attitudes toward the DA.

Results Seventeen patients participated; fifteen desired as much information about their illness as possible; sixteen wished to be actively involved in the decision-making process. The majority rated the DA as highly acceptable, clear and informative, and would recommend it to others facing this treatment decision.

Conclusion This is the first DA for patients with advanced metastatic breast cancer considering chemotherapy. A randomized trial is underway to evaluate its role in clinical decision-making.

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Introduction

Cancer patients have a demonstrated need for information about their disease and the treatment options they face, although the detail preferred varies from one individual to another. Many patients wish to be actively involved in their own care and medical decision-making. Active involvement has been shown to have a positive impact on treatment decisions and quality of life. To play an active role in decision-making, patients need to be accurately informed about pertinent factors including their diagnosis, prognosis and treatment options. However, clinical audits have shown that many incurable patients are not informed about relevant factors including life expectancy (42.4%), the impact of treatment on quality of life (63.6%), and the uncertainty of obtaining a benefit from treatment (27.1%).

Even when patients are informed of their disease status, misunderstanding of the information may prevent accurate perception of the situation. The majority of patients overestimate the ability of treatment to improve their condition, and physicians check understanding in only 10% of consultations. Overestimation of prognosis and the likely benefit from therapy may distort rational treatment decisions. Weeks and colleagues found that patients with advanced cancer who were overly optimistic about their prognosis were much more likely to seek aggressive treatment, which did not result in improved survival.

Thus the provision of accurate information to enhance the understanding of advanced cancer patients facing treatment decision-making is essential. Coulter and colleagues advocate that accurate understanding is essential for informed consent and empowered participation in decision-making. Evidence suggests this process strongly benefits patients. Patients who are offered options in their care show superior psychosocial outcomes with lower rates of anxiety and depression. Greater perception of involvement in decision-making also heightens patient’s satisfaction with their decision and physician loyalty.

To facilitate shared decision-making, decision aids (DAs) have been developed as tools specifically designed to help patients make difficult treatment decisions. DAs differ from traditional educational materials in that they explicitly present options and their risks and benefits, tend to use quantitative as well as qualitative information about such risks and benefits, and engage patients in considering treatment options in light of their own personal values and preferences. They come in many forms, including audio-guided workbooks, patient letters, computer programs, interviews, and group presentations.

DAs have been utilized in a wide range of conditions and treatment choices, including post-menopausal hormone replacement therapy, prenatal screening, and adjuvant therapy in cancer. They have been shown to provide benefit to patients in terms of improved knowledge about disease and treatment, greater satisfaction with the decision, and more active participation in decision-making.

Although the benefits of DAs in facilitating treatment decisions have been well documented, their role in the advanced cancer setting is still being established. Treatment decision-making in advanced cancer differs substantially from the early stage or adjuvant setting. When the goal of treatment is not cure, prognosis and treatment goals, emotional well-being and treatment trade-offs become more complex. In addition to tumour response and survival, quality of life and symptom control are important end points to consider in the management of metastatic cancer. Thus, medical decision-making in advanced cancer is multidimensional and complex, involving both subjective and objective goals of treatment.

With such considerations in mind, we developed and evaluated a DA for patients with metastatic breast cancer considering first-line chemotherapy where hormonal treatment was not appropriate. Although DAs have been developed and evaluated for breast cancer patients facing primary or adjuvant treatment decisions, this is to our knowledge the first DA designed specifically for the advanced breast cancer setting to assist patients in deciding whether to opt for supportive care alone or together with chemotherapy.
**Methods**

Development of decision aid

The DA was developed at the Princess Margaret Hospital, Toronto, Canada and the Medical Psychology Research Unit/Royal Prince Alfred Hospital, Sydney, Australia. The study was conducted with ethics approval at all participating centres.

Modeled on the Ottawa Decision Support Framework,17 the objective of the DA was to assist women with metastatic breast cancer to make decisions together with their oncologist about chemotherapy treatment. The information content and format were developed through a comprehensive process including literature review, input from an expert panel, and feedback from women with advanced breast cancer in Sydney, Australia, and Toronto, Canada.

Information content

A literature review of major medical databases such as Medline was undertaken to incorporate the highest level and quality of medical evidence for use in the DA, e.g. data from randomized trials, and to identify standard treatment options for metastatic breast cancer patients for whom hormonal treatment was not, or no longer, appropriate. An expert panel including seven oncologists, one psychologist and two nurses reviewed and identified standard treatment options accepted by the oncology community. These standard options included anthracycline- and taxane-based chemotherapies, vinorelbine, capecitabine and 5-FU based combinations (FAC, CMF). Trastuzumab was noted as a treatment option for some, but not all, patients. Supportive care alone was also identified as an option, and defined as treatment aimed at symptom control (e.g. pain medication, transfusion or growth factor support, radiation or palliative surgical intervention), without the use of systemic chemotherapy.

Systematic reviews and randomized trials were identified comparing supportive care with and without the addition of chemotherapy in patients with metastatic breast cancer.18–21 From these studies, estimates of survival effects from supportive care with and without chemotherapy in metastatic breast cancer patients after failure of hormone therapy were presented to the multidisciplinary breast tumour board at the Princess Margaret Hospital for review prior to incorporation into the DA. Bergh and colleagues18 estimate that first-line chemotherapy adds 6–9 months to survival time over supportive care alone.

There has been no direct comparison of quality of life on first-line chemotherapy compared to supportive care alone. However, chemotherapy’s potential for symptom improvement and potential toxicity was included, as was data regarding duration of therapy and its impact on quality of life.22 Additional information presented includes risks and benefits of a number of common chemotherapy regimens, and the common side effects of each. Calendars illustrating treatment schedules, a flowchart of different treatment pathways, a guide to support and information services, and references were also included. Clinical trials were also described, with a general description of the potential benefits of trial participation, similarities and differences with standard treatment options, trial funding, and definitions of phase 1, 2 and 3 trials, and eligibility. Sample pages from the DA are shown in Figs 1–5.

Selection of DA format and values clarification exercise

A workbook format was selected for ease of implementation for most medical centres and patient accessibility. The values clarification exercise was adapted from the Ottawa DA ‘weigh scale’,17,23,24 in which patients are invited to weigh up the pros and cons regarding chemotherapy treatment or supportive care alone. Two examples of hypothetical patients were included (e.g. Fig. 5), including sample ‘pros’ in favour of chemotherapy, such as extended life expectancy, improvement of cancer symptoms, and psychological benefits to pursuing chemotherapy (e.g. ‘feeling fighting
the cancer). Example ‘cons’ were also listed as drawbacks to chemotherapy, including the side effects induced by chemotherapy, the frequent hospital visits and difficulty of pursuing chemotherapy treatment, and the uncertainty that treatment may work. Patients then shade in each field according to its importance – full shading for very important items, partial shading for less important items, and none for items considered unimportant to the patient. This weigh scale exercise, allowing patients to quantify their own considerations and assess which treatment option they are ‘leaning’ towards, has been shown to predict final decisions with 84–95% accuracy.23,24

Pilot evaluation of the DA
Patients with advanced breast cancer attending outpatient oncology clinics in two major cancer centres in Sydney, Australia, and Toronto, Canada, who had made a decision about first-line chemotherapy or supportive care were invited to review the DA. Potential participants were identified by their oncologist to review and provide feedback on the aid. All participants gave written informed consent prior to participation. Evaluations were conducted in semi-structured interviews with a researcher in a quiet room. Patients completed questionnaires assessing demographics, their informa-
Survival of patients with metastatic breast cancer

(After failure of hormone therapy)

At 1 year
Supportive care plus chemotherapy
70%
30%
70 out of 100 women alive
30 out of 100 women passed away

Supportive care alone
50%
50 out of 100 women alive
50 out of 100 women passed away

At 2 years
Supportive care plus chemotherapy
45%
55%
45 out of 100 women alive
55 out of 100 women passed away

Supportive care alone
70%
30%
30 out of 100 women alive
70 out of 100 women passed away

Figure 2. Estimates of patient survival with and without chemotherapy treatment in metastatic breast cancer. This page was made optional, allowing patients to skip viewing the survival estimates if desired.18–21

Results

Patient demographics

Nineteen patients consented to participate in the study, however one patient withdrew during the assessment due to fatigue and one patient did not return the DA evaluation. Demographic characteristics are summarized in Table 1. All participants were women with a median age of 58 years. 83% had completed high school and 88% spoke English as their first language. All but one had received prior chemotherapy.

Feasibility

Time required for review of the DA, including feedback from patients, was 45 to 60 minutes.

tion and involvement preferences regarding medical decision-making, and whether these preferences had been achieved. Decision-making preferences were rated using the Control Preferences Scale.25 Patients evaluated the content and acceptability of the DA using Likert rating scales and written and verbal comments. Revisions based on patient feedback were made before review of the DA by seven Canadian and Australian medical oncologists. These revisions included modifications in wording, changes to design of the values clarification exercise, and increased examples with the goal of making the DA clearer and easier to use. Content was not added or omitted. The oncologists evaluated the acceptability and content of the DA by questionnaire.

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Reading level of the DA was evaluated as Grade 8 (Flesch-Kincaid reading level, MS Word, Microsoft, Redmond, WA, USA).

**Information and involvement preferences and outcome**

Information and involvement preferences are summarized in Tables 2 and 3. A majority (88%) of patients indicated a preference for as much information, both good and bad, as possible about their illness. Most patients (94%) indicated a preference for shared decision-making regarding treatment, with no patients preferring their doctor to take sole responsibility for the decision. Sixteen of seventeen patients were satisfied with their treatment decision.

**Acceptability**

Patient responses regarding acceptability of the DA are summarized in Table 4. Most patients found the aid very acceptable and reviewed it favourably. The majority (65%) reported that the DA contained an appropriate amount of information, and most felt the length was appropriate, although 24% reported it was slightly too long. All patients were given the option of omitting the survival statistics section if they wished; one chose to do so. Most patients did not find the DA upsetting, although one patient reported it was ‘somewhat upsetting’. 89% reported that everything or most things in the DA was clear whilst one patient reported some things were unclear. Some patients found the values clarification exercise difficult to follow. Overall 82% of patients reported the DA was either very or somewhat helpful in making a treatment decision and 94% would recommend it to others facing this treatment decision.

Nine medical oncologists were invited to provide feedback, and seven responded. In general, the DA was positively received, and felt to be appropriate for all or most patients, although two physicians noted it may be more effective for younger, better educated patients and those wishing to take a more active role in their cancer care. Two physicians thought the DA could be shortened, one expressed concern that it may raise anxiety levels, and one felt trastuzumab should be addressed in more detail. Two of the physicians felt that a DA regarding this treatment decision was not useful, as they believed supportive care alone was a less desirable treatment option.

**Discussion**

In this study, we developed and pilot tested the first DA designed for use in a metastatic breast cancer setting. Most patients and oncologists reviewed the DA positively, considering it to be informative, balanced and clear and an important tool in helping to make a treatment decision.

That patients reviewed this DA favourably, suggests that this and similar DAs may improve the decision-making process even in the setting of advanced cancer. Use of a workbook format may facilitate implementation in general cancer clinics. The use of DAs for advanced cancer patients has the potential to greatly enhance informed decision-making, as well as improving patient satisfaction with decision-making. Longer term satisfaction for physicians would also be expected, with a decrease in pursuit of
futile therapy accompanying the enhanced understanding of patients and their families. For example, many clinicians are not comfortable offering supportive care as an option in advanced cancer, and both clinicians and patients may be uncomfortable discussing prognosis. Thus the DA may help facilitate important discussions about the options available and the impact on a person’s quantity and quality of life beyond what currently occurs in the cancer consultation.

This pilot indicates that a group of selected metastatic breast cancer patients found the aid informative, balanced and potentially useful in making a treatment decision. However, the true impact of the aid on decision-making in advanced cancer must be determined prospectively, through a randomized trial design. A randomized controlled trial of the DA booklet with an accompanying audio recording is ongoing, to evaluate the impact of the aid on treatment decisions, patient knowledge, anxiety and decisional conflict, as well as decision satisfaction.

The current pilot does have limitations. Its use in experienced cancer patients may underestimate the impact on anxiety, distress and psychosocial functioning. In addition, the patients in the pilot were highly educated, and
Our group has previously developed DAs in advanced cancer using a similar format which has been pilot tested in patients with a non-English speaking background. As part of the randomized trial evaluation, patients will all receive the booklet, scripted at Grade 8 reading level, with an accompanying audiotape for those with poor literacy. Patients will be guided to share the aid with family and other health-care providers (to facilitate use, particularly for those with non-English speaking backgrounds). The ongoing randomized trial targets sequential patients considering supportive care with or without first-line chemotherapy, and will enable testing of the aid in a more generalizable patient population, to evaluate whether the DA positively impacts decision-making in advanced breast cancer patients.

**Conclusion**

The first DA for patients with metastatic breast cancer considering chemotherapy has been developed and evaluated positively by a pilot group of patients. In our study most partici-

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**Example: Susan's Worksheet**

1. **Weighing up the pros and cons of anti-cancer treatment or supportive care alone.**
   In the chart below list the pros and cons that are important to you – you can use the sub-headings to help you if you wish. [Susan’s comments are below the sub-headings]

<table>
<thead>
<tr>
<th>Pros of Adding Chemotherapy</th>
<th>Cons of Adding Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>I may live longer:</td>
<td>Chemotherapy side effects:</td>
</tr>
<tr>
<td>I have young children to live for</td>
<td>I am strong I can handle it</td>
</tr>
<tr>
<td>My cancer symptoms may improve:</td>
<td>My friend had chemo &amp; tolerated it OK</td>
</tr>
<tr>
<td>I am having a lot of back pain</td>
<td>Frequent tests and trips to the hospital:</td>
</tr>
<tr>
<td>I feel like I’m fighting the cancer:</td>
<td>My husband can drive me</td>
</tr>
<tr>
<td>I can’t stop fighting because of my family.</td>
<td>No guarantee treatment will work:</td>
</tr>
<tr>
<td>Other pros to consider:</td>
<td>True, I accept this</td>
</tr>
<tr>
<td>My friend had chemo &amp; tolerated it OK</td>
<td>Other cons to consider:</td>
</tr>
</tbody>
</table>

2. In the chart above colour in the whole box if the statement is very important, half of the box if it is somewhat important to you and do not colour the box at all if the statement is not important to you. (Susan’s colourings are in pink for pros and green for cons).

3. **Where am I leaning?**
   Based on how Susan has coloured the chart (above), it may help her decide which way she is leaning.
   (She then checks the relevant box below)

**Adding Anti-cancer Treatment**

4. **Are there any more questions you would like to ask?**
   Susan: Do I need any more tests? When can I start?

5. **Who should make the decision about treatment?**
   Susan ticks the box that is closest to her preference:

**Figure 5** Completed values clarification exercise by an example patient, “Susan”, who has completed the exercise with her own personal pros and cons of chemotherapy treatment.
pants indicated a strong need for information and a desire for active involvement in the decision-making process; suggesting that tools such as this DA can fulfill an important role in facilitating such involvement. Not all oncologists perceived the same value for patient involvement in decision-making in the first-line metastatic setting with two believing that a decision at this stage is not required. However, most patients and oncologists received the DA positively.

The promising results of the current pilot study parallel previous studies suggesting an important and emerging role for DAs in the treatment of advanced cancer. Aids developed to provide decision support to patients with advanced ovarian cancer, metastatic and locally advanced lung cancer, metastatic prostate cancer, and metastatic colorectal cancer have been evaluated via randomized trial. Results from these studies generally indicate that DAs facilitate sharing of prognostic information with patients, enhance decision satisfaction among patients, reduce decision uncertainty, and improve patient knowledge regarding options and outcomes without significant increase in anxiety. Evaluation of the present DA via randomized trial will allow us to explore further whether this DA leads to similar endpoints in a larger population of metastatic breast cancer patients, improving the decision-making process, patient satisfaction and perhaps even quality-of-life.

Conflict of interest
None declared.
Table 4 Patient responses regarding acceptability of DA

<table>
<thead>
<tr>
<th>Amount of information provided</th>
<th>1 (6)</th>
<th>11 (65)</th>
<th>1 (6)</th>
<th>1 (6)</th>
<th>2 (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much less than needed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly less than needed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>About the right amount of information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly more than needed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Much more than needed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Upsetting</strong></td>
<td>10 (59)</td>
<td>6 (35)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Not at all upsetting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A little upsetting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Somewhat upsetting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very upsetting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td>12 (71)</td>
<td>6 (35)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Much too long</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly too long</td>
<td>4 (24)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>About right</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should be slightly longer</td>
<td>0 (0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should be much longer</td>
<td>0 (0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clarity</strong></td>
<td>12 (71)</td>
<td>6 (35)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Everything was clear</td>
<td>3 (18)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most things were clear</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some things were unclear</td>
<td>1 (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Everything was unclear</td>
<td>0 (0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Helpful in treatment decision</strong></td>
<td>12 (71)</td>
<td>6 (35)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Very helpful</td>
<td>8 (47)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Somewhat helpful</td>
<td>6 (35)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A little helpful</td>
<td>2 (12)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not helpful</td>
<td>0 (0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>1 (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended to others</strong></td>
<td>12 (71)</td>
<td>6 (35)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Definitely</td>
<td>7 (41)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probably</td>
<td>9 (53)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probably not</td>
<td>1 (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Definitely not</td>
<td>0 (0)</td>
<td></td>
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</tr>
</tbody>
</table>

Values are expressed as n (%). DA, decision aid.

Acknowledgements

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