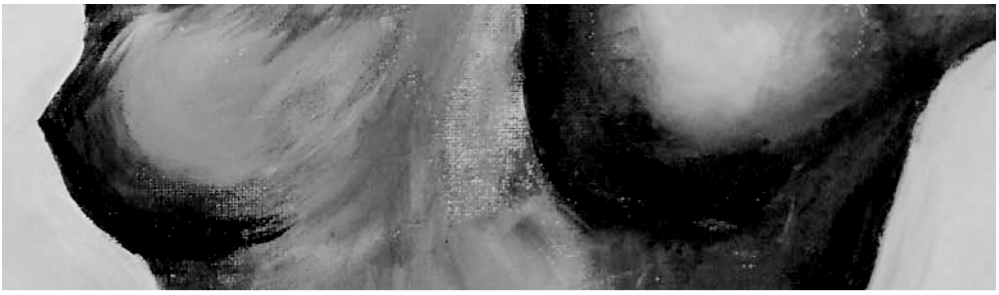
CHAPTER 8 SUMMARY, DISCUSSION AND IMPLICATIONS



1. Summary

1.1. Motivations for breast reconstruction

The motivations of women who opted for either implant or DIEP flap breast reconstruction (BR) after prophylactic or therapeutic mastectomy, were qualitatively explored by using interviews (Chapter 2). Before surgery, women were asked why they had opted for reconstruction and why they preferred a certain method. We observed that women generally decided in favour of reconstruction because they felt too young to live without breasts, wanted to avoid wearing an external prosthesis, and wished to feel feminine and self-confident which is in congruence with previous findings [1-3]. Motives to specifically opt for implant reconstruction were often primarily related to practical issues: preferring a short recovery period and a minimum number of scars in order to regain their daily life as soon as possible. Whilst they preferred a quick recovery, these patients may not have been aware of the fact that a complete BR course can take 21 months, which was the mean duration to the end of the BR in this study. Women who chose DIEP flap BR especially focused on regaining a breast that resembles their own lost breast as closely as possible. In addition, they had the idea that the complication risk of DIEP flap BR was lower compared to implant BR. Furthermore, they felt DIEP flap BR would offer long-term benefits and less secondary operations, whereas in fact the number of reoperations following complications after a mean follow-up period of 21 months was comparable in both groups (Chapter 4 and 5). Some patients preferred DIEP flap BR as it offered the additional advantage of an abdominoplasty. Nevertheless, it was apparent that next to personal motivations, clinical variables (such as therapeutic or prophylactic mastectomy, breast irradiation, availability of plastic surgeons with microsurgical expertise and long waiting lists) need to be taken into account when considering a certain type of BR, as these can have a marked influence in the decision making process as well.

1.2. Information seeking regarding breast reconstruction

As information provision concerning BR is not standardized in our country, being properly informed also depends on patients' information seeking behavior. Therefore, before surgery, we explored women's coping style and information seeking behavior (Chapter 3). We observed that women who had an active coping style and who were independent in their decision-making opted for DIEP flap BR. Women who were less well-informed and who depended more on their surgeon with regard to their decision opted for implant BR rather than DIEP flap BR. Before their operation, forty percent of the implant BR patients was not aware of the possibility of undergoing reconstruction with autologous tissue. To be well-informed about breast reconstructive surgery, an active coping style and independent information seeking was required, as not all women were sufficiently informed by their surgeon.

1.3. Complications after breast reconstruction

We found an overall complication rate of 40% after BR. These complications had a distinct impact on distress one month after BR (Chapter 4), when anxiety and cancer distress

significantly declined, but depression significantly increased. Forty percent of the patients with complications reported high levels of anxiety, depression and cancer-specific distress. Furthermore, we found a distinct difference between patients with implant and DIEP flap BR, in which the former were more anxious and had more cancer-specific distress, before their operation. This effect might have been affected by the timing of BR, as more women with implant BR underwent immediate reconstruction, meaning they had to undergo therapeutic mastectomy for breast cancer as well, ultimately resulting in higher cancer-distress.

