Patient-Reported Outcomes Following Breast Reconstruction Surgery and Therapeutic Mammoplasty: Prospective Evaluation 1 Year Post-Surgery with BREAST-Q Questionnaire

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Abstract Breast Cancer (BC) treatment leads to mutilation and destruction of breast shape with negative effects on body image and self-esteem. One of the main goals of reconstructive and oncoplastic breast surgery is to satisfy patients and improve their quality of life (QoL). Therefore, it is important to assess the patient experience post-surgery by means of patient-reported outcome measures (PROMs) that focus on the patient's perception of the surgery and surgical care, as well as psychosocial well-being and physical functioning. The objective of the current study was to identify predictors of patient satisfaction such as breast appearance including implant type in a selective sample of women who underwent breast reconstruction surgery using implants. Participants in this prospective study were women, (age 26–75 years) that were newly diagnosed with breast carcinoma. All consecutive patients who underwent breast reconstruction between January 2013 and October 2014 were asked to complete the BREAST-Q questionnaire 1 year after surgery. 120 patients underwent unilateral breast reconstruction using implant. While 38 patients underwent reconstruction with opposite breast reduction symmetrization, 27 patients underwent therapeutic mammoplasty. The response rate for BREAST-Q questionnaire completion was 98 % with 147 out of 150 study participants completed the questionnaire. From the data collected from 147 patients, the responses could be distributed into 4 distinct groups based on the reconstruction outcomes

namely “very much satisfied” (93 %) or “definitely and mostly satisfied” (94 %) or “satisfied” with the outcome (88 %) or “definitely agree on having reconstruction rather than the alternative of having no breast” (91 %). The results showed significant improvement in all four areas that were evaluated after surgery namely satisfaction with the appearance of the breasts, psychosocial, sexual and physical well-being. While the reconstruction surgery had an overall positive impact on quality of life it was observed that in patients that did not undergo breast reconstruction psychological issues related to sexuality were observed. Many newly diagnosed BC patients do not opt for these new surgical procedures due to psychological trauma or lack of information. Based on these observations, we propose that Breast Cancer Management protocols should also include additional counselling support for the newly diagnosed BC patients on the option of breast reconstruction along with conventional medical treatment counselling by the Oncosurgeon.

Keywords Breast carcinoma · Breast reconstruction · Mastectomy · Post mastectomy reconstruction · Quality of life

Introduction

The incidence of Breast Cancer (BC) is rising in India and is now the second most common cancer diagnosed in women after cervical cancer. It is estimated that in 2008 there were 115,251 new cases of Breast Cancer with an age standardized incidence rate of 22.9 per 100,000. It is estimated that by 2030 the number of newly diagnosed cases of Breast Cancer in India will be in the vicinity of 200,000 per year.

It is now well documented that breast reconstruction can help patients restore acceptable body image and re-establish psychological equilibrium [1]. Understanding the wide

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reaching impact of cosmetic and reconstructive breast surgery has thus, become increasingly important for clinical research endeavors and surgical quality improvement efforts [2]. Traditional surgical outcomes that are centered on morbidity and mortality remain important but are no longer sufficient on their own. Thus, patient's perceptions of the impact of disease and treatment are increasingly being considered as integral to understanding overall health outcomes [3, 4].

Breast Cancer can impact patients psychologically as well as organically, which can manifest as post mastectomy depression, increased anxiety, shame, and occasional ideas of suicide [5]. Mastectomy has considerable impact in the form of psychosocial effect of the physical and aesthetic deformity which can include anxiety, depression, and negative effects on body image and on sexual function [6]. Specific types of psychological distress resulting from radical surgery include clinically significant mood disturbances, decreased sexual interest and satisfaction and increased self-consciousness in association with negative changes in body image and fear about recurrence [7, 8].

Breast conditions and their associated surgical interventions have a major impact on quality of life. In fact, in specialties such as breast surgery it has been suggested that “quality of life should be considered as the major if not the only end point” [9].

