Safety of Partial Breast Reconstruction in Extended Indications for Conservative Surgery in Breast Cancer

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Received: 18 November 2009 / Accepted: 5 April 2010 / Published online: 4 March 2011
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Abstract Breast conservation surgery after large volume excisions for women with relatively larger or multicentric operable breast cancer (OBC) and in some locally advanced breast cancers (LABC) post neo-adjuvant chemotherapy (NACT), is known to be a feasible option using a latissimus dorsi flap. However, the oncological safety of such a procedure is not well reported in literature. Two hundred and twenty one women with breast cancer (148-OBC, 73-LABC) underwent BCT plus LD during March 1998 to August 2009. One hundred and forty six women (72-LABC, 66-OBC) received prior NACT for downstaging, followed by completion of adjuvant therapy in all, including postoperative radiotherapy and hormone therapy where indicated. Women aged 20–62 years, with tumors 1.5–15 cm (median 5.0 cm), underwent volume replacement surgery with LD flap. All positive cut margins (total-4.9%, gross positive-1.3%) were re-excised to ensure negative margins. The mean surgical time for excision of primary with axillary clearance followed by volume replacement by LD was 5 h and mean hospital stay 6 days. Donor site morbidity was seen in 11 patients and 3 had minor recipient

site infection. At a median follow up of 36 months, ten of 221 patients (4.5%) had failed locally (7-OBC, 3-LABC). The determinants of local recurrence were presence of lymphatic vascular invasion ($p=0.016$) and axillary metastasis ($p=0.003$). BCT plus LD flap is an oncologically safe, technically quick procedure with minimal morbidity, and should be offered to all eligible women as an extended breast conservation procedure.

Keywords Breast conservation surgery · Latissimus dorsi flap · Recurrence

Introduction

Many randomized clinical trials have clearly shown the safety and equivalence of breast conservation compared to mastectomy in early breast cancer [1–3]. Breast conservation (BCT) is also increasingly being offered to locally advanced tumors that have been adequately downstaged by neo-adjuvant chemotherapy (NACT) in spite of inadequate level I evidence regarding the safety of such a procedure. In multifocal tumors and in partial responders after chemotherapy, with relatively large residual tumors, breast conservation surgery may not be feasible due to a relatively large excision volume and consequent poor cosmetic outcome. Also, the oncological safety of reconstructive surgery in such patients is not supported by strong evidence.

Breast reconstruction surgery has undergone tremendous advances in the last two decades and also is the need of an ever increasing number of women who undergo mastectomy for breast cancer. It is a well established fact that the aesthetic restoration of the breast plays an important role in the overall rehabilitation of the patient. Quality of life studies have clearly shown that women with breast

Informed Consent: Taken from all participants in study

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conservation have a better ‘Body Image’ than after mastectomy [4–8]. Total breast reconstruction is mostly required in women after mastectomy and can be performed by pedicled flaps or microvascular free tissue transfer. However, the logistics of performing such extensive procedures is associated with increased surgical time, higher morbidity, longer hospital stay and escalating costs. The expertise required for the above also needs the services of a trained reconstructive plastic surgeon. We present the audit of 221 cosmetic partial breast reconstructions using LD flap in both operable and locally advanced breast cancers performed in the Breast Unit from March 1998 to August 2009, evaluating the recurrence rates and the oncological safety.

Material and Methods

Women with large or multicentric operable breast cancer and locally advanced breast cancer who underwent a partial breast reconstruction for breast conservation with a LD flap were included in this audit. All women with locally advanced disease and large operable cancers received neo-adjuvant chemotherapy to downstage the tumor. Post-chemotherapy the first assessment for feasibility & extent of surgery was performed at the end of 4 cycles of chemotherapy, and if found unsuitable for conservative surgery with good cosmesis, were planned for a partial breast reconstruction with LD flap. Some women, who had focal microcalcification or multicentric disease unlikely to be reduced by NACT, and restricted to a single quadrant or two adjacent quadrants, were identified and also planned electively for primary BCT with LD flap.

The eligibility criteria for LD reconstruction followed in operable and locally advanced breast cancers are summarized below:

Indications in operable breast cancer are for central quadrant tumors (with or without Paget's disease of nipple) with localized microcalcification; multifocal disease (extensive microcalcification limited to one quadrant or two adjacent quadrants, within or outside the primary tumor); and anticipated poor cosmesis following post-excision biopsy breast conservation surgery.

