



The added value of immediate breast reconstruction to health-related quality of life of breast cancer patients



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ABSTRACT

Background: Postmastectomy immediate breast reconstruction (IBR) may improve the quality of life (QoL) of breast cancer patients. Guidelines recommend to discuss the option IBR with all patients undergoing mastectomy. However, substantial hospital variation in IBR-rates was previously observed in the Netherlands, influenced by patient, tumour and hospital factors and clinicians' beliefs. Information provision about IBR may have a positive effect on receiving IBR and therefore QoL. This study investigated patient-reported QoL of patients treated with mastectomy with and without IBR.

Methods: An online survey, encompassing the validated BREAST-Q questionnaire, was distributed to a representative sample of 1218 breast cancer patients treated with mastectomy. BREAST-Q scores were compared between patients who had undergone mastectomy either with or without IBR.

Results: A total of 445 patients were included for analyses: 281 patients with and 164 without IBR. Patients who had received IBR showed significantly higher BREAST-Q scores on "psychosocial well-being" (75 versus 67, $p < 0.001$), "sexual well-being" (62 versus 52, $p < 0.001$) and "physical well-being" (77 versus 74, $p = 0.021$) compared to patients without IBR. No statistically significant difference was found for "satisfaction with breasts" (64 versus 62, $p = 0.21$). Similar results were found after multivariate regression analyses, revealing IBR to be an independent factor for a better patient-reported QoL.

Conclusions: Patients diagnosed with breast cancer with IBR following mastectomy report a better QoL on important psychosocial, sexual and physical well-being domains. This further supports the recommendation to discuss the option of IBR with all patients with an indication for mastectomy and to enable shared decision-making.

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Introduction

Against the background of good prognosis and limited local treatment associated morbidity for primary breast cancer patients

who undergo curative treatment [1], attention shifts to maintaining quality of life as an important goal of care. Quality of life can be objectified through patient-reported outcome measures (PROMs). PROMs aim to assess the actual feelings and thoughts of a patient and help clinicians and patients to measure, interpret, and understand quality of life as perceived by the patient [2]. As such, it may enhance communication between clinicians and patients in shared decision-making. In addition, PROMs may be used for comparative effectiveness analyses and to monitor quality of care [3,4].

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Approximately 40% of patients with invasive breast cancer and 30% of patients with ductal carcinoma in situ (DCIS) undergo mastectomy in the Netherlands [5]. To restore the breast contour, breast reconstruction may be performed either at the time of initial breast cancer surgery (immediate breast reconstruction, IBR) or as a delayed procedure some time later [6]. IBR has positive effects on body image and psychosocial well-being [7,8] and current guidelines recommend to offer IBR to every patient with an indication for mastectomy [9–11]. Nonetheless, a rather low mean IBR rate of 18% for patients undergoing mastectomy for invasive breast cancer was observed in The Netherlands and IBR-rates varied substantially between Dutch hospitals [12,13]. In previous studies, case-mix variation [12], hospital organizational factors [14], attitudes of clinicians towards IBR [15], and information provision about IBR were identified as possible causes of this hospital variation [16]. Even after adjustment for tumour, patient and hospital variables, IBR rates varied from 0 to 64% between hospitals in The Netherlands [12,14].

To investigate the clinical significance of the observed variation of IBR rates in terms of patient-reported quality of life, the aim of the present study was to compare health-related quality of life of breast cancer patients treated with mastectomy with IBR versus mastectomy without IBR.

Materials and methods

Study population

Twenty-nine hospitals (1/3rd of the total number of hospitals in the Netherlands), serving varying patient volumes and proportions of patients undergoing IBR, were selected from the Netherlands Cancer Registry (NCR) to participate in the survey [16]. The selection process was described by de Ligt et al. and was based on achieving a representative sample of hospitals treating breast cancer patients [17]. The inclusion criteria of patients eligible for the present study consisted of female breast cancer patients from the age of 18 years and surgically treated for primary breast cancer or DCIS by mastectomy either with or without IBR between January 2013 and October 2014. Patients with distant metastases were excluded. From January 8th, 2015, the identified patients were invited to participate in an anonymous, self-administered survey and consented to the use of the data for the purpose of this study. Responses were collected until July 30th, 2015. After collection of the responses, exclusion of patients with incomplete questionnaires (defined as completion of less than one outcome domain in one of the two modules), patients with delayed breast reconstruction and patients waiting for at least one additional reconstructive breast procedure were excluded. The NCR has no information on delayed breast reconstruction, leading to respondents treated with delayed breast reconstruction in the mastectomy only group, which we were unable to exclude beforehand. Since these patients received the questionnaire focusing on the mastectomy and not the reconstruction, patients with delayed breast reconstruction were excluded for further analyses. Patients awaiting still one or more additional procedures were excluded due to the heterogeneity of this group.