The most-observed potential benefit of Breast Cancer reconstructive surgery is to increase the patient's post-surgical quality of life and alleviate the post-traumatic psychological sequelae of Breast Cancer surgery. Consequently, Breast reconstruction has now become an integral part of modern day breast surgery following mastectomy as it is considered oncologically safe and aesthetically satisfying. Numerous studies in the past have confirmed the positive psychological effects of breast reconstruction [10, 11]. However, to the best of our knowledge, there is a paucity of data examining the interaction between specific treatment variables and patient satisfaction with breast reconstruction surgery. Furthermore, relatively little is known about the extent to which quality of life is impacted in patients that have undergone reconstructive breast surgery in India.

There are a number of reasons for this paucity of data. Firstly, there is a non-availability of detailed qualitative and quantitative research using valid, reliable, and responsive instruments to measure patient-reported outcomes in cosmetic and reconstructive breast surgery. Secondly, very few clinical researchers have tried to understand the exact psychological perceptions of a woman newly diagnosed with BC and what impact surgery then has on these perceptions. Finally and importantly, there is a major lack of awareness in India about breast cancer in general and breast reconstruction surgery options in particular.

The primary aim of this study was to determine the quality of life of patients who underwent immediate breast

reconstruction (IBR) following mastectomy at our Breast Cancer unit in India over a 1 year period.

Materials and Methods

A cross-sectional study was undertaken at Orchids Breast Health Centre, Pune between months January 2013–October of 2014 under the care of Breast Oncosurgeons. Patients were asked to complete the standardized BREAST-Q evaluation of their care. Patients that underwent unilateral and bilateral mastectomies along with those that also were offered immediate reconstructions were included. Patients were considered eligible for participation if they had undergone implant-based breast reconstruction. Patients were contacted or approached in person at our Breast Health Center. Patients that participated in the study were selected based on purposive sampling. Informed consent was obtained from all patients. Patient's demographic data and treatment records were collected from patient medical files. Collected data included marital status, level of education, employment status, income, ethnicity, and medical history.

Questionnaire

BREAST-Q

The BREAST-Q Reconstruction Module is a patient-reported outcome measure that was developed to assess Hr-QOL and patient satisfaction after breast reconstruction surgery. The BREAST-Q reconstruction module is divided into multiple independent scales. The scales used in this study were as follows: (1) Satisfaction with Breasts—a 16-item body image scale that addresses issues such as Satisfaction with Breast shape, symmetry, feel to the touch, and appearance clothed or unclothed; (2) Satisfaction with Outcome—a 7-item scale that measures a woman's overall appraisal of her breast surgery outcome, including whether her expectations were met, the impact of surgery on her life, and the decision to have reconstructive surgery; (3) Psychosocial Well-Being—a 10-item scale that asks women to rate their confidence in a social setting and how normal or equal to other women they feel; (4) Physical Well-Being—a 16-item scale on how often women experience pain or discomfort in the breast area and upper body; and (5) Sexual Well-Being—a 6-item scale that addresses the impact of a woman's breast condition and surgery on her sex life. Item responses for each scale are summed and transformed to provide a score ranging from 0 to 100. Higher scores indicate greater satisfaction or quality of life. Psychometric evaluation of the scales has

demonstrated high levels of internal consistency and test–retest reliability (Cronbach α 0.96; intraclass correlation coefficient 0.96) [12].

Scoring

Scoring of the BREAST-Q was performed using QScore that analysed data based on RUMM 2020 – a program developed by Rasch Unidimensional Measurement model [41, 42]. This software automatically transforms raw data into summary scores ranging from 0 (Very dissatisfied) to 100 (Very Satisfied). All scales are scored on a 0-to 100-point scale. For all scales, higher scores indicate greater satisfaction/function.

Results

A total of 150 women participated in the study. The response rate for BREAST-Q was 98 % with 147 of 150 participants completing the questionnaire. We excluded from the analysis 3 respondents who either did not answer or indicated “not sure” with regard to the questions that were asked about their implant type.