After completion of the full BR course, anxiety decreased and depression was not significantly different from baseline levels. Both mean anxiety and depression levels were within the normal range (Chapter 5). Mean cancer distress was above the cut-off score before undergoing BR, but this significantly decreased, to normal levels, at the end of BR. In the long term, at the 21 months follow-up, complications and subsequent surgery generally did not lead to increased anxiety, depression or cancer distress, however, a permanent loss of BR (total removal of the reconstructed breast) did. The total loss of BR was significantly related to more depression and more cancer distress. Remarkably, women who had lost their BR already had higher cancer distress before undergoing BR. Younger patients had more anxiety and depression and their cancer distress was significantly higher at the end of BR. Furthermore, a longer period since mastectomy appeared to result in more anxiety and depression at the end of BR. These findings highlight that younger patients and women, who had the diagnosis of breast cancer a longer time ago, may still experience psychological adjustment problems even after the completion of the total BR course.

Before surgery, risk factors for developing higher psychological distress should be checked and women at risk for psychological distress should be carefully monitored after surgery with regard to their psychological wellbeing.

1.4. Body image and sexual satisfaction after breast reconstruction

The impact of either implant or DIEP flap BR on body image and sexual relationship satisfaction was prospectively investigated in women with delayed BR after a history of breast cancer (Chapter 6) and in healthy women with immediate BR after bilateral prophylactic mastectomy (Chapter 7). In the first group body image improved significantly after 20 months. A better body image was related to a better general mental health, less cancer distress and a higher partner relationship satisfaction. Sexual relationship satisfaction improved as well and a better partner relationship satisfaction was positively related to sexual relationship satisfaction; however, women who had hormonal therapy were less satisfied with their sexual relationship. No differences in body image and sexual relationship satisfaction were found with regard to the type of BR.

In healthy women, at risk for developing hereditary breast cancer, who underwent bilateral prophylactic mastectomy with immediate BR, body image significantly declined after 6 months and after 21 months body image still tended to be worse compared to the body image at baseline. The sexual relationship satisfaction tended to decline up to 21 months. However, the overall scores were within the normal ranges for body image and sexual satisfaction. Body image was positively related to general physical health, and negatively

to cancer distress. After completion of the total BR course, a significant subgroup reported that their breasts felt unpleasant, that they were not satisfied with their breast appearance and that they felt embarrassed about their naked bodies. Regardless of surgery, both before and after the operation one third indicated they felt uncomfortable when touched by their partner. These results indicate the psychosocial impact of bilateral prophylactic mastectomy with BR in healthy women should not be underestimated.

2. Discussion

Initially, the aim of this study was to compare the psychological impact of two types of BR: implant and DIEP flap BR in women who had breast cancer or who decided to have prophylactic surgery after being identified as carrier of a BRCA1/2 mutation. With a prospective multi-center design about 100 patients with implant and 100 patients with DIEP flap BR would be included. However, at the start of the study, many barriers were presented which made patient inclusion complicated. Each hospital appeared to have its favourite method of BR and showed a preference for offering BR either immediately or directly after mastectomy. Bilateral prophylactic mastectomies were generally performed in the academic hospitals. However, as patients were included in nine different hospitals, including academic centers as well as peripheral hospitals, patient inclusion for this study can be considered as representative for the Dutch patient population. Nevertheless, the reality is that the BR patient group is highly heterogeneous which would complicate statistical analyses and generalization of the study results.

Patient inclusion resulted in a study sample of 202 women who underwent BR. A total of 152 women had mastectomy as a treatment for breast cancer of whom 31 (20.4%) underwent contralateral prophylactic mastectomy as they were at high risk for developing breast cancer in the other breast as well. The remaining 50 women had bilateral prophylactic mastectomy to prevent the development of breast cancer as they had an increased risk for developing familial breast cancer. In total, about half of the women received implant BR and the other half had DIEP flap BR. However, due to practical (long waiting lists) as well as clinical (unavailability of autologous tissue) reasons bilateral prophylactic mastectomy was seldom followed by DIEP flap BR and therefore only concerned 10 out of 50 women in this sample. Consequently, the majority of these patients had implant BR. This impeded the statistical analyses from comparing the impact regarding the type of BR within the prophylactic group.

Next to the uneven distribution of the type of BR, the timing of BR was also unequally divided in the implant and DIEP flap group. Because DIEP flap BR requires an operative time of about four hours per breast, depending on the number of microsurgeons involved, bilateral prophylactic mastectomy followed by DIEP flap BR would take at least eight hours of surgery time, including closing of the abdominal donor-site. This requires the availability of an oncological surgeon, a plastic and reconstructive surgeon with microsurgical skills, a team of operating theatre personnel and enough theatre time on one day. However, the availability of microsurgeons with skills in perforator flap surgery is low. These practical limitations make it impossible to perform bilateral DIEP flap BR on a large scale, which is one

of the reasons why after bilateral (prophylactic) mastectomy the most commonly performed BR method is immediate implant BR [4;5].

Due to these difficulties a direct comparison between women with either implant or DIEP flap BR was strongly restricted. The difference between the types of BR was statistically measured by including the type of BR as a covariate in the longitudinal analyses. Nevertheless, we found that the type of BR was generally not related to most psychosocial outcomes after BR. As DIEP flap BR was generally performed as a delayed reconstruction method whereas implant BR was more commonly performed immediately after mastectomy, the role of the timing of BR may have been of great influence. Therefore, to specifically measure the impact of each type of BR, future studies should focus on an equal distribution of women with immediate and delayed BR for each BR type. It is to be expected that this type of patient inclusion would take many more years, to include a statistically acceptable sample size of women with DIEP flap BR after bilateral prophylactic mastectomy.

Ultimately, as each hospital has its own commonly performed type of BR, patient information provided before their operation is likely to have been biased. In Chapter 2 and 3 we found that not every patient was well informed regarding the possibility of implant BR or BR with autologous tissue. Autonomous patients and active information seekers chose the more sophisticated method of DIEP flap BR. In Chapter 5 it was demonstrated that women with DIEP flap BR had an overall higher satisfaction rate with the aesthetic end result compared to women with implant BR. This was expected as it is well-known that autonomous, aware patients are better-informed and have more realistic expectations, ultimately resulting in higher satisfaction with their decision afterwards [6-12]. On the other hand, cognitive dissonance [13] can lead to higher satisfaction as well: their intensive search for complete information and their physical efforts to undergo DIEP flap BR may have resulted in a positive attitude afterwards, reinforcing the notion that all the effort had been worth it.

Women with implant BR, the most commonly performed BR method, relied more heavily on their surgeon's advice regarding their decision for BR. In the interviews it appeared that some women were not prepared to go to a different hospital to get an autologous BR method, as for example a DIEP flap. As already mentioned, this technique requires microsurgical expertise and special education for the reconstructive surgeon and this expertise is only available in specialized centers. This availability consequently resulted in long patient waiting lists for DIEP flap BR, which in turn was a further restriction for some patients. However, Damen et al. demonstrated that aesthetics and the complication risk were of greater importance than the long waiting lists in the decision for BR [14]. Nevertheless, the results of this study demonstrate that standardized information provision regarding BR options, and availability of the different techniques per hospital, is needed for patients to enable them to make the best decision.

As mentioned, autologous BR requires highly skilled and qualified surgeons and the operation takes a long time, resulting in much larger costs compared with implant BRs. Health care costs are increasing rapidly in the western world and efforts are being made to reduce these costs. Expensive operations, such as autologous BR should be given due credit

for their ability to improve the quality of life compared to, for example, implant BR and more research on the (cost-) effectiveness of autologous BR, using QALYs (Quality Adjusted Life Years) is needed [5].

The impact of the overall complication rate after BR (40%) was investigated in Chapter 4 and 5. A major limitation of these studies was that the questionnaires were not sent directly after a complication occurred and consequent additional surgery was conducted, therefore a causal relationship could not be identified. It was demonstrated that women with a failed BR had worse psychosocial outcomes. However, the clinical experience is that currently these women are rarely followed up by most hospitals, except for the period until all surgical wounds have healed. Once it becomes clear that the plastic surgeon cannot offer a new BR during this period, women often leave the outpatient clinic without a future planned follow-up consultation or the offer of psychological counseling.

In Chapters 6 and 7 the impact of BR on body image was described. A study-specific questionnaire was used which was adapted from the previous studies of our research line [15;16]. Some questions were revised and other questions were added designed specifically to address the impact of BR. We collected a total number of observations on the body image questionnaire of n=442, which provided more statistical power compared to the previous studies (n=14 and n=19) [15;16]. A new three-factor solution revealed different outcomes than Lodder et al. [15] had reported, and therefore study results could not be easily compared to previous study findings [15-17].

We decided not to include a control group of women undergoing mastectomy without BR as it had been previously demonstrated that generally psychosocial outcomes do not differ between women with BR and patients without BR [18-32]. In addition, our data on the standardized and validated questionnaires could be compared with normative data to place the data in context. Motivations whether to choose for BR or not were also previously explored, however to compare motivations for either implant BR, DIEP flap BR or no BR, we interviewed a small sample of women who had not undergone BR.

Undergoing the process of having breast cancer and/or dealing with an increased familial breast cancer risk requires many resources from the patient as well as from the partner. The intimate relationship can be negatively influenced after mastectomy [33-50]. We measured the course of overall sexual and partner relationship satisfaction during the process of BR using the validated NRV questionnaire (Dutch Relationship Questionnaire) [51]. As this instrument was designed only for couples or persons with a partner, single women were excluded. Because mastectomy and BR will undoubtedly impact single women's intimate relationships, future studies need to assess sexuality outcomes in this group well.

Psychological distress and its predictors were evaluated by means of both global distress measures (anxiety and depression) as well as a breast cancer-specific questionnaire, as an indicator for psychological adjustment. These instruments have been frequently used in similar studies world-wide and their psychometric values have been well established. However, these measures may not have been sensitive enough to capture the specific concerns and personal issues of our study population as has been recently demonstrated by Vos et al [52].

2.1. Implications for future studies

This prospective multi-center study regarding two types of BR represents the heterogeneous patient population undergoing BR for breast cancer. The majority of patients had good psychosocial outcomes after both BRs. However, subgroups of patients reported worse outcomes, such as women who had experienced a loss of the reconstructed breast(s). Remarkably, we noticed that psychosocial issues after having BR are hardly discussed and explored during routine follow-up consultations by medical professionals. Future studies should focus on the care and communication with psychologically vulnerable patients.

Future studies aiming to evaluate the psychological outcomes after therapeutic and prophylactic mastectomy, and/or being at risk for hereditary breast cancer should also include outcome measures specific to the field of mastectomy and hereditary breast cancer. In view of the potential impact of mastectomy and BR, the Breast-Q would be a worthwhile addition [53]. For the specific impact hereditary breast cancer has on self-concept, we support the idea of Esplen et al. [54] that it would be particularly interesting to use the BRCA Self-Concept Scale as an outcome measure for this patient group. In addition, we recommend to include validated questionnaires regarding intimate or relational aspects for single persons as well.

Furthermore, more prospective studies with a follow-up period beyond 18 months to assess the psychosocial impact of BR are needed [55;56]. Most prospective studies include a maximum follow-up of 12 months [27;57-61], therefore a longer follow-up period after BR is recommended for future research to explore longer term outcomes after BR as well. Also, the specific issues and help needs of patients with regard to intimacy, including single women as well as partnered patients together with their partners, should be further scientifically explored.

Overall, we have to bear in mind that quantitative research reduces the individual impact to mean group scores, whereas in clinical practice we should focus on the individual and inter-relational impact. This means the individual impact of BR on body image, sexual and partner relationship satisfaction, anxiety, depressive feelings and cancer worries. Qualitative studies are therefore a useful addition to the quantitative data. Our range of research on BR will be expanded in the near future and will include qualitative interviews as well with patients and partners.

2.2. Recommendations for the clinical practice

Based on the study findings, participants' comments during the follow-up and patient reactions at the patient day, organized at the end of the study, our recommendations for the clinical practice are the following:

- include the partner from the beginning in the medical consultations
- stimulate each patient to be assertive; encourage her to explicitly ask for the information she is missing during the process of mastectomy with BR
- before the operation, show the patient pictures of good and moderate BR results (organize show and tell sessions)

- before the operation, inform the patient about the complication risks and possible psychological adjustment problems, particularly regarding the period shortly after surgery
- involve a case-manager (e.g. the mamma-care nurse) in the mastectomy and BR process from before surgery to the end of BR
- routinely provide, before the operation, a psychological consultation for the patients who are about to undergo prophylactic mastectomy, in order to inform and prepare these often young women on possible (adverse) changes in body image and intimacy
- after the operation, offer a consult with a psychologist to the women who underwent prophylactic mastectomy
- the impact of severe complications on general wellbeing should be addressed by the surgeon or mamma-care nurse
- at any time, the mamma-care nurse and other specialists involved should refer patients with persisting psychological adjustment problems to a psychologist.
- emphasize that psychological help remains available during the whole recovery process
- Inform patients about patient organizations and websites (BVN, Pink Ribbon; www.borstkanker.nl; www.BRCA.nl; www.pinkribbon.nl)

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