Approval from the Committee of Privacy of the NCR was obtained for this study. The Medical Ethical Committee of the University Medical Centre Groningen (METc2014/473) declared the Medical Research (Human Subjects) Act was not applicable for this study.

Questionnaire

Health-related quality of life was assessed using the BREAST-Q

version 1.0 [18,19]. This validated PROM is available in Dutch. Patients without IBR completed the postoperative BREAST-Q mastectomy module and patients who had received IBR completed the postoperative BREAST-Q reconstruction module [18]. Both modules have multiple domains examining health related health-related quality of life (perceived psychosocial, physical and sexual well-being) and patient satisfaction with the treatment result (satisfaction with breasts) in common. Every domain of the BREAST-Q has 4 to 16 items and the raw domain scores expressing the extent of satisfaction or well-being are transformed to Q-scores ranging from 0 (low) to 100 (high) [19]. In addition, patient characteristics (age, educational level, marital/relationship status, working status, nationality, length and weight, comorbidities, breast size and menopausal state) were asked. Information on breast reconstruction (no reconstruction, immediate reconstruction, delayed reconstruction), type of reconstruction, nipple reconstruction and additional procedures to achieve a favourable result were included as treatment characteristics (Supplementary file).

The questionnaire was tested and approved by a panel of patient representatives before distribution. Mean time to complete the survey was about 30 min. Patients responded via PROFILES, an online secured web-based environment [20], or received the questionnaire on paper on request.

Statistical analysis

First, clinical characteristics of respondents and non-respondents were analysed. Baseline characteristics of the respondents were presented for patients treated with mastectomy and IBR and for those without IBR. BREAST-Q domain scores were calculated with the Q-Score scoring software system to transform the raw BREAST-Q data [19]. The BREAST-Q outcomes were compared between patients with mastectomy and IBR and patients without IBR. Sub-analyses were performed for the various reconstructive techniques. Chi-square tests were used for categorical data and Student's T-tests were used for comparison of continuous BREAST-Q scores. Finally, a multivariate linear regression analysis was performed to investigate the impact of IBR on the different domain outcomes, adjusted for confounding factors. Factors included in the model were chosen on their possible relevance. Two-sided p-values <0.05 were considered statistically significant. All statistical analyses were performed using SPSS (SPSS for MAC Version 20.0; SPSS Inc., Chicago, IL).

Results

Study population

Questionnaires were sent to a total of 1218 patients: 502 who had undergone mastectomy with IBR and 716 who had not received IBR after mastectomy. The overall response rate was 46% (558/1218). No statistically significant differences between responders and non-responders were found for most patient characteristics, except that older patients and patients without IBR were slightly underrepresented in the respondent group compared to the non-respondent group (Supplementary table). A total of forty-seven patients without IBR were excluded; 25 patients because they had received delayed breast reconstruction and 22 patients who returned incomplete BREAST-Q modules, leading to 511 patients available for analyses.

Fifty-five percent of the responders (n = 281) had undergone a mastectomy without IBR, 45% (n = 230) had received mastectomy with IBR. Of these latter, 66 patients were still waiting for at least one additional reconstructive breast procedure and were therefore excluded for further analyses, resulting in a total of 164 patients in

the mastectomy with IBR group.

Patients undergoing IBR were significantly younger, were more often employed, had a lower Body Mass Index (BMI), a lower disease stage and received less frequently radiotherapy compared to patients without IBR (Table 1). In the IBR group, two-stage tissue expander-implant reconstruction (57%) and direct-to-implant reconstruction (32%) were the most often performed breast reconstruction methods. Most patients had not (yet) received a nipple reconstruction when the questionnaire was completed (66%).

Patient-reported outcomes (BREAST-Q scores)

BREAST-Q outcomes per domain are presented in Table 2.

