Quality of Life after Bilateral and Contralateral Prophylactic Mastectomy with Implant Reconstruction

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Abstract

Background: Prophylactic mastectomy is an effective approach to breast cancer risk reduction in patients at high risk. Further studies using standardized measures for quality of life are needed to better understand the effect of prophylactic mastectomy on individual patients and, thereby, allow for better patient counseling and selection. **Methods:** In this prospective study patients undergoing bilateral mastectomy were asked to complete the BREAST-Q questionnaire before and 1 year after surgery. All patients underwent bilateral mastectomy with implant-based breast reconstruction. Patient- and surgery-related information was collected in a database. **Results:** In total, 48 patients underwent bilateral skin-sparing mastectomy. Of these, 29 (60.4%) suffered from breast cancer. A 2-stage reconstruction with intermediate expander implantation was conducted in 19 (39.6%) patients. All patients completed the BREAST-Q questionnaire. The domain “psychosocial well-being” was significantly improved from a mean score of 74.98 preoperatively to a postoperative score of 81.56 ($p = 0.021$). In contrast, the domain “physical well-being” dropped –8.38 points on average to a postoperative score of 74.96 ($p < 0.001$). Interestingly, pa-

tients with the lowest preoperative score in the domain “satisfaction with breast” showed the greatest increase after surgery (50.31 vs. 67.25, $p < 0.001$). On the contrary, patients with the highest preoperative values experienced the strongest decrease in satisfaction (91.60 vs. 75.27, $p = 0.012$). **Conclusion:** Implant-based prophylactic mastectomy leads to good quality-of-life results in patients at high risk for breast cancer. Especially, patients with a low preoperative satisfaction with their breasts have a significantly higher chance of experiencing substantial improvements in their quality of life.

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Introduction

Prophylactic mastectomy (PM) is the therapeutic option offering the strongest breast cancer risk reduction for women at high risk such as those with BRCA1 or BRCA2 mutations or a strong family history of breast cancer [1]. Women with BRCA1 or BRCA2 mutations have a lifetime risk of developing breast cancer of 40–80% [2]. Furthermore, patients with BRCA1/BRCA2 mutations already diagnosed with breast cancer have an elevated risk of contralateral breast cancer ranging between 20 and 80%. According to a recent meta-analysis, bilateral PM (BPM) as well as contralateral PM (CPM) for patients al-

ready diagnosed with breast cancer offer a strong risk reduction of 90 and 93%, respectively [1]. Consequently, there has been an increasing demand for these procedures over the last years. However, these surgeries might be associated with perioperative complications as well as severe affection of the body image, which might impact the patient's psychosocial, physical, and sexual well-being [2–8]. Besides extensive experience in the field of PM, reliable data of multiple studies is mandatory for comprehensive counseling of patients. However, most studies analyzing satisfaction and quality of life after BPM or CPM have only evaluated postoperative results. A few studies have recorded preoperative values which allow for sufficient evaluation [9–11]. The publication by McCarthy et al. [8] reports a particularly important study. They assessed the patients' satisfaction and quality of life using the BREAST-Q questionnaire in 204 patients with BPM (implant-based and autologous reconstruction). The BREAST-Q questionnaire is a patient related outcome instrument on satisfaction and quality of life designed for patients undergoing breast related surgery [12]. McCarthy et al. [8] were able to show that the domains "psychosocial well-being" and "satisfaction with breast" were significantly higher postoperatively compared to preoperative results. However, "physical well-being/chest and upper body" was significantly worse at 1 year follow-up. More studies, specifically focused on implant-based surgery, evaluating pre- and postoperative satisfaction with breast cancer specific questionnaires are urgently needed to better understand the effect of PM on the patients' quality of life. Especially, CPM for patients with already diagnosed breast cancer has not been evaluated in most studies. In this study, we aimed to analyze the effect of BPM and CPM for patients with high risk for new or additional breast cancer on satisfaction and quality of life using the BREAST-Q questionnaire.

