ORIGINAL ARTICLE

A CLINICAL STUDY OF LOCALLY ADVANCED CARCINOMA OF BREAST

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ABSTRACT: BACKGROUND: In India it is observed that most of the patients of breast cancer clinically present in late stage due to their ignorance of disease despite so much advancement in its detection and management. Locally advanced breast cancer (LABC) accounts for 30-35% of all cases of breast cancers in India. This study aims to evaluate Clinical features, Investigations, various Treatment modalities and the Clinico-pathological correlation & outcome of various treatment modalities of LABC, with special emphasis on Neo-adjuvant chemotherapy (NACT) in Indian setting. **MATERIAL AND METHOD:** This was a non-randomised prospective observational study. We analyzed 57 patients of LABC Stage IIIB & IIIC presenting at Government Medical College, Nagpur, Maharashtra, a tertiary care Centre from September 2012 to November 2014. **RESULTS:** Stage IIIB comprised 84.21% patients while remaining 15.79% were having Stage IIIC disease. Skin involvement was observed in 91.23% patients. 15.79% showed supraclavicular lymph node involvement. 32 patients received NACT (2 to 6 cycles). Out of these 32, complete clinical response (cCR) was 12.5%, partial response (cPR) was 68.75% and pathological CR (pCR) was 6.25% with Total Objective response (cCR+cPR) 81.25%. Feasibility of Breast Conserving Surgery (BCS) was observed in 12.5% patients. 25 patients underwent primary surgery followed by adjuvant chemotherapy. Modified Radical Mastectomy was performed in 89.48% patients. **CONCLUSIONS:** With overall clinical response of 81.25%, neoadjuvant chemotherapy is the best treatment option for patients with Locally Advanced Breast Cancer with added advantage of in vivo testing the sensitivity of chemotherapeutic agents, early management of micrometastasis and down staging the primary tumour with feasibility of BCS. Patients presenting LABC constitute a diverse group for which a variety of treatment modalities should be instituted with coordinated treatment planning among surgeons, medical oncologists and radiation oncologists.

KEYWORDS: LABC, NACT, Down staging.

INTRODUCTION: Breast cancer has evolved from an era of being left untouched to mutilation to radical surgery and finally now to less radical means in the form of Modified Radical Mastectomy (MRM), Breast Conserving surgery (BCS) with Adjuvant systemic therapy (Chemotherapy, Radiotherapy & Hormonal therapy).

In India, it is observed that most of the patients of breast cancer clinically present in late stage due to their ignorance of disease despite so much advancement in its detection and management. Locally advanced breast cancer LABC[(1)] {i.e. TNM Stage IIIB (T4, any N, M0) & Stage IIIC (any T, N3, M0)} accounts for 30-35% of all cases of breast cancers in India.[(2)]

Locally Advanced Breast Carcinoma (LABC) encompasses a wide spectrum of malignant breast tumors with varying presentation and remains a clinical challenge because majority of

patients develop distant metastasis despite appropriate therapy. Choice of management oscillates between primary surgery with adjuvant chemo-radiotherapy and neo-adjuvant therapy followed by surgery. Two basic principles of treatment are to reduce chance of local recurrence and risk of metastatic spread.

Multidisciplinary therapy has now become the standard for women with LABC which includes Chemotherapy, appropriate surgery along with Radiotherapy & hormonal therapy.[1]

Chemotherapy plays an important role in the treatment of LABC, which could be delivered as Neoadjuvant Chemotherapy (NACT) or postoperative Adjuvant Chemotherapy. The introduction of neo-adjuvant Chemotherapy in LABC has advantages like initiation of early systemic therapy, delivery of drugs through intact vasculature, helping in vivo assessment of response and down-staging of tumors, which makes inoperable tumors operable.

Surgery has evolved from Radical Mastectomy to MRM to present era where BCS is being attempted. MRM still remains the standard of care in the surgical management of LABC. The role of BCT in LABC is establishing slowly.

Radiotherapy is an integral component in the loco-regional management of LABