Supporting women with breast cancer in making an informed decision about immediate breast reconstruction: the development and evaluation of a patient decision aid

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Appendices

SUMMARY

The decision for immediate breast reconstruction (BR) is a preference-sensitive decision. For preference-sensitive decisions, shared decision making is propagated but not yet properly implemented. In women considering BR, prior studies identified unmet decision support needs. Patient decision aids (pDAs) have been found to support the process of shared decision making in a variety of healthcare decisions.

With this thesis we aimed to optimally support women in making an informed decision about BR. For this purpose, we developed and evaluated an online pDA for breast cancer patients considering immediate BR after mastectomy.

We addressed the following research questions:

1. What are the information needs of patients and healthcare professionals regarding the decision about breast reconstruction?
2. Is the pDA acceptable and usable for patients and healthcare professionals?
3. What are the levels of decisional conflict in patients considering immediate BR, and what factors are associated with clinically significant decisional conflict?
4. Is the pDA effective as compared to care-as-usual?
    a. What is the effect of the pDA in reducing decisional conflict?
    b. What is the effect of the pDA on the decision-making process, decision quality, and patient-reported health outcomes?
5. What are the experiences of patients and plastic surgeons with the pDA in terms of usage and satisfaction with the tool?

In **chapter 2** we describe the steps in which we developed the pDA. First, we established a multidisciplinary team of 16 experts including plastic surgeons, oncological surgeons, psychologists, industrial designers, and researchers to co-create the pDA. Hereafter, we assessed patients' and healthcare professionals' information needs regarding the decision for BR. Interviews with 17 women who considered BR after mastectomy in the past demonstrated that patients had unmet information needs regarding their BR decision. Patients emphasized the challenging period in which they had to make a decision and reported a variety of personal motivations for their BR decision. For example women reported a desire for improving their body image after mastectomy with BR, or to recover as fast as possible after mastectomy without BR. They emphasized the importance of identifying personal values regarding the BR decision. Furthermore, patients reported a need for a clear overview of reconstructive options, information about the consequences of each option on patients' daily lives, and experiences of other women who previously faced the decision. Thirty-three healthcare professionals completed a study-specific questionnaire about their preferences for information about BR. They valued the development of a pDA, especially to prepare patients for consultation. In concordance with patients' and healthcare professionals' needs, the content, design and

technical system of the pDA were created. The developed pDA contained three parts: first, a consultation sheet for oncological breast surgeons to introduce the choice; second, an online tool including an overview of reconstructive options, the pros and cons of each option, information on the consequences of each option for daily life, exercises to clarify personal values and patient stories; and third, a summary sheet with patients' values, preferences and questions to help inform and guide the discussion between the patient and her plastic surgeon. As a final step in the development of the pDA, we tested the tool's acceptability and usability by using a think-aloud approach in six patients and by interviews with seven healthcare professionals and seven representatives of the Dutch Breast Cancer Patient Organization. Both patients and healthcare professionals perceived the pDA as informative, helpful and easy to use.

In **chapter 3** we describe the design of our multicenter randomized controlled trial to assess the efficacy of the pDA in reducing decisional conflict, improving the decision-making process, decision quality and health outcomes in breast cancer patients considering immediate BR. Women with breast cancer or ductal carcinoma in situ who will undergo a mastectomy and are eligible for immediate BR were invited to participate. Patients were allocated to either the intervention group receiving care-as-usual with access to the pDA, or the control group receiving care-as-usual including a widely available information leaflet. Participants completed online questionnaires at baseline prior to consultation with a plastic surgeon, 1 week after the consultation, and at 3 and 12 months after surgery. The primary outcome was decisional conflict, measured using the Decisional Conflict Scale. Secondary outcomes reflected the decision-making process (i.e. satisfaction with information, satisfaction with the plastic surgeon, preparedness for decision making, patients' perceived levels of shared decision making during consultation with their plastic surgeon, and patients' perceived level of involvement in decision making), decision quality (i.e. decision regret, and knowledge of BR), and patient-reported health outcomes (i.e. patients' actual choice regarding breast reconstruction, patient satisfaction with breast, satisfaction with outcome, body image, sexual functioning, breast symptoms, and anxiety).

In **chapter 4** we report on the levels of decisional conflict in patients considering immediate BR, and the identified factors associated with clinically significant decisional conflict (score > 37.5 on decisional conflict). For this purpose, we analyzed baseline data of our randomized controlled trial evaluating the efficacy of the pDA. Participants (N = 250) completed questionnaires assessing sociodemographic and clinical characteristics, decisional conflict and other patient-reported outcomes related to decision making such as BR preference, knowledge, information resources used, preferred involvement in decision making, information coping style, and anxiety. Multivariable logistic regression analysis was performed to identify factors associated with clinically significant decisional conflict. A majority of breast cancer patients considering immediate BR after mastectomy (68%) experienced clinically significant decisional conflict. Patients with a *slight* preference *for* BR, with *no preference* for or against BR, and with a *strong* preference for *no* BR were more likely to experience clinically significant decisional conflict than patients with a *strong* preference *for* BR. Furthermore, patients with more anxiety were

more likely to experience clinically significant decisional conflict. The findings emphasize the need for decision support, especially for patients who do not have a strong preference for BR.

Chapter 5 presents the results on the efficacy of the pDA in reducing decisional conflict, improving the decision-making process, decision quality and health outcomes. 250 patients from eight hospitals participated. Decisional conflict decreased in the course of time in both the intervention- and the control groups, with no between group differences. Patients in the intervention group felt better prepared for decision making than controls, measured by the Preparation for Decision Making Scale at one week after consultation with a plastic surgeon. No significant between group differences were observed in any other outcome.

Chapter 6 describes patients' and plastic surgeons' usage of and satisfaction with the pDA during the trial and their views on barriers and facilitators for widespread implementation. For this study, the intervention group of the trial completed process measures in the questionnaire at one week after consultation with a plastic surgeon and 22 plastic surgeons who participated in the trial completed a study-specific questionnaire. Also, usage data collected at the back-end of the pDA was analyzed. Almost all patients (97%) accessed the pDA. Most of them were satisfied with the pDA and would recommend the pDA to other women facing the same choice (72% and 74%, respectively). Patients' preferences for the type, the amount and the presentation of information they desired varied. Plastic surgeons were also satisfied with the pDA. Their key factors for implementation included the perceived match between information and clinical practice, costs, impact on patients, and support from peers and management for the tool.

Chapter 7 highlights the main findings of this thesis, including the limitations and strengths of our study, and suggestions for future research and clinical practice. This study resulted in the development of a pDA to support women with breast cancer and ductal carcinoma in situ in making informed decisions about immediate BR after mastectomy. The pDA addressed the information needs of patients and healthcare professionals, and was highly valued by the end users. Patients benefited from the pDA by feeling better prepared for decision making regarding immediate BR, compared to care-as-usual including a widely available information leaflet. However, our randomized controlled trial showed that the pDA had limited added value for patients' decision making in terms of decisional conflict, decision-making process, decision quality and patient-reported health outcomes. Several limitations of this thesis should be acknowledged, related to the study design and the generalizability. Several strengths are also worth mentioning, such as the rigorous developmental process of the pDA. Future research should focus on explaining the heterogeneous results regarding the efficacy of pDAs in different contexts and on ways how to optimally support other subgroups of women deciding about BR who were excluded in this project. Other strategies to implement shared decision making beyond the usage of a pDA, such as training of healthcare professionals in their SDM skills, should be undertaken to further optimize the decision-making process regarding BR. In clinical practice, efforts should be made to further optimize and maintain the pDA and on nationwide implementation of the tool in routine clinical practice.