Methods

Patients

Between 2014 and 2016 patients at high-risk for breast cancer who sought for bilateral postmastectomy breast reconstruction were offered to participate in this study. Inclusion was restricted to patients undergoing bilateral skin-sparing mastectomy with direct implant- or expander-based reconstruction. Patients were excluded if they declined participation or if they have already been included in another surgical study. BPM in patients with already diagnosed breast cancer is further summarized under the term CPM. Before and 1 year after the PM, the participating women were asked to complete the BREAST-Q questionnaire.

Patient- and procedure-related information was collected from the patient's medical records and archived in a database.

Surgery

In all of the patients bilateral skin-sparing or nipple-sparing mastectomy was performed with immediate implant or expander

reconstruction in a submuscular position. We used anatomical (i.e., 312, 322, 323) textured implants from Mentor (Mentor Worldwide LLC, Irvine, CA, USA). Mastectomy and reconstruction were done in one procedure by the senior author. We used acellular dermal matrix or a mesh in order to add an extra layer of tissue between the expander/implant and the skin and to fix the implant position as described in the literature [13, 14]. As acellular dermal matrix we used Strattice (Allergan, Dublin, Ireland) and as mesh we applied TiLOOP® Bra (pfm medical, Cologne, Germany) or TIGR Matrix (Novus Scientific, Uppsala, Sweden). For women with a larger breast size a wise pattern mastectomy with a tissue expander using a dual plane of vascularized tissue coverage was used as published by other authors [15, 16]. Nipple-sparing mastectomy, nipple reconstruction, and tattooing were offered to the patients after a detailed explanation of the risks and benefits.

BREAST-Q

The BREAST-Q questionnaire is a patient-related outcome instrument that includes various modules regarding satisfaction and quality of life after breast-related surgery as described in by Pusic et al. [12]. We used the reconstruction module provided in German by the Mapi Research Trust (<https://mapi-trust.org/>). Answers were provided according to a 4- or 5-point ordinal scale. The results of the individual questions were summarized in a domain-specific score ranging from 0 (worst) to 100 (best) according to a provided protocol. Patients were invited for a follow-up examination at the office. A hard-copy of the questionnaire was handed out and a standardized photo was taken to document postoperative results.

Statistical analysis was performed using R (<http://www.cran.r-project.org>). Mean scores were compared using a paired *t* test. *p* < 0.05 was considered statistically significant.

Results

In total, 49 patients were asked to participate. One patient declined participation. We included 48 patients undergoing bilateral skin-sparing mastectomy in this study. All of the patients were at high risk for breast cancer (breast cancer-promoting genetic mutation or family history). BRCA1 and BRCA2 mutations were detected in 39 out of 48 (81.3%) patients. In total, 29 (60.4%) patients underwent surgery due to already diagnosed breast cancer. All breast cancer patients in this study were treated with additional CPM. Most cancer patients (44.8%) presented with T2 tumors. A 2-stage reconstruction with intermediate expander implantation was conducted in 19 (39.6%) patients. Synthetic mesh and acellular matrices were applied in 29 (60.4%) and 15 (31.3%) patients, respectively. In total, 30 (62.5%) patients opted for a nipple-sparing mastectomy. Of the remaining 18 patients, 9 received immediate reconstruction of the nipples with a modification of a CV flap. Of these, 3 patients decided to have a tattoo of the reconstructed nipple and an areola tattoo. One patient decided to have a tattoo of the nipple-areola complex without reconstruction of the nipple. The remaining 7 patients refused to have nipple reconstruction or tattoo. Perioperative complications occurred in 7

out of 96 (7.2%) breasts. Further details on the patients' characteristics, tumor characteristics, and surgical procedures are shown in Table 1.

