

## Patient-reported outcomes for immediate breast reconstruction with mastectomy among breast cancer patients in Pakistan

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### Abstract

**Objective:** To evaluate the effect of immediate breast reconstruction with mastectomy in the local population.

**Method:** The quasi-experimental, control study was conducted at the Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore, Pakistan, and comprised patient data from April 2017 to December 2020, of breast cancer patients who underwent mastectomy with or without immediate breast reconstruction. Those who underwent mastectomy were labelled as control group A, while patients with immediate breast reconstruction were labelled as intervention group B. Data was analysed using SPSS 20.

**Results:** Of the 66 patients, 33(50%) were in each of the 2 groups. Group B had significantly more patients aged <40 years than group A ( $p=0.01$ ), more patients with graduate-level education ( $p=0.04$ ), and more patients who were either unmarried or divorced ( $p=0.05$ ) than group A. Group B patients had higher mean scores for satisfaction with breasts ( $p=0.001$ ) and psychosocial wellbeing ( $p=0.001$ ) than those in in group A. Mean scores for adverse effects of radiotherapy were significantly higher in group B than in group A ( $p=0.04$ ).

**Conclusion:** Better health-related outcomes were reported by patients who underwent immediate breast reconstruction with mastectomy.

**Keywords:** Immediate breast reconstruction, IBR, Quality of life, Mastectomy, Psychosocial wellbeing.

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### Introduction

Breast cancer (BC) is the most common cancer among women worldwide.<sup>1</sup> Due to recent advancements in screening, early detection and neoadjuvant treatment, more patients are offered breast conserving surgery (BCS), but one-third of the patients still undergo mastectomy.<sup>2</sup> In developing countries, the rate of mastectomy is higher due to the lack of a national screening programme, and more patients presenting with locally advanced BC.<sup>3</sup>

Current guidelines recommend immediate breast reconstruction (IBR) to be offered to every patient undergoing mastectomy due to positive body image and psychological impact on the patient.<sup>4</sup> It is being offered to up to 82% of patients in most of the developed countries, but the rate of reconstruction in Pakistan is <1% with only two tertiary cancer hospitals offering these procedures.<sup>3,5,6</sup> The reason for these low figures is generally lack of awareness among BC patients in the country, less women being educated, poor socioeconomic status (SES), remote geographical location within the country, and paucity of surgical training/expertise.<sup>6</sup>

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To our knowledge, no study has assessed the outcome of mastectomy with IBR on BC patients in Pakistan. The current study was planned to fill the gap in literature by evaluating the effect of IBR with mastectomy in Pakistani BC patient population.

### Patients and Methods

The quasi-experimental control trial was conducted at the Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC), Lahore, Pakistan, and comprised patient data from April 2017 to December 2020, of BC patients who underwent mastectomy with or without IBR. IBR with mastectomy procedure was introduced at the centre in 2017. Those who underwent mastectomy were labelled as control group A, while patients with IBR were labelled as intervention group B. Patients with metastatic BC and inflammatory BC were excluded.

Data related to patient demographics, outcomes, type of mastectomy and type of implant was retrieved from the electronic database after approval from the institutional ethics review board. Informed written consent had been taken from all the patients at the time of the procedure.

The sample size was calculated with 80% power and 95% confidence interval (CI) using mean values  $60.33 \pm 19.18$  in group A and  $70.46 \pm 17.9$  in group B.<sup>6</sup>

The groups were matched for the time of surgery and stage

of tumour. The questionnaire survey was conducted in the follow-up clinics at the mean follow-up time of  $1.5 \pm 0.6$  years post-surgery.

Patient satisfaction and health-related quality of life was assessed using a validated patient-reported outcome measures (PROM) tool, called Breast-Q version 2.<sup>8</sup> Post-operative mastectomy module was used for group A patients, and post-operative reconstruction module for group B patients. Each of the modules had 6 sub-themes, but 4 of them were used in the current questionnaire, including satisfaction with breast, as well as physical, psychosocial and sexual wellbeing of the patient. Each sub-theme had 4-16 questions, and the raw scores were converted to Q-Score ranging 0-100, with higher score depicting higher patient satisfaction. A change of 4 points on a 0-100 scale was considered a minimal important difference (MID), denoting significant change.<sup>9</sup> A supplementary questionnaire was also used to seek additional information from the patients (Annexure) about their residential address, marital status, educational background, SES, prior knowledge about reconstructive surgery and the reason for not opting for reconstruction.