Patients who had received IBR reported significantly better mean “psychosocial well-being” scores (mean, 75 versus 67, $p < 0.001$) and “sexual well-being” scores (mean, 62 versus 52, $p < 0.001$) than patients who had not undergone IBR. Similar results were found for “physical well-being” scores (mean, 77 versus 74, $p = 0.021$). On the domain “satisfaction with breasts” patients with IBR reported similar mean scores compared to patients without IBR (mean, 64 versus 62, respectively, $p = 0.21$). Due to small numbers of autologous reconstruction ($n = 9$) and latissimus dorsi combined with implant reconstruction ($n = 9$), no meaningful comparisons between these breast reconstruction techniques could be made. Patients with direct-to-implant breast reconstruction had similar BREAST-Q subscale scores compared to patients with two-stage

Table 1
Baseline respondents characteristics ($n = 511$) categorized by surgical treatment (mastectomy without immediate breast reconstruction, $n = 281$; mastectomy with immediate breast reconstruction, $n = 164$).

		Mastectomy (N = 281)		Mastectomy with IBR (N = 164)		Total (N = 445)		P Value
		N	%	N	%	N	%	
Patient characteristics								
Age	<50	47	17%	51	31%	98	22%	<0.001
	50–65	126	45%	98	60%	224	50%	
	≥65	108	38%	15	9%	123	28%	
SES ^a	Low	102	36%	43	26%	145	33%	0.086
	Mediate	100	36%	70	43%	170	38%	
	High	79	28%	51	31%	130	29%	
Employment status ^b	Student/Unemployed/Disabled	71	25%	39	24%	110	25%	<0.001
	Employed	93	33%	105	65%	198	45%	
	Retired	116	41%	18	11%	134	30%	
Partner ^b	Married/Partner	202	72%	134	82%	336	76%	0.020
	Single/Divorced/Widow	79	28%	30	18%	109	25%	
Comorbidities ^b	No other disease	173	62%	120	73%	293	66%	0.043
	1 other disease	78	28%	33	20%	111	25%	
	2 or more diseases	30	11%	11	7%	41	9%	
Body Mass Index ^b	≤25 kg/m ²	126	45%	118	72%	244	55%	<0.001
	>25 kg/m ²	155	55%	46	28%	201	45%	
Breast size ^b	AA - B	123	44%	82	50%	205	46%	0.436
	C	71	25%	38	23%	109	25%	
	≥D	87	31%	44	27%	131	29%	
Tumour characteristics								
Type of breast cancer	Ductal carcinoma in situ	55	20%	42	26%	97	22%	0.137
	Invasive breast cancer	226	80%	122	74%	348	78%	
Stage ^c	0	55	20%	42	26%	97	22%	<0.001
	I	61	22%	68	42%	129	29%	
	II	103	37%	50	31%	153	34%	
	III	62	22%	4	2%	66	15%	
Treatment characteristics								
Type of breast reconstruction ^b	Tissue expander or immediate implant			146	89%	146	89%	
	Latissimus dorsi flap with implant			9	6%	9	6%	
	Autologous reconstruction			9	6%	9	6%	
Nipple reconstruction ^b	No reconstruction			94	57%	94	57%	
	Nipple reconstruction ^d			47	29%	47	29%	
	Nipple sparing surgery			23	14%	23	14%	
Radiotherapy	Yes	95	34%	25	15%	120	27%	<0.001
Chemotherapy	Yes	143	51%	71	43%	214	48%	
Hospital characteristics								
Hospital	General	133	47%	60	37%	193	43%	0.120
	Educational	128	46%	80	49%	208	47%	
	Academic	20	7%	24	15%	44	10%	
Hospital volume ^e	Low	50	18%	19	12%	69	16%	0.001
	Intermediate	106	38%	43	26%	149	34%	
	High	125	45%	102	62%	227	51%	

^a Socio-economic status (SES) of the patients was based on four-digit postal code at time of surgery. SES-scores are provided by the Netherlands Institute for Social Research (Sociaal Cultureel Planbureau) and divided into three groups based on the delivered rank numbers: low (1st-3rd deciles), intermediate (4th-7th) and high (8th-10th) SES.

^b Self-reported data from the patient survey.

^c Stage according to American Joint Commission on Cancer TNM classification.

^d Nipple reconstruction, either tattooing of the nipple-areola complex, nipple reconstruction or a combination of the two techniques.

^e Hospital volume was calculated by number of mastectomies: number of surgical treated breast cancer patients per year (average over 2012–2014), categorized as low (<150), middle (150–249), and high (>250) volume.

Table 2

Mean BREAST-Q domain scores categorized by surgical treatment (Mastectomy without immediate breast reconstruction, n = 281; Mastectomy with immediate breast reconstruction, n = 164).

BREAST-Q DOMAINS	Mastectomy (N = 281)		Mastectomy with IBR (N = 164)		P value
	Mean	SD	Mean	SD	
Satisfaction with breasts	62	18.46	64	18.08	0.21
Psychosocial well-being	67	18.97	75	18.76	<0.001
Sexual well-being	52	24.28	62	20.70	<0.001
Physical well-being: chest	74	16.44	77	16.08	0.021
Satisfaction with outcome			71	21.15	
Satisfaction with nipples ^a			67	22.51	
Physical well-being: Abdominal Region ^b			62	30.46	

IBR; Immediate Breast Reconstruction. SD; Standard Deviation.

^a Patients with a nipple reconstruction, either by tattooing of the nipple-areola complex, a nipple reconstruction or a combination of the two techniques.

^b Only patients who had a reconstruction with tissue from the abdomen such as Transverse Rectus Abdominis Myocutaneous (TRAM)-flap or Deep Inferior Epigastric Artery Perforator (DIEP)-flap or Superficial Inferior Epigastric Artery Perforator (SIEA)-flap.

tissue expander-implant reconstruction (data not shown).

Multivariate analyses of patient-reported outcomes in patients with and without IBR

All BREAST-Q outcomes showed a normal distribution with the mean and median closely related, enabling linear regression modelling. Confounding factors included in the multivariate model were age, socio-economic status, employment status, comorbidities, BMI, breast cancer stage and radiotherapy.

IBR proved to be independently associated ($p < 0.001$) with favourable “psychosocial” and “sexual well-being” BREAST-Q domain scores and showed a borderline association with “physical well-being” ($p = 0.049$). IBR did not appear to be significantly associated with the BREAST-Q domain “satisfaction with breasts” ($p = 0.483$).

For “psychosocial well-being” and “sexual well-being”, no other independently associated factors were found in multivariate linear regression analyses. Younger age and a higher tumour stage were independently associated with “satisfaction with breasts” and the presence of multiple comorbidities was independently associated with “physical functioning”.

Discussion

The present study investigated health-related quality of life of patients with and without IBR following mastectomy. After adjusting for confounding factors, IBR was associated with significantly better BREAST-Q outcomes for “psychosocial functioning”, “sexual functioning” and “physical functioning” compared to patients without IBR. Interestingly, no statistically significant differences were found for the BREAST-Q domain “satisfaction with breasts”. Overall, the results of this reasonably large, and representative sample of more than 400 breast cancer patients in the Netherlands underscore the importance that all patients with an indication for mastectomy should be offered the possibility of IBR in order to achieve favourable quality of life outcomes and to enable shared decision-making. Ultimately, it is up to the patient, together with her clinician, to decide whether or not IBR is preferred or feasible.

Breast cancer survival rates are high, enabling and demanding a shift of focus towards quality of life after cancer treatment. Mastectomy still has a prominent place to achieve locoregional control of breast cancer. Learning from patient preferences and outcomes of breast cancer surgery guides us through a better understanding of the actual care given. PROMs as the BREAST-Q enable us to

understand outcomes beyond mortality and survival rates and to identify outcomes that also matter to patients.

A minimal important difference of 4 points on all outcome domains of the BREAST-Q, except for physical functioning (3 points), was found clinically relevant when interpreting whether a specific treatment is perceived beneficial for patients [21]. The results of our study showed, aside the statistical significance favouring IBR over mastectomy only, also obvious clinically relevant differences on the BREAST-Q outcomes for “psychosocial functioning” (75 versus 67), “sexual functioning” (62 versus 52) and “physical functioning” (77 versus 74). Several other studies have examined health-related quality of life in patient populations following mastectomy with versus without IBR using the BREAST-Q [22–24]. Most studies showed similar results for psychosocial and sexual functioning favouring IBR. They also demonstrated a less apparent difference in physical functioning using multivariate regression analyses [22–24]. A common finding of these previous and our current study was that patients consistently reported lowest scores for sexual well-being. However, these low scores were also reported in a general population of women without breast cancer treatment, indicating that the low sexual well-being scores may also reflect an overall satisfaction of sexual well-being at a certain age instead of alterations due to breast cancer treatment only [25].

Unexpectedly, the present study did not show a significant difference in the BREAST-Q domain “satisfaction with breasts”. The difference between the two groups (2 points) was below the clinically relevant threshold and both patient groups had similar scores compared to normative data [21,25]. However, this finding is contradictory to the results of previous studies [22–24]. An explanation might be that patients without IBR accept the aesthetic consequences for the chest area. This is supported by the additional comments found in the survey where 16 patients stated they deliberately decided not to undergo IBR. Patient satisfaction with their breasts is also significantly associated with preoperative information provision by and shared decision-making with the reconstructive surgeon, which highlights the importance of adequate preoperative information provision [26].

Only the outcome domain “physical well-being” was lower compared to normative data which are used internationally [25]. Patients who had received either mastectomy or IBR scored around 75 compared to the normative score of 93 [25]. A recent single centre study in the Netherlands investigating a breast cancer population showed mean data of around 70 [24]. Surgery in general, including reconstructive surgery, leads to altered anatomy and scarring, which may lead to pain and discomfort and therefore decreased physical well-being.

A strength of the current study is that it included a representative sample of the breast cancer population in the Netherlands. Limitations are the possibility of recall bias, due to the retrospective design, and response bias, which is inherent to the use of questionnaires. Also, our response rate of 46% was lower compared to other studies, which varied from 56% to 74% [22–24,27,28] possibly because we did not send any reminders. The mean time between mastectomy and the questionnaire was approximately 17.5 months (range 3–34 months), which is relatively short, however, we excluded patients still in the process of reconstruction. Unfortunately, no preoperative information on the outcome domains was available in our study, similar to most breast cancer surgery studies using the BREAST-Q [29]. The difference in baseline characteristics (younger, employed, more healthy patients and patients with lower stage tumours without radiotherapy have a higher change of receiving IBR), might have resulted in treatment indication bias. A multivariate linear regression analysis was performed to adjust for patient characteristics when comparing mastectomy with IBR versus without IBR. Nevertheless, other (unknown) factors may have contributed to health-related quality of life and may therefore limit the conclusions drawn from this research.

Patients with an indication for mastectomy should receive sufficient preoperative information enabling informed shared decision-making about IBR. It may be seen as a challenge to inform patients about all available and relevant surgical options for breast cancer, including their advantages and disadvantages, enabling a patient to make her own informed decision. In a study previously reported by our group, patients who had received IBR had been better informed about IBR and felt more involved in shared decision-making compared to patients without IBR. Moreover, patients being preoperatively informed about IBR had a 14-fold higher chance of receiving IBR [17]. Others reported that one third of the patients who underwent a mastectomy felt they had not received sufficient information about breast reconstruction, or were dissatisfied with the reconstruction decision-making process (13%) [30].

Understanding health-related quality of life and the effects of breast cancer surgery by using PROMs longitudinally is essential to guide patients in the future, since outcomes may alter over years [28,31]. Recommendations for future practice should involve implementation of these outcome measures in every day practice in the complete care path for breast cancer patients, as advocated by Michael Porter and the International Consortium for Health Outcomes Measurement [32,33] who defined an international standard set of outcomes to track for all breast cancer patients [34]. Fortunately, first implementation efforts are on their way [35].

Conclusion

A significantly better health-related quality of life on various outcome domains including psychosocial, sexual and physical well-being was reported by patients with IBR compared to patient without IBR. It is therefore justified to offer the possibility of IBR with all patients with an indication for mastectomy. More importantly, this enables shared decision-making in an era where the patient herself, after having received all relevant information including advantages and risks, decides whether or not she wants to undergo IBR.

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Ethics committee approval

The Medical Ethical Committee of the University Medical Centre Groningen (METc2014/473) declared the Medical Research (Human Subjects) Act was not applicable for this study. Approval to send questionnaires and collect patient data for analysis and reporting was obtained from the Committee of Privacy of the NCR. Informed written consent was obtained from women as part of answering the questionnaires.

Declaration of competing interest

The authors declare that they have no conflict of interest. None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

CRedit authorship contribution statement

A.C.M. van Bommel: Conceptualization, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing - original draft. **K.M. de Lig:** Conceptualization, Formal analysis, Methodology, Project administration, Writing - original draft. **K. Schreuder:** Conceptualization, Methodology, Writing - review & editing. **J.H. Maduro:** Conceptualization, Methodology, Supervision, Writing - review & editing. **T. Van Dalen:** Conceptualization, Methodology, Supervision, Writing - review & editing. **M.T.F.D. Vrancken Peeters:** Conceptualization, Methodology, Supervision, Writing - review & editing. **M.A.M. Mureau:** Conceptualization, Methodology, Supervision, Visualization, Writing - review & editing. **S. Siesling:** Conceptualization, Funding acquisition, Project administration, Supervision, Visualization, Writing - review & editing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejso.2020.06.009>.

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