All of the patients completed the BREAST-Q questionnaire before and 1 year after surgery. The results for the main domains are shown in Table 2. As indicated, the domain "satisfaction with breast" appeared to be slightly, but not significantly, improved after surgery, with a mean increase of 3.08 points ($p = 0.319$). Interestingly, the domain "psychosocial well-being" was significantly improved from a mean score of 74.98 preoperatively to a postoperative score of 81.56 ($p = 0.021$). In contrast, the domain "physical well-being/chest and upper body" dropped an average of -8.38 points to a postoperative score 74.96 ($p < 0.001$). The noncomparable postoperative domains "satisfaction with result," "with nipples," "with information," "with surgeon," and "with medical team" congruently achieved high results ranging from 61.10 points for "satisfaction with nipples" to 94.11 points for "satisfaction with surgeon."

Comparing patients undergoing BPM with patients already diagnosed with breast cancer, we did not observe significant differences regarding the different domains (data not shown). Analyzing pre- and postoperative results in the separate groups, we found a significant decrease in the domain "physical well-being/chest and upper body" for oncological patients from 83.41 to 73.66 ($p = 0.001$). This difference could not be observed in the PBM group. Table 3 displays the exact results.

Additionally, we thoroughly investigated how the postoperative domains depended on the preoperative results regarding the domain "satisfaction with breast." Table 4 shows the results. The entire cohort was divided into 3 subgroups depending on the score of the preoperative domain "satisfaction with breast." Interestingly, we observed a clear difference regarding the change in values between pre- and postoperative assessments. The third group with the lowest preoperative satisfaction showed the greatest increase after the operation (50.31 vs. 67.25, $p < 0.001$). On the contrary, the patients with the highest preoperative values experienced the strongest decrease in satisfaction (91.60 vs. 75.27; $p = 0.012$). Figures 1 and 2 show exemplary pre- and postoperative images of patients in the respective group. Similarly, we noticed a significant increase in scores regarding sexual well-being (48.06–66.39, $p = 0.03$) and unchanged scores regarding physical well-being/chest and upper body (66.50 vs. 67.07, $p = 0.729$) in the group of patients with the lowest preoperative satisfaction with the breast. In contrast, patients with the highest preoperative satisfaction reported unchanged scores regarding sexual well-being (82.64 vs. 83.36, $p = 0.843$) and decreased scores on physical well-being (100.00 vs. 82.93, $p = 0.002$). Of note, regarding absolute scores all postoperative scores in the high-satisfac-

Table 1. Patient characteristics

Age, years	39 (24–55)
BMI	24 (17–31)
History of diabetes	0 (0.0)
Active smoker	1 (2.1)
History of radiotherapy	1 (2.1)
<i>Surgery</i>	
Prohyalactic (BPM)	19 (39.6)
Breast cancer + CPM	29 (60.4)
Bilateral skin-sparing mastectomy	48 (100)
Uni- or bilateral nipple-sparing mastectomy	30 (62.5)
Expander/implant reconstruction	19 (39.6)
Direct implant reconstruction	29 (60.4)
Axillary lymph node dissection	2 (4.2)
Acellular matrix	15 (31.3)
Synthetic mesh	29 (60.4)
Vascularized dermal-subcutaneous pedicle	2 (4.2)
Complete muscular cover	2 (4.2)
Hospital stay, days	12 (7–24)
<i>Resected breast tissue</i>	
Right	242.5 (74.8–766.0)
Left	250.0 (70.9–792.0)
Expander volume, mL	270.0 (140.0–460.0)
Implant size, mL	295.0 (175.0–475.0)
<i>Tumor</i>	
Size	
pTis	2 (4.2)
cT1	11 (22.9)
cT2	12 (25.0)
cT3	3 (6.3)
<i>Adjuvant therapy</i>	
Chemotherapy	8 (16.7)
Neoadjuvant chemotherapy	18 (37.5)
Radiotherapy	5 (10.4)
<i>Complications</i>	
Major	12 (25.0)
Hematoma with revision	5 (10.4)
Implant loss	0 (0.0)
Implant rotation	1 (2.1)
Wound healing disorder with revision	1 (2.1)
Minor	
Wound healing disorder	1 (2.1)

Values are presented as medians (range) or numbers (%).

tion group were still higher compared to those of the low-satisfaction cohort. The results are shown in Table 4.

There were no recurrences during the study period.

Discussion

In this study we were able to show that patients undergoing BPM or CPM with 1- or 2-stage reconstruction experience significantly better BREAST-Q scores, regarding psychosocial well-being, 1 year after surgery. However, reduced scores were detected regarding physical

Table 2. Pre- and postoperative BREAST-Q scores for all of the included patients

Domain (<i>n</i> = 49, range 0–100)	Preoperative score	Postoperative score	Mean difference (95% CI)	<i>p</i> value
Satisfaction with breast	69.54±18.31	72.63±14.99	3.08 (9.24 to –3.07)	0.319
Psychosocial well-being	74.98±18.20	81.56±20.48	6.58 (12.12 to 1.05)	0.021
Physical well-being/chest and upper body	83.33±14.20	74.96±14.12	–8.38 (–4.22 to –12.53)	<0.001
Sexual well-being	61.53±15.35	69.19±21.44	6.89 (13.18 to 0.6)	0.033
Satisfaction with result		85.44±16.46		
Satisfaction with nipples		61.10±36.66		
Satisfaction with information		81.26±20.22		
Satisfaction with surgeon		94.11±11.46		
Satisfaction with medical team		87.94±18.98		

Values are presented as means ± SD unless otherwise stated. Bold numbers represent statistically significant values.

Table 3. Change in BREAST-Q results for prophylactic and oncological patients after surgery

Domain	Preoperative results	Postoperative results	Mean difference (95% CI)	<i>p</i> value
Oncological (<i>n</i> = 28)				
Satisfaction with breast	73.41±18.42	72.52±15.68	–0.90 (7.50 to –9.30)	0.828
Psychosocial well-being	74.79±18.24	80.38±19.42	5.59 (12.60 to –1.42)	0.113
Physical well-being/chest and upper body	83.41±13.14	73.66±12.45	–9.76 (–4.10 to –15.42)	0.001
Sexual well-being	59.65±15.40	67.71±18.82	6.62 (13.69 to –0.45)	0.065
Prophylactic (<i>n</i> = 21)				
Satisfaction with breast	63.63±16.94	72.79±14.30	9.16 (18.31 to 0.01)	0.050
Psychosocial well-being	75.26±18.64	83.37±22.43	8.11 (17.84 to –1.62)	0.097
Physical well-being/chest and upper body	83.21±16.06	76.95±16.52	–6.26 (0.28 to –12.80)	0.060
Sexual well-being	64.11±15.30	71.37±25.21	7.26 (19.40 to –4.88)	0.227

Values are presented as means ± SD unless otherwise stated. Bold numbers represent statistically significant values.

Table 4. Pre- and postoperative BREAST-Q results depending on preoperative values for the domain “satisfaction with breast”

	Preoperative result	Postoperative result	Mean difference (95% CI)	<i>p</i> value
Upper third (<i>n</i> = 16)				
Satisfaction with breast	91.60±10.65	75.27±18.07	–16.33 (–4.12 to –28.54)	0.012
Psychosocial well-being	96.92±4.05	95.46±7.73	–1.46 (3.26 to –6.18)	0.510
Physical well-being/chest and upper body	100.00±0.00	82.93±16.15	–17.07 (–7.67 to –26.47)	0.002
Sexual well-being	82.64±12.27	83.36±12.44	0.73 (8.69 to –7.23)	0.843
Lower third (<i>n</i> = 16)				
Satisfaction with breast	50.31±5.68	67.25±12.60	16.94 (23.94 to 9.93)	<0.001
Psychosocial well-being	53.60±5.54	68.13±25.16	14.53 (30.18 to –1.12)	0.066
Physical well-being/chest and upper body	66.50±8.71	67.07±11.91	0.57 (4.09 to –2.94)	0.729
Sexual well-being	48.06±5.46	66.39±21.97	18.33 (29.41 to 7.26)	0.003

Values are presented as means ± SD unless otherwise stated. Bold numbers represent statistically significant values.