Indications in locally advanced / large operable breast cancer after chemotherapy are primarily for relatively large residual tumor after NACT in a small breast; evidence of multifocal disease limited to one quadrant or maximum to two adjacent quadrants; and in cases with skin scarring (healed ulcer, skin infiltration or satellite nodule) requiring excision of skin and large breast volume defect.

In women with large operable breast cancer and locally advanced breast cancer, the decision for partial reconstruction was taken post NACT after maximum response had

been achieved with persistent significant residual disease. In those women where the preoperative examination revealed multifocal disease or presence of extensive microcalcification on mammogram, elective wide excision with latissimus dorsi flap reconstruction was planned upfront. The compliance to post-operative radiotherapy (RT) was also confirmed in each case prior to surgery.

The treatment was planned in a multidisciplinary joint clinic with the surgical oncologist, radiation oncologist, medical oncologist, and after detailed discussions with the patient herself as well as the immediate responsible next of kin. All patients were counseled on the extent of disease resection which would be required, the degree of morbidity expected and resultant functional loss. An informed consent for breast conservation surgery with partial breast reconstruction using a latissimus dorsi myocutaneous flap was obtained in all patients. Postoperatively, after completion of chemotherapy, sequential radiotherapy was administered (with a Linear Accelerator with bi-tangential portals) to the breast to a maximum dose of 50 Gy in 25 fractionated doses over 5 weeks. A tumor bed boost of 15–20 Gy was also administered. Supraclavicular radiation was given to a dose of 50 Gy in 25 fractions to supraclavicular fossa (SCF) in all patients of locally advanced, large operable breast cancer, and OBC with >3 metastatic axillary lymph nodes. In case of pathological positive supraclavicular nodes an additional boost of 10 Gy was administered to supraclavicular fossa.

Cosmesis was assessed by the treating clinician using the Joint Center for Radiation therapy (JCRT) criteria [9] with four categories as ‘excellent’, ‘good’, ‘fair’ and ‘poor’ cosmesis. All patients were assessed for cosmesis at the end of RT, and subsequently re-evaluated by the clinician in the out-patient clinic at 6 monthly intervals. The patients had a mammogram every 18 months, during their follow up, and any other necessary investigation based on symptoms.

The outcome analysis was carried out using the *SPSS 14.0 program* and univariate analysis for local recurrence was performed by the *Kaplan-Meier test* and a *p* value <0.05 was considered as significant. The comparative analysis was carried out with an *a priori* assumption that a ‘very happy’ or ‘satisfied’ mindset of the patient should correspond with an ‘excellent’ or ‘good’ cosmetic end-result as judged by the clinician. The *Chi-square test* was applied to look for significance of the observations made by the patient versus clinician with respect to overall breast cosmesis.

Results

In all, 221 patients who underwent breast conservative surgery with latissimus dorsi flap were included in the

Table 1 Clinical and histopathological features by clinical stage at presentation

Factors analyzed		LOBC(<i>n</i> =148)	LABC(<i>n</i> =73)	Total (<i>N</i> =221)
Age	≤ 50 years	131 (88.5%)	65 (89.0%)	196
	> 50 years	17	8	25
Prior procedure	FNAC/Nil	53 (36%)	11 (15.5%)	64
	IB / EB	93	60	153
NACT	Yes	66 (45.2%)	72	138 (63%)
	No	80	1	81
EIC	Positive	26(19.3%)	6 (9.1%)	32 (15.9%)
LVI	Positive	19 (14.1%)	12 (17.1%)	31 (15.1%)
ER	Positive	68 (48.2%)	32 (44.4%)	100 (45.2%)
PgR	Positive	75 (52.8%)	32 (44.4%)	107 (48.4%)
CerbB2(114)	Positive	22 (29.3%)	4 (10.3%)	26 (22.8%)
T size (median)	Clinical (cm)	1.5–11 (4.1)	1.5–15(6.7)	1.5–15(5.2)
	Pathological (cm)	0–8 (2.5)	0–9 (2.9)	0–9 (2.7)
Cut margin	Focal +	1 (0.7%)	2 (2.7%)	3 (1.3%)
	Gross +	6 (4.1%)	2 (2.7%)	8 (3.6%)
	Negative	141	69	210
Axillary LN	Dissected (median)	1–37 (15)	3–30 (16)	1–37 (15)
	Positive (%)	52.7	60.3	55.3
	Median positive	2	3	3