Of these 150 patients, the mean age was 48 (range 29–72). Ninety three percent (139) of patients are married, 3 % of patients are widow and other 4 % are single (Table 1). Also 129/150 (86 %) patients are educated and 52/150 (34 %) were currently employed. In addition to surgery, 84 patients received chemotherapy and 59 patients received radiation therapy. Eighty two patients underwent unilateral breast reconstruction using implant, 38 patients underwent reconstruction with opposite breast reduction symmetrization. Thirty patients underwent therapeutic mammoplasty. In three patients implants were

removed due to complications. Total four patients had exchange of implants, 7 patients developed capsular contracture and 5 patients developed grade I radiation skin reaction while on radiation (Tables 2, 3 and 4).

Of the 30 patients that underwent breast reduction only 27 patients completed BREAST-Q. Changes in patient-reported satisfaction and quality of life after breast reductions were assessed. The results showed significant improvement in all four areas evaluated after surgery, satisfaction with the appearance of the breasts and psychosocial, sexual and physical well-being. 94 % of study participants were satisfied when probed on 100 point scale related to satisfaction with breast appearance and outcome after surgery. 86 % patients were satisfied on the total cosmetic outcome and satisfaction with breast after the surgery. On psychological wellbeing questions 88 % were satisfied. In therapeutic mammoplasty patients reported low score on sexual wellbeing. 95 % patients were satisfied with the surgeon and information provided by the surgeon (Table 5).

Discussion

With the evolution of BC management protocols over the last decade radical mastectomy has become less popular in clinicians as well as patients. The current thinking is centralized around the theme that the aim of the surgical treatment of Breast Cancer should not be just to eliminate or reduce the size of a tumor but also to attain the best aesthetic result possible with the least psychological and physical impact. Breast reconstruction especially immediate breast reconstruction can help attain this goal. The goal of post-mastectomy breast reconstruction is to restore the appearance of the breast and to improve psychological outcomes after breast removal surgery [13–15]. Thus, the assessment of patient outcomes using appropriately constructed and validated instruments by using specific patient-reported measures such as the BREAST-Q is essential to evaluate and quantify the success of these surgeries from the patient’s perspective [16, 17].

Mastectomy is potentially a very traumatic event. Besides immediate concerns over health and longevity associated with

Table 1 Demographics Details N = 150

Variable	N = 150	Percent
Mean age	48 (29–72)	
Married	139	93 %
Widow	5	3 %
Single	6	4 %
Educated	129	86 %
Working	52	34 %
Treatment		
Surgery		
Unilateral Breast SSM with Implant	64	42.6 %
Unilateral Breast NSM with Implant	18	12 %
MRM with reconstruction with implant + opposite breast symmetrization	38	25.3 %
Therapeutic mammoplasty	30	20 %

Table 2 Treatment Details of Patients

	Unilateral mastectomy with reconstruction Using implant	MRM with reconstruction using implant + opposite breast symmetrization	Therapeutic mammoplasty
Surgery	82	38	30
Chemotherapy	47	26	11
Radiation	32	16	11

Table 3 Incidence of Complication

	MRM with reconstruction using implant unilateral sided N = 82		MRM with reconstruction with implant + reduction opposite breast N = 38		Therapeutic mammoplasty N = 30	
Implant Exchanged	2	24 %	2	5 %		
Implant Removed	3	3.6 %	0	0		
Capsular Contracture	4	4.8 %	3	7 %		
Radiation Skin reaction	2	2.4 %	1	2.6 %	2	6.6 %

Breast Cancer patients most likely agonize over their future appearance, social interactions, and sexual life. For these women, breast reconstruction has been proposed as a possible solution. In this current study, it was observed that women with successful breast reconstruction at our Breast Health Centre were significantly more satisfied with the appearance of their chest/breasts (80 %). It was also observed that they also fared better psychosocially (94 %). In relation to the administrative aspect of the care, patients were generally satisfied with the provided information, the operating surgeon, associated medical and office staff. It was also apparent that women in the present study had less physical pain and this was not influenced by the operation. This may suggest that women that underwent reconstruction may be physically more active than other women and may represent a healthier lifestyle than average subset of the population [18].