Scores Breast-Q domain 'Satisfaction with breast'

	Patient 1	Patient 2	Patient 3
Preoperatively	43	48	53
Postoperatively	81	75	85

Fig. 1. Exemplary pre- (top) and postoperative (bottom) pictures of 3 patients with low scores in the preoperative domain "satisfaction with breast." The table shows the exact scores of each patient.

well-being/chest and upper body 1 year after surgery. We showed that patients with a high satisfaction with their breast in the preoperative questionnaire have a higher risk of reduced scores postoperatively. On the contrary, patients who are less satisfied with the preoperative examination are more likely to have improved scores postoperatively.

As mentioned in the Introduction, decision making regarding PM is a complex process. On the one hand we are aware of the strong breast cancer risk reduction of PM for women at high risk [1]. On the other hand these procedures are complex surgeries possibly associated with severe perioperative complications and have a potential impact on the body image and quality of life of the patients [2–8]. Healthy patients with an elevated breast cancer risk have the medically accepted choice to decline surgery and undergo screening [17, 18]. Additionally, most patients eligible for prophylactic surgery are young [19]. The effects on these patients' body image and quality of life might be different to those on older patients or patients already diagnosed with breast cancer [20]. All of these concerns have to be addressed during individual counseling. The advantages of PM have to be weighed

against the above mentioned possible negative effects. Therefore, more data is required to better select and counsel patients considering individual factors.

In our cohort, we saw major complications in 7 out of 96 (7.2%) breasts. These rates appear to be in line with those already published in various studies on BPM, which vary extremely depending on the selected surgical approach and follow-up [8, 21, 22]. All our complications could be treated without removing the implant. Our patients stayed comparably long in our hospital. This can be explained by our quite conservative postoperative management. Our patients stay in hospital until the drains are removed. We remove the drains if there is <30 mL of secretion per day.

From previous studies on PM we know that 50–100% of patients are satisfied with their result and 80–90% of patients are satisfied with their decision to have a PM performed [3–6, 9]. Regarding the patient's body image after PM, previous studies have reported different results ranging from increased to decreased scores in postoperative questionnaires [4, 5, 7]. A major limitation on a comprehensive comparison with most studies is the diversity of the applied questionnaires. There was a lack of specific

Scores Breast-Q domain „Satisfaction with breast“			
	Patient 4	Patient 5	Patient 6
Preoperatively	100	100	100
Postoperatively	100	78	65

Fig. 2. Exemplary pre- (top) and postoperative (bottom) pictures of 3 patients with high scores in the preoperative domain “satisfaction with breast.” The table shows the exact scores of each patient.

questionnaires for breast reconstruction before the BREAST-Q questionnaire had been introduced [12]. Focusing on one comprehensive questionnaire in future studies will definitely improve the comparability of the results from different studies. Also, after having analyzed the wide heterogeneity of the quality-of-life assessment tools used after PM, Razdan et al. [9] recommended in their review the use of the BREAST-Q questionnaire in future studies. Therefore, the use of this standardized breast-specific questionnaire on patients undergoing solely implant-based BPM and CPM makes our study unique.

In our study, we noted high scores (ranging from 81 to 88) regarding the postoperative items (“satisfaction with result,” “with information,” “with surgeon,” and “with medical team”) except for the domain “satisfaction with nipples” (score 61.1). Interestingly, comparing pre- and postoperative domains we also observed a slightly, but not significantly, improved score for “sexual well-being” and a significantly improved score for “psychosocial well-being.” The “physical well-being/chest and upper body” slightly decreased after surgery. Comparing our results to the only large study on PM which also used the BREAST-

Q questionnaire, we noticed similar values and trends except for the item “satisfaction with breast” [8]. Interestingly, the baseline score in the study by McCarthy et al. [8] was apparently lower (i.e., 59.3) than ours (i.e., 71.98). The baseline characteristics of the included patients were quite similar; McCarthy et al. [8] also included women treated with autologous breast reconstruction. This, however, should not affect preoperative BREAST-Q scores. In contrast to McCarthy et al. [8], we also included patients already diagnosed with breast cancer undergoing therapeutic mastectomy and CPM. Interestingly, we did not see any significant differences regarding the postoperative items related to the surgical procedure and result between patients treated with BPM or CPM. Patients already diagnosed with cancer appeared to have a higher preoperative “satisfaction with breast” (i.e., 74.54 vs. 68.57) as well as a stronger decrease in the domain “physical well-being/chest and upper body” (–8.86 vs. –2.76). There are no comparable studies on the difference between BPM and CPM using the BREAST-Q questionnaire with which or results can be compared. In the study by Altschuler et al. [23] using open-ended questions to assess satisfaction with the surgery, the percentage of pa-

tients with negative or disparate responses was twice as high for BPM (52%) compared to CPM (26%). Other groups reported good quality-of-life results after CPM which are comparable to those of BPM from other studies [24, 25].

To our knowledge, there is only one small study with 10 women correlating the preoperative satisfaction with the breast with postoperative outcomes [26]. According to our results, the information on preoperative satisfaction does have a significant influence on the postoperative results. Women highly satisfied with their breast preoperatively (domain score 91.60) experienced a significant decrease regarding the domains “satisfaction with breast” (-16.33 , $p = 0.012$) and physical well-being/chest and upper body (-17.07 , $p = 0.002$) and no change regarding “psychosocial” and “sexual well-being.” In contrast, in patients with a low satisfaction with their breast (domain score 50.31) we noticed a significant improvement in the domains “satisfaction with breast” (i.e., 16.94 , $p = 0.001$) and “sexual well-being” (i.e., 18.33 , $p = 0.003$). These results might be of particular importance when counseling patients before PM. Especially, patients with a low preoperative satisfaction with their breast have significantly higher chances of experiencing substantial improvements in their postoperative quality of life. Highly satisfied patients will more likely be less satisfied after surgery. However, in our study, they still reported good to excellent scores for body image and quality of life. In future studies it would be very interesting to look deeper into the reasons for a lower preoperative satisfaction with the breasts and the impact on postoperative results.

Due to the small groups, we did not test for the impact of nipple-sparing mastectomy on BREAST-Q outcomes [10, 11].

Finally, some limitations of this study have to be mentioned. With 48 included patients, we did not reach significance in some analyses. However, we report an average sample size compared to similar studies and our prospective assessment supports the reliability of our results. We report results from surgeries and counseling by one highly experienced surgeon. This led to good and reliable

results in this study. It has to be kept in mind when transferring our results into clinical practice that counseling, a physician-initiated discussion, complications, and postoperative results are surgeon dependent and they are associated with postoperative satisfaction [3]. In this study we reported a 1-year follow-up. The quality of life and complications might change over time. Therefore, further follow-up visits are planned to assess late effects.

Experts agree that patient counseling and patient selection before PM are the key to a high postoperative satisfaction and quality of life. Using the BREAST-Q questionnaire for preoperative assessment could improve the individual counseling and set reasonable expectations regarding the postoperative result.

Statement of Ethics

All of the patients provided informed consent. This study was approved by the institutional Ethics Committee.

Disclosure Statement

U.H.-B. participated in the ESSBR study. Patients from the EBSSR study were not included in this analysis. All of other authors declare no conflict of interests.

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Author Contributions

All of the authors materially participated in this research, were involved in the preparation of this article, and approved the final version. U.H.-B., R.K., and C.W. were involved in the study conception and design. U.H.-B., A.P., J.E., and C.W. were involved in acquisition of data. R.K., U.H.-B., and C.W. were involved in analysis and interpretation of the data. R.K. and U.H.-B. wrote the initial draft of this paper. R.K., U.H.-B., C.W., A.P., F.K., E.K., and J.E. were involved in critical revision of this work.

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