### Annexure

#### Separate Questionnaire

1. What is your Date of Birth?
2. What is the Level of your education?  
No education – Primary education – College education
3. What is your marital status?  
Married, Divorced, Unmarried
4. Are there any of the following comorbidities?  
Cardiovascular disease, pulmonary disease, hypertension, diabetes mellitus.
5. Year of surgery?
6. Your present residential city? rural/ urban
7. How did you know about breast reconstruction?  
My surgeon told me about different reconstruction options and also recommended it, I know about reconstruction options and I opted this by my own choice, I did not know about any reconstruction options nor my surgeon recommended this.
8. In Reconstruction group, do you think it helped in?  
Improving body image, Comfort of not wearing prosthesis, Overcoming cancer
9. Were you informed on the possible effects of irradiation on breast reconstructive procedure?  
Yes, No, No radiation required
10. In mastectomy only patients, why didn't you opt for reconstruction?  
My surgeon recommended mastectomy alone because of the nature of disease or else – My surgeon did not tell me about reconstruction nor I know about any reconstruction techniques available – My surgeon recommended reconstruction but I denied.
11. In mastectomy group, do you want reconstruction now?  
Yes and why – No and why

Data was analysed using SPSS 20. Chi-square test was used for categorical variables, and independent t-test was used for continuous variables. Two-tailed  $p \leq 0.05$  was considered statistically significant.

## Results

Of the 66 patients, 33(50%) were in group A with mean age  $44.36 \pm 8.64$  years, and 33(50%) were in group B with mean age  $38.36 \pm 8.19$  years. Initially, there were 42 mastectomy patients with IBR, but 9(21.4%); loss of implant 7(77.8%)

**Table-1:** Socio-demographic and clinical variables.

	Mastectomy n (%)	Mastectomy with IBR n (%)	Total n (%)	p-value
<b>Patients characteristics</b>				
<b>Age (years)</b>				
<40	11 (33)	23 (69.7)	34 (51.5)	0.01
40-65	20 (60.6)	10 (30.3)	30 (45.5)	
> 65	2 (60.1)	0 (0)	2 (3)	
<b>Socioeconomic status</b>				
Self-paying	8 (24.2)	11 (33.3)	19 (28.8)	0.19
Partial support	10 (30.3)	4 (12.1)	14 (21.2)	
Full support	15 (45.5)	18 (54.5)	33 (50)	
<b>Marital status</b>				
Married	32 (97)	26 (78.8)	58 (87.9)	0.05
Unmarried/ Divorced	1 (3)	7 (21.2)	8 (12.1)	
<b>Educational status</b>				
Primary school education	9 (27.3)	4 (12.1)	13 (19.7)	0.04
College education	19 (57.6)	27 (81.8)	46 (69.7)	
Illiterate	5 (15.2)	2 (6.1)	7 (10.6)	
<b>Geographical distribution</b>				
Within 100 KM	15 (45.5)	25 (75.8)	40 (60.6)	0.02
>100 KM	18 (54.5)	8 (24.2)	26 (39.4)	
<b>Comorbidities &gt;2</b>				
Yes	9 (27.3)	5 (15.2)	14 (21.2)	0.23
No	24 (72.7)	28 (84.8)	52 (78.8)	
<b>Tumour characteristics</b>				
<b>Type of breast cancer</b>				
DCIS	3 (9.1)	5 (15.2)	8 (12.1)	0.63
IDCa	21 (63.6)	15 (45.5)	36 (54.5)	
IDCa+DCIS	8 (24.2)	11 (33.3)	19 (28.8)	
ILCa	0 (0)	1 (3)	1 (1.5)	
ILCa+LCIS	1 (3)	1 (3)	2 (3)	
<b>Treatment Characteristics</b>				
<b>Type of breast reconstruction</b>				
SSM + Expander	-	17 (51.5)	-	
SSM+LD+PI	-	7 (21.2)	-	
SSM+PI	-	7 (21.2)	-	
SRM+PI	-	2 (6.1)	-	
<b>Axillary surgery</b>				
ALND	24 (72.7)	19 (57.6)	43 (65.2)	0.19
SLNBx	9 (27.3)	14 (42.4)	23 (34.8)	
<b>Chemotherapy</b>				
No	5 (15.2)	6 (18.2)	11 (16.7)	0.74
Yes	28 (84.8)	27 (81.8)	55 (83.3)	
<b>Radiotherapy</b>				
No	5 (15.2)	18 (54.5)	23 (34.9)	0.01
Yes	28 (84.8)	15 (45.5)	43 (65.1)	

IBR: Immediate breast reconstruction, KM: Kilometer, DCIS: Ductal carcinoma in situ, IDCa: Invasive ductal carcinoma, ILCa: Invasive lobular carcinoma, SSM: Skin sparing mastectomy, LD: Latissimus dorsi flap, PI: Permanent implant, SRM: Skin reducing mastectomy, ALND: Axillary lymph node dissection, SLNBx: Sentinel lymph node biopsy.

**Table-2:** Breast-Q domain scores.

Breast-Q Domains	Mastectomy	Mastectomy with IBR	Mean Difference	p-value
	Mean±SD	Mean±SD		
Satisfaction with breasts	35.67±13.34	78.45±16.16	42.8	0.001
Psychosocial well-being	44.79±10.252	87.30±15.408	42.51	0.001
Physical well-being	93.12±8.852	96.88±10.723	3.76	0.126
Sexual well-being	44.07±13.781	55.77±30.639	11.7	0.065
Adverse effects of radiation	15.36±2.725	17.00±1.359	1.64	0.040
Satisfaction with implant	-	7.67±0.692	-	-

IBR: Immediate breast reconstruction; SD: Standard difference.

and death 2(22.2%). The cause of death was metastatic breast disease in both patients and was not related to reconstruction surgery.

Group B had significantly more patients aged <40 years than group A ( $p=0.01$ ), more patients with graduate-level education ( $p=0.04$ ), and more patients who were either unmarried or divorced ( $p=0.05$ ) than group A. After having information about reconstructive options, 1(3%) group A patient showed willingness to consider delayed reconstruction. There was no significant difference with respect to comorbidities between the groups ( $p=0.23$ ).

There was no significant difference between the groups for patients receiving neoadjuvant chemotherapy (NAC) ( $p=0.74$ ), and the number of axillary node clearance ( $p=0.19$ ). However, patients undergoing chest wall radiotherapy were lower in group B ( $p=0.01$ ). There was no significant difference in terms of tumour biology between the groups ( $p=0.63$ ). Patient characteristics and procedural details were noted in detail (Table 1).

Group B patients had higher mean scores for satisfaction with breasts ( $p=0.001$ ) and psychosocial wellbeing ( $p=0.001$ ) than those in in group A. Mean scores for adverse effects of radiotherapy were significantly higher in group B than in group A ( $p=0.04$ ). There was no significant difference between the groups for mean sexual ( $p=0.065$ ) and physical wellbeing ( $p=0.13$ ). The mean score for satisfaction with implant was 7.67±/0.69 among group B patients (Table 2).

The main advantages of IBR were reported to be comfort of not wearing prosthesis or freedom from clothing restrictions in 32 (97%) patients, improved body image in 30 (91%) patients and assistance in overcoming cancer in 25 (75%) patients.

## Discussion

To the best of our knowledge, the current study is the first to use patient-reported outcome measures in Pakistani BC patients. There is only one study from Pakistan in which only surgical outcomes were examined in reconstruction

patients which included 64 patients in a 10-year study period.<sup>6</sup>

The incidence of BC has been on a constant rise globally, especially in the last couple of years it has increased by 0.5% per year.<sup>10</sup> Advances in the early diagnosis, screening and adjuvant treatment modalities have improved survival outcomes of BC patients. Breast reconstruction has recently gained importance worldwide to improve the quality of life of BC patients with increased survival. There is an increase in the rate of IBR of approximately 27% from 2005 to 2015.<sup>11</sup> Having breast reconstruction not only provides patients with social and emotional support, but also helps to improve their body image and sexuality.<sup>12</sup>

The rate of breast reconstruction in BC patients in Pakistan is <1% due to lack of awareness campaigns, low education level, poor SES and transport issues.<sup>6</sup> Owing to the prevalence of various religious and social beliefs, low literacy rate and lack of independent decision-making, especially by females in Pakistani society, it seems quite challenging to convince patients about the need of breast reconstruction, and make them understand various reconstructive techniques.<sup>6</sup> In the current study, none of the patients who underwent mastectomy alone had any prior knowledge provided to them by their community family doctor or local surgeon. Even after counselling in the clinic, no patient showed willingness except 1(3%) to consider delayed reconstruction. It seemed that they may have adapted to their body image and were satisfied by the fact that they were at least alive without the disease, not willing to undergo any further surgery.

The results of the current study were comparable to previous studies conducted on other populations.<sup>13,14</sup> The current study showed higher satisfaction with breast and psychosocial wellbeing among patients with IBR, which was similar to previous studies in Western populations.<sup>13,14</sup> Breast reconstruction offered the women comfort of not wearing prosthesis or freedom from clothing restrictions, improved body image and assistance in overcoming cancer. A study also reported similar factors, in addition to the association with improvement in social relationships.<sup>15</sup> Similarly, women with low education and those living in rural areas were shown not to opt for reconstruction. In earlier studies, the rate of reconstruction in patients living in rural areas, with less education and having dependent children, was seen to be low in developing countries.<sup>16,17</sup>

Age is one of the important factors that influence a patient's decision in opting for reconstruction.<sup>18</sup> This was also noted in the current study. Previous studies have also shown that surgeons are also reluctant to offer reconstructive options to older women.<sup>19</sup> With more

oncoplastic surgeons performing the reconstructive procedure, the rate of complications among reconstructive cases is getting reduced.<sup>20</sup> Other studies have also shown that older patients show willingness for reconstruction when offered. This suggests that surgeons should offer reconstruction to BC patients regardless of their age if they are fit to undergo surgical procedure.<sup>21</sup>

The current study had certain limitations. It was a non-randomized study which was prone to selection bias. There were more patients who underwent axillary dissection in the mastectomy alone group. Studies have shown that nodal surgery is associated with increased rate of overall complications and flap necrosis in patients with implant-based reconstruction, which may contribute to less satisfaction with the overall results following the surgery.<sup>22,23</sup> Similarly, there were fewer mastectomy patients with IBR who underwent chest wall radiotherapy compared to patients who had mastectomy alone. Radiation therapy is associated with reduced risk of local recurrence in BC patients. A study reported that post-operative radiation influences final shape and touch of the reconstructed breasts and negatively impacts patient's general and aesthetic satisfaction.<sup>24</sup>

Besides, the second questionnaire used to obtain demographic information from the patients was not a validated tool. It briefly tried to assess the subjects' prior knowledge about reconstruction and the reason for not opting for reconstruction. However, further detailed analysis is required to ascertain various factors that influence their decision-making. This requires further research. In addition, the questionnaire survey was not conducted pre-operatively to assess the change in effect post-treatment. This would have provided more information about the degree of change in the patients undergoing IBR.

## Conclusion

Patient-related outcome scores were better among those undergoing reconstruction in psychosocial and satisfaction with breast domains. Considering the positive results of reconstruction, it should be offered routinely to BC patients undergoing mastectomy in Pakistan irrespective of their educational level or SES.

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**Author Contribution:**

SA: Study concepts, data acquisition, analysis, interpretation and writing.

MAP: Study concepts and reviewing.

NJ: Data acquisition, analysis, interpretation and reviewing.

MAB: Statistical analysis.