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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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Citation

Stege, J. A. ter. (2024, May 28). *Supporting women with breast cancer in making an informed decision about immediate breast reconstruction: the development and evaluation of a patient decision aid*. Retrieved from <https://hdl.handle.net/1887/3754781>

Version: Publisher's Version

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Note: To cite this publication please use the final published version (if applicable).



Chapter 1a

Introduction

IN SHORT

Women undergoing mastectomy as a treatment for invasive breast cancer or ductal carcinoma in situ often face the decision of whether or not to have breast reconstruction. This decision can be challenging, particularly given the short and stressful period following a cancer diagnosis. Patient preferences play a crucial role in this decision, and it is essential to provide women with the information and support to make the best decision for their individual circumstances. In this project, we aimed to support breast cancer patients in making an informed decision about immediate breast reconstruction by developing and implementing an online patient decision aid. Additionally, we aimed to evaluate the efficacy of this online patient decision aid in reducing decisional conflict compared to a widely available information leaflet.

BREAST CANCER

Breast cancer is the most common cancer worldwide (1, 2). Incidence rates are still increasing. In the Netherlands, in 2022 over 15.000 women were diagnosed with invasive breast cancer and over 2.300 women were diagnosed with non-invasive breast cancer, known as ductal carcinoma in situ (DCIS) (3). In Western European countries, including the Netherlands, one out of seven women develops breast cancer in her lifetime (2, 3). Thanks to improvements in treatment and national screening, the chances of survival have greatly increased (3). In the Netherlands, the 10-year survival rate of all patients with breast cancer increased from 40% in 1970 to 80% in 2020 (3). This increase in survival has made quality of life issues after cancer and its treatment more important.

SURGICAL TREATMENT OF BREAST CANCER

Approximately 90% of all breast cancer patients undergo surgery (3). Surgical treatment options include breast conserving surgery, in which only the tumor and some of the surrounding tissue is removed, or mastectomy, in which the entire breast tissue including the tumor is removed. Although there is a trend towards more breast conserving treatment, still around 25% - 40% of breast cancer patients undergo a mastectomy (3-6). In the Netherlands, around 40% of patients with invasive breast cancer and 30% of patients with DCIS undergo a mastectomy (7). In addition to surgery, (loco)regional radiotherapy, and/or systemic therapies such as chemotherapy, antihormonal therapy, and targeted therapy may be indicated. A patient's treatment plan largely depends on tumor and clinical characteristics, as well as patient preferences.

BREAST RECONSTRUCTION AFTER MASTECTOMY

Breast reconstruction (BR) after mastectomy is a surgical procedure to recreate a breast. Surgical treatment, and especially mastectomy, can negatively impact psychosocial outcomes such as body image and sexual functioning (8-11). To restore breast contour after mastectomy, and potentially improve psychosocial outcomes, women may opt for BR. Breast reconstruction is oncologically safe and does not increase the risk of recurrence, nor does it affect the ability to detect a recurrence (12-18). Breast reconstruction can be performed in different ways and on different timings (see 'Breast reconstruction choices and options').

Whether or not a patient is eligible for BR after mastectomy depends on multiple factors. There are only few absolute contraindications to BR after mastectomy. According to Dutch guidelines: *“Any request for breast reconstruction should be seriously considered; only metastatic disease with a short life expectancy should be considered a contraindication”* (19). However, contraindications may apply to specific types of reconstruction. Furthermore, certain factors increase the risk of complications or poor outcomes of reconstruction. These factors include smoking, high body mass index, larger cup size, comorbidities such as diabetes and high blood pressure, bilateral surgery, age > 55 years, prior radiotherapy on the breast and adjuvant radiotherapy (20-23).

1a

BREAST RECONSTRUCTION CHOICES AND OPTIONS

Patients who will have mastectomy for invasive breast cancer or DCIS face a choice to have an immediate BR (in the same surgery as the mastectomy) or not. Patients who do not have immediate BR, can consider to have BR later in an extra surgical procedure (delayed BR) or remain without BR (no BR). Breast reconstruction can be performed in different methods. These methods can be divided into implant-based BR and autologous BR or a combination of both techniques. The technique of implant-based BR involves using silicone or saline breast implants, preceded or not by a temporary tissue expander, to restore the breast mound. The technique of autologous BR involves using patient's own fat and skin tissue from another part of the body, such as the abdomen, back, or buttock, to transplant to the thoracic wall and create a new breast. The BR options of an individual patient depend on multiple factors such as a patient's availability of donor tissue, health status, and her oncological treatment (19).