The most common motivation women reported for undergoing immediate reconstruction was elimination of the need to wear an external prosthesis. Several reports have described the inconvenience and problems experienced with an external prosthesis. Furthermore, it is documented the improvement in these external prosthesis problems could be eliminated by breast reconstruction [19, 20]. We also observed that equally important to the BC patients was the wish to feel whole again after surgery and retain self-esteem. The participating women seemed to have realistic expectations from breast

reconstruction surgeries and wanted to choose reconstruction voluntarily. Our observations are in agreement with those recorded in previous reports that similarly analyze the motivating factors in breast reconstruction [21–23].

Result from the current study results indicate that in one year the gains in satisfaction and psychosocial wellbeing was as high as 87 % in the patients. Al-Ghazal [24] and Schain [11] have assessed the psychological impact of immediate breast reconstruction (IBR) and delayed breast reconstruction (DBR) and concluded that women with IBR were less likely to suffer psychological difficulties. Rubino et al. [25] reported that no differences exist between these groups in terms of anxiety and depression.

Anxiety and depression are the most common psychological problems in women who have undergone a mastectomy. Many studies including the present analysis indicate that there is a significantly positive impact of Breast reconstruction has on psyche on women. Women who have undergone IBR are more likely to be satisfied with the aesthetic results achieved and are least likely to feel a loss of sexual attractiveness. In general, there is agreement in the medical community on the negative impact on psychological profile in patients living with a deformity such as breast removal. Such negative psychological profile is expected to affect post-surgery rehabilitation and influences the outcomes of the prolonged chemotherapy/radiation therapy phase of BC management. Given the agreement in the findings of our present study with those reported earlier that suggest IBR to offer psychosocial

Table 4 Post-operative analysis of Breast reconstruction with implant N = 120 after 1 year of post op surgery.

Question	Mean	range (min-max)
Satisfaction with breasts	88	40–100
Satisfaction with outcome	89	39–100
Psychosocial well being	87	36–100
Physical well-being of chest	80	46–100
Physical well-being of abdomen (7/120)	87	79–100
Satisfaction with nipples (17/120)	65	41–100
Satisfaction with information	88	23–100
Satisfaction with Surgeon	95	31–100
Satisfaction with Medical Staff	92	36–100
Satisfaction with office staff	91	45–100
Sexual well being	68	0–100

Table 5 Post-operative q score analysis of therapeutic mammoplasty N = 27 1 year of post op surgery

Question	Mean	range (min-max)
Satisfaction with breasts	86	56–100
Satisfaction with outcome	94	65–100
Physical well-being of chest	84	56–100
Satisfaction with nipples	78	23–100
Satisfaction with information	89	51–100
Satisfaction with Surgeon	95	56–100
Satisfaction with Medical Staff	94	59–100
Satisfaction with Office staff	96	75–100
Sexual well being	48	21–100

advantages, breast reconstruction (especially IBR) should be carried out whenever feasible [26–35]. Breast Reconstruction Surgery should no longer be considered as an option but should be treated as a standard of medical care in Breast Cancer surgery.

In our current study patients with immediate breast reconstruction reported lowest domain scores on the sexual wellbeing (68 %) and 48 % score on the sexual wellbeing after therapeutic mastoplastic. Results of this study suggest the need for further exploration of the complex area of the potential impact of surgery on sexuality. Gham and colleagues have observed in a study of women undergoing prophylactic bilateral mastectomy with reconstruction that such surgery can still impact negatively a patient's sexual sensation and enjoyment [22]. The desire to improve sexual relationship is less common and should be viewed with caution when presented as primary motivation for the purpose [36]. These coinciding results from two different breast surgeries suggest the need for further exploration.

In this study, women that underwent breast reconstruction using Siltex© Becker implants were highly satisfied (89 %) with their post reconstruction body image and level of overall satisfaction. The other parameters such as anxiety and femininity showed a positive trend after reconstruction surgery. The common motivation for reconstructive surgery in all the patients was to restore the feeling of femininity and wholeness, to avoid disfigurement to eliminate use of external prosthesis and to improve overall self-confidence [37]. It was also observed that 80 % women were highly satisfied with their physical quality of life after breast reconstruction. Dean et al. also reported greater satisfaction with breast appearance 3 and 12 months post reconstruction, compared with those who underwent mastectomy alone [38].