audit. The age ranged from 20–62 years with a mean age of 40.0 years; 76% were pre and perimenopausal. The mean weight of patient was 56 Kg (range 31–80 Kg). One hundred and forty eight women (67%) presented with operable breast cancer, 73 (33%) were locally advanced. Seventy two women with locally advanced breast cancer were treated with chemotherapy first and 66 of 148 (44.6%) women with operable breast cancer received chemotherapy before surgery. The overall primary tumor size ranged from 1.5–15 cm in size (median 5 cm, mean 5.2 cm). The tumors were relatively larger at presentation in the locally advanced group with a mean of 6.7 cm (range 1.5–15) as compared to the large operable (mean 4.1 cm, range 1.5–11). The clinical and histopathological details are summarized in Table 1 according to the clinical stage at presentation.

Overall, 94% of the tumors were infiltrating duct carcinoma, 2.8% was infiltrating lobular variety and 3.2% were ductal carcinoma-in situ. Seventy three percent of the tumors were of grade III. The overall margin positivity rate (focal plus gross positives) at first excision was 4.8% (seven out of 146) in women with OBC and 5.4% (four of 73) in those with LABC. However, all

positive margins were revised to ensure negative excision margin status.

Short-term Outcome of Partial Breast Reconstruction

The duration of surgery ranged from 1.2 h to 7 h (mean 5 h) and the average hospital stay was 6 days (Table 2). The average duration of surgery for BCT alone or modified radical mastectomy with no reconstructive procedure is 1.5 h and hospital stay is 3 days. This is important as it directly correlates with cost of the procedure and as is obvious, it did not add to the overall cost burden to the patient.

The short-term outcome was evaluated in terms of morbidity at donor site, LD flap complications and post RT hyper-pigmentation, and cosmesis. LD flap complications were mostly minor and noted in four patients and were mainly hematoma in 1, minor infection in 2 and superficial flap discoloration in 1. Donor site complications were prolonged seroma in 1 and margin necrosis requiring secondary suturing in 4. Post RT hyper-pigmentation was noted in 20 patients.

Table 2 Logistics of performing volume replacement BCT with LD flap

Postoperative stay	Range: 1–19 days	Mean: 6 days
Duration of surgery	Range: 70–420 min (1.2–7 h)	Mean: 300 min (5 h)
Average cost to patient	General category: INR 5000 (~ 125 USD)	
	Private category: INR 50000 (~ 1250 USD)	

Table 3 Predictors of local recurrence (LR) after partial breast reconstruction with LD Flap (Univariate analysis by Kaplan Meier)

Factor	Variable	Local DFS (%)	Significance
Age	≤50 years	94.4	$p=0.930$
	>50 years	94.7	
Clinical stage	OBC	94.0	$p=0.767$
	LABC	95.3	
Extensive intraductal carcinoma	Positive	85.2	$p=0.069$
	Negative	95.7	
Lymphatic vascular invasion	Positive	80.0	$p=0.003$
	Negative	96.5	
Neo-adjuvant chemotherapy	Given	94.2	$p=0.722$
	Not given	94.9	
Axillary lymph nodes	Positive	90.6	$p=0.016$
	Negative	98.8	
Estrogen receptor	Positive	97.6	$p=0.092$
	Negative	91.3	
Progesterone receptor	Positive	95.4	$p=0.279$
	Negative	93.2	

Long-term Outcome After Partial Breast Reconstruction in Relatively Large Breast Cancers

The potential prognostic factors for local recurrence were analyzed by the Kaplan Meier survival tables in univariate analysis. The following variables were evaluated: age, clinical stage, EIC, LVE, neo-adjuvant chemotherapy administration, positive axillary nodal status, positive cut margins, and hormone receptor status (ER and PgR).

At a median follow up of 36 months, the recurrences were documented as local, regional or distant failures. In operable breast cancer there were seven local (4.7%) and 11 (7.4%) distant relapses. In locally advanced breast cancer,

there were three local relapses (4.1%), and 13 (17.8%) distant failures. In all, the local failures were ten of 221 (4.5%).

Outcome with regards to local recurrence was evaluated by the Kaplan-Meier univariate analysis to determine the factors responsible for local failures in these women with relatively larger or locally advanced tumors. The results are summarized in Table 3. There was no significant difference in local recurrence-free survival (Fig. 1) being 95.3% in LABC versus 94.0% in OBC. The disease-free survival was better in women with operable breast cancer (90.6%) as compared to those with LABC (79.7%) (Fig. 2).

Fig. 1 Local recurrence-free survival by clinical stage in women after BCT with LD **Fig. 2** Disease-free survival by clinical stage in women after BCT with LD

Table 4 Predictors of local recurrence (LR) after partial breast reconstruction with LD Flap (multivariate cox regression analysis)

Factor	Cox regression	Significance
Axillary lymph nodes	HR 1.12 CI (1.019–1.247)	$p=0.02$
Lymphatic vascular invasion	HR 5.62 CI (1.58–19.9)	$p=0.008$

The main predictors of higher local recurrence rate were positive axillary nodal burden (Log Rank 5.85, $p=0.016$) and the presence of lymphatic vascular invasion (Log Rank 8.99, $p=0.003$) in the breast. There was no significant impact of age, menopausal status, clinical stage, neoadjuvant chemotherapy administration, or presence of extensive intraductal component.

On multivariate Cox Regression analysis, the only variables significant were axillary lymph node metastases with a 12% exponential increase in risk of local relapse with each node positive (HR 1.12, 95% CI 0.19–1.25, $p=0.02$) and presence of lymphatic vascular emboli (HR 5.62, 95% CI 1.58–19.9, $p=0.008$) (Table 4). Age, clinical stage or administration of neo-adjuvant chemotherapy, and pathological residual tumor size did not affect the risk for local recurrence.

Discussion

Safety of breast conservation is well established in early breast cancers with smaller tumors but no such evidence exists in larger tumors and locally advanced breast cancers even after downstaging with chemotherapy. The NSABP B18 [10, 11] had included 1,523 women with operable breast cancers with a median tumor size of 2 cm, comparing pre-operative versus post-operative administration of adjuvant chemotherapy. A 79% response rate was noted and a 7% higher rate of breast conservation was achieved. An updated outcome and correlation of pathological complete response and outcome has been reported through 9 years of follow-up further supporting the earlier reports. The NSABP B27 [12] trial, on the other hand, had included women with operable breast cancers with relatively larger tumors (with a median tumour size of 4 cm). This was a randomized trial in 2,411 women evaluating the worth of docetaxel preoperatively or postoperatively following 4 cycles of AC chemotherapy, and reported a better local response with a 3% higher rate of breast conservation surgery with docetaxel arm. Both these studies, however, did not analyze safety of breast conservation in locally advanced breast cancers. The only available evidence in literature is single institution experiences with small numbers but long follow up (reported by MD Anderson Cancer Center, US) [13] or single institutional experience with large number of women with locally advanced breast cancer but with short follow up (local recurrence 8% after

BCT post NACT versus 11.7% after mastectomy with axillary clearance) as reported from Tata Memorial Hospital, India [14]. Most of the studies have actually evaluated only short term results in terms of feasibility and cosmesis. But the oncological safety of such extensive procedures as partial breast reconstruction in larger tumors should also be confirmed before adopting it as standard of care.

Various methods of breast remodeling have been described with emphasis on proper planning of incisions, minimum scarring and refashioning of breast tissue itself (mammoplasty) or using partial breast augmentation with latissimus dorsi flap for compensating for the loss of volume and better cosmetic outcome [15]. Latissimus dorsi has been described as an ‘ideal mini-flap’ for breast remodeling [16, 17]. Various other procedures in addition to LD flap have also been described for breast remodeling after wide excision such as total breast reconstruction with prosthesis, total breast reconstruction with myocutaneous flap (Transverse rectus abdominis myocutaneous flap or TRAM flap) [18–23]. The main concern after using implants or prosthesis for breast reconstruction is the fact that most of our patients require post-operative adjuvant radiotherapy which would result in lot more morbidity and capsular contracture after implants. The steep cost of implants would also be a major limitation for wider acceptability of the procedure amongst patients, and the need for multiple visits for achieving final matched cosmetic end-result makes the technique undesirable as most of the patients seen at TMH are from outstation since the institute is a tertiary referral center.

The satisfaction survey also indicated a very high level of satisfaction amongst women who underwent breast conservation and augmentation with LD flap supporting strongly the decision for the procedure. There have been studies looking at the quality of life and self assessment and have reported that women have better self opinion with a better breast cosmesis ($p=0.004$), feel that the reconstructed breast is more like the opposite breast, they have less loss of self-confidence and would choose this operation over total breast reconstruction ($p=0.002$) and also reported less change in the attitude of their spouse ($p=0.003$) after the surgery [16]. The cosmetic outcome was described as better after partial reconstruction with LD, than after total mastectomy followed by breast reconstruction with free flaps. The basic outcome is dependent on an ideal case selection for a total or partial reconstruction with or without autologous flaps. The

patient also needs to have a proper counseling on the fact that at times minor corrective procedures may be required later for exact match between the two breasts with a probable need for aesthetic replacement or refashioning of the nipple-areola complex [23].

The tumor response pattern after chemotherapy has always been debated widely raising doubts on safety of conservative surgery as well of extent of excision required after chemotherapy response. A comparative positive margin result as seen here in LABC versus OBC (4.1% versus 4.7%, $p=NS$), suggests a centripetal shrinkage of tumour in response to chemotherapy and hence, safety of conservative surgery. Post-chemotherapy outcome was favorable in the terms of immediate morbidity, low positive margin status and low local relapse rate thus supporting the use in larger tumors after downsizing, as also reported in some other small studies [24].

As long as the wide excision width is adhered to with adequate margin clearance, and adjuvant radiotherapy is offered to all women as after any breast conservation surgery, the local recurrence rates should be comparable. On an average, our patients received a margin excision width of 2.0 cm, wider if evidence of microcalcification was seen on preoperative mammography suggesting presence of DCIS. In the present study, the local recurrence rates were very low (overall 4.5%) and 3-year DFS at a median follow up of 36 months was 92%. Since the follow-up is very short (only 36 months) the long-term outcome has not been evaluated for overall or distant disease-free survival in the present report. This would be evaluated in the future analysis evaluating the long-term safety of LD flap for breast conservation in larger tumours.

Krishna B Clough reported a 4 year follow-up on 101 patients who underwent partial breast remodeling for larger tumors, as in the current series, with some having had received neo-adjuvant chemotherapy, with a median tumor 32 mm and reported a recurrence rate of 9.4%, overall survival of 95.7% and recurrence-free survival of 82.8%. The margin excision in their study was at least 1 cm and they had a positive margin status in 11 of 101 patients (10.9%) but in our series, with a wider excision we had a very low margin positive status (overall 4.9%). In fact, as adequate tissue is being transposed to fill in the surgical defect with a LD flap, it is advisable to have a wider margin clearance to ensure negative margins and we follow a margin of 1.5–2.0 cm in all cases [25, 26].

There were no documented delays in starting adjuvant therapy in these women after surgery as per the records evaluated. At the same time, neither chemotherapy nor adjuvant radiation therapy after chemotherapy had any adverse effect on outcome (early morbidity or late cosmetic appearance) and therefore, can be offered to all patients where indicated. The cosmetic satisfaction survey and

physician assessment of cosmesis at the two time points of before and after completion of radiotherapy also showed no significant difference in other studies [27, 28].

Follow up evaluation after BCT with partial reconstruction using a LD flap with mammography is on the same lines as after routine BCT. The LD flap does not come in the way of evaluation of the rest of the breast parenchyma. In fact, if at all, it actually appear less dense due to higher fat content and therefore, clearer. Imaging has been the issue after implants and ultrasonography and MRI have been suggested as the ideal methods for imaging the breast after implant placement to evaluate the residual breast for possible recurrences [29]. However, after LD reconstruction, a routine mammography is able to evaluate the remaining breast parenchyma effectively with no additional expensive imaging support.

Finally, the cost and time factor still remains an important issue for developing countries like India where the primary cost is borne by the patient and family and insurance coverage is available only for few. The additional costing, if mastectomy with implant placement was to be offered instead, would be very steep, and would be a major limiting factor. The ease of acceptability of LD flap for partial breast reconstruction is definitely higher in our setting due to its associated lesser postoperative pain, hospital stay and more versatility of the LD flap, as compared to a total breast reconstruction with perforator or free microvascular flaps.

Conclusions

Partial breast reconstruction is a definite and safe onco-plastic option to offer to women wishing for breast conservation where technically not feasible and aesthetically contraindicated due to larger volume primary excision. Duration of surgery, morbidity, hospital stay, cost per patient are all within acceptable limits and therefore can be offered to large number of women. Breast surgeons should adapt and perform these simpler reconstructive surgeries as a routine procedure to reduce the workload on the Reconstructive Surgeons who can then focus their efforts, time and expertise for more demanding reconstructions.

Financial Disclosure None

Funding None

Conflict of Interest None

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