PROS AND CONS OF THE OPTIONS

All BR options after mastectomy have their own pros and cons. These pros and cons are numerous. In the following paragraph, some examples of pros and cons are provided to illustrate the decision. First, BR after mastectomy can benefit patients' quality of life and psychosocial functioning including women's sexual functioning, body image, and feeling of femininity (4, 24-29). However, BR increases the risk of surgical complications and generally leads to higher postoperative pain compared to mastectomy without BR (30-32). *Immediate BR* prevents women from being without a breast for a period of time and, if considered oncologically safe, offers the opportunity to save their own skin envelop and nipple. However, the decision for immediate BR needs to be made in a limited time period before mastectomy and recovery time from the surgery is longer compared to mastectomy alone (12). *Delayed BR* provides women more time to decide for reconstruction. However, it requires at least one extra surgery compared to immediate BR, and may require adding (skin) tissue from other body parts and consequently scarring. *Implant-based BR* is a relatively simple surgery and performable by all plastic surgeons, but looks and feels less natural compared to autologous BR (19). *Autologous BR* leads to a more natural-looking and feeling breast compared to implant-based BR, but requires longer and more complex surgery and entails additional scarring to the donor site (19, 33).

NUMBERS OF BREAST RECONSTRUCTION

Since the first attempt at BR in 1895, significant advancements have been made in breast reconstructive techniques (34). Over the past decades, the number of women choosing BR, particularly *immediate* BR, has been increasing (4, 35-40). In the Netherlands, in 2020, 29% of breast cancer patients and 46% of women with DCIS undergoing mastectomy had *immediate* BR (41). Around 10% of breast cancer patients undergoing mastectomy choose *delayed* BR (42-44). However, there is a substantial variation in immediate BR rates across hospitals and geographical locations, both nationally and internationally (40, 45-48). In Dutch hospitals, immediate BR rates range from 0-75% for invasive breast cancer and 0-86% for DCIS (41). Besides case-mix variation, hospital organizational factors and attitudes of clinicians towards immediate BR, information provision has been identified as possible causes of this hospital variation (45, 49-51). A study among Dutch women who had mastectomy found that being informed about immediate BR increased the odds of receiving immediate BR fourteen-fold (51).

DECISION MAKING ABOUT BREAST RECONSTRUCTION

Decision making about whether to have BR is a preference-sensitive decision that needs to be driven by patients' informed preferences (21). Dutch guidelines recommend discussing the possibility of immediate BR with every patient prior to mastectomy (52).

Decision making regarding BR can be complex and challenging for women. Women often have to consider multiple options, each with numerous advantages and disadvantages. The outcomes of the decision are uncertain and the decision will have a lasting impact on women's lives. Furthermore, women need to make the decision about immediate BR within a limited time period between diagnosis and surgery (47). During this period, it is common for patients to feel distressed and anxious (53-55), which may limit their cognitive functioning and decision-making skills (56, 57).

Women's motives to have BR include the expectation of increased sense of femininity, a strive for symmetry, and prevent limited clothing possibilities (58). Common reasons for women to omit BR are a strive for fast recovery and preventing potential complications (58).

There remains an unmet need for support in the context of decision making about BR, as both knowledge and decisional preparedness are suboptimal among patients deciding about BR after mastectomy (58-61). One study found that less than half (43%) of participants made a high-quality decision regarding BR, defined as having knowledge of important BR facts and undergoing treatment in accordance with one's personal preferences (62). Women have reported not to be aware of the full range of BR options (58).

Previous studies have highlighted the importance of high-quality, realistic preoperative information and decisional support to enable patients to make a long-term satisfying decision about BR (63-70). A study investigating women's expectations regarding their wellbeing immediately after BR found that often expectations were unmet, and that women with unmet

expectations were more likely to experience decisional regret (71). Although most women are satisfied with their reconstructed breast, and decision regret is generally low (72), a minority of women experience mild to moderate levels of regret (63, 73).

SHARED DECISION MAKING

For preference-sensitive decisions such as the decision about immediate BR, shared decision making (SDM) is increasingly advocated as the preferred approach (74, 75). Shared decision making is a patient-centered approach in which physicians and patients collaborate and share information about the best available evidence and patient preferences, values, and circumstances to reach a health decision (74, 76, 77). In this approach, physicians are considered experts about the medical evidence, and patients are considered experts about what matters most to them (78). By engaging patients in the decision-making process, healthcare professionals can help patients make informed decisions that align with their goals and preferences. Studies to objectify the levels of SDM during clinical encounters in oncology, including breast cancer care, suggest that there is room for improvement (79-82). Most patients prefer to be actively involved in decision making, and this has increased over time (83). In women with early-stage breast cancer, only 44-51% of patients achieve the degree of participation they desire (84-87). Practicing SDM is therefore much needed and even demanded by the government, policy makers, patient advocacy and healthcare organizations (78, 88).

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PATIENT DECISION AIDS

Patient decision aids (pDAs) are tools developed to support the process of SDM between patients and physicians, as adjuncts to standard counselling (89). They explicitly describe the choice that patients face, provide evidence-based information about treatment options including their pros and cons, and support in clarifying personal values relevant to the decision (89). Over the last two decades, there has been an increase in the development and evaluation of pDAs across a range of medical and health contexts (90).

The efficacy of pDAs is most frequently evaluated with decisional conflict as the primary outcome (91). Decisional conflict is defined as a state of uncertainty about the course of action to take (92). Behavioral manifestations of decisional conflict include feeling unsure about what to choose, wanting to delay the decision, questioning what is important, feeling distressed, wavering between the options, and constantly thinking about the options (93).

Patient decision aids for a variety of treatment decisions have shown to reduce decisional conflict and increase knowledge and insight into personal values related to the decision (90, 94). Although there is growing evidence on their efficacy, the implementation of pDAs in clinical practice is only progressing slowly, and remains a challenge (95, 96). Frequently reported barriers include a lack of time perceived by clinicians (95, 97, 98), and a lack of ownership of the pDAs (95). Strategies suggested to support implementation include linking pDAs to hospitals' electronic medical records, reimbursing their use, and making the use of pDAs a

quality of care indicator (99). For more detailed information on the definition, efficacy and current issues regarding pDAs, we refer to our description in **Chapter 1b**.

SHARED DECISION MAKING IN BREAST RECONSTRUCTION

Worldwide, there are few interventions to support patient decision making about BR (100). Most interventions facilitate decision making about BR in general, and only a few specifically focus on the decision about immediate BR. A systematic review assessing the effectiveness of these interventions found that patient satisfaction and involvement in decision making improved following pDA exposure, yet, results on other outcomes were mixed (100). In three out of five studies, the intervention reduced decisional conflict (101-103), in two out of three studies the intervention reduced regret (101, 104), and in one out of three studies the intervention improved knowledge (105). However, most studies were methodologically flawed (e.g., small sample size, single-center design), and neglected to control for potential confounding variables such as complications (100, 106). More research is needed to develop and evaluate effective interventions to support patient decision making about BR (100).

AIM OF THIS THESIS

The aim of this thesis was to support breast cancer patients in making an informed decision about immediate BR after mastectomy, by developing and implementing an online pDA. Additionally, we aimed to evaluate the efficacy of the pDA in reducing decisional conflict, and in improving the decision-making process, decision quality, and patient-reported health outcomes. Furthermore, we aimed to get insights into process outcomes and important factors for sustainable implementation of the pDA by evaluating end-users' usage of and satisfaction with the tool.

The research questions addressed in this thesis are:

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 breast reconstruction, 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?

OUTLINE OF THIS THESIS

Chapter 1b provides general background information on pDAs, including a definition of a pDA and a short summary of evidence on their efficacy and status of implementation. **Chapter 2** describes the development of our pDA, including the information needs of patients and healthcare professionals regarding the decision about BR and the tool's acceptability and usability among its end-users. **Chapter 3** describes the protocol of our randomized controlled trial to study the efficacy of the pDA. **Chapter 4** provides the efficacy of the pDA in reducing decisional conflict and in improving the decision-making process, decision quality and patient-reported health outcomes. **Chapter 5** reports on the experiences of patients and healthcare professionals with the pDA in terms of use and satisfaction. **Chapter 6** describes the general discussion, including strengths and limitations, and future directions for research and practice.

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