Wehrens et al. have reported significantly better psychological profile of the women undergoing reconstruction group. These women were found to be more extroverts; more active socially and sexually, more talkative, more animated and took the initiative [39]. It is with these positive observation many studies recommend opting for immediate reconstruction in order to reduce psychological morbidity postoperatively [40, 41]. The widespread belief in the field now is that immediate breast reconstructions can be performed with an acceptable rate of complications, high level of patient satisfaction and these patients had less recalled distress about mastectomy [42].

Technically, immediate reconstruction allows for the preservation of the infra-mammary fold and maximizes the amount of native skin available for the reconstructive process, thereby maximizing the overall aesthetic result. In addition, the preservation of body image, femininity, and sexuality through the immediate reconstruction of a breast mound can be psychologically beneficial and significantly reduces post-operative emotional stress. For these reasons, immediate reconstruction is generally preferred [24, 43].

Limitation

The scope of this study is limited by the fact that this was single institution, single PI study with smaller sample size. The concept of Breast Oncoplastic Surgery in BC management is still nascent in India. Our Breast Health Center is one of the very few centers in India which offers this surgical option for BC surgery. Given the lack of similar centers in other parts of India, the results from this study cannot be generalized to patients in other settings or compared across multiple locations. Our patient sample was also relatively homogenous in its sociodemographic characteristics consisting primarily of educated Indian women. This study therefore cannot comment objectively on the psyche on Indian women from uneducated and underprivileged strata of the society. Also it is well known that many factors can affect a woman's satisfaction with reconstruction including the surgeons' ability, complication rates, use of radiation or even convenience of hospital services. Since such factors vary from institution to institution the conclusion from this study may not apply to all women undergoing breast reconstruction.

The ideal study design to assess outcomes of breast reconstruction would be a prospective cohort study that includes 2 observations arms (women undergoing mastectomy) and (women undergoing mastectomy with reconstruction study arm). Such a study would have a population-based sample large enough to detect differences in the predetermined outcomes between the two groups. It would measure patient psychosocial characteristics and key outcomes at baseline prior to surgery as well as patients' preferences about issues that influence decisions about reconstruction. Efforts are underway at our breast center to embark on such well-designed study in future.

In summation, this study provides essential information about importance of breast reconstruction from the point of view of the BC patient. Owing to the many inherent cultural and socio-economic parameters associated with the nature of the surgical procedure, breast reconstruction in itself is not necessarily a quality measure for Breast Cancer care. However, with the help of the observations from this study on how breast reconstruction can influence the psyche of BC patients we intend to design and develop patient counseling tools at our Breast Health Center. These patient-help tools will address various psycho-somatic issues related to option of breast reconstruction surgery. In addition to the standardized medical management protocols of breast surgery such breast reconstruction-associated counseling tools are expected to enhance the overall quality of medical management in Breast Cancer thereby ultimately enhancing patient care and comfort.

Conclusions

Given its significant benefits in altering the psychosocial profile of a BC patient breast reconstruction surgery seems to be a much

beneficial strategic option in fighting breast cancer. The results from the present data set could be considered as a pilot study for further systematic evaluation with a better study design and adequate sample size. It should be noted that immediate breast reconstruction surgery is being increasingly recommended to all women undergoing mastectomy. However, in patients opting for reconstruction surgery the desire to improve sexual relationship is less common and should not be considered as primary motive for reconstruction. The current study is particularly relevant because it is one of the first studies to address psychological impact of immediate breast reconstruction in Indian women. It is our hope that future studies in breast reconstruction from our group as well as other onco-surgical groups elsewhere would usher the widespread acceptance of Breast Oncoplastic Surgeries in India.

Conflicts of Interest The authors had no conflicts of interest to declare in relation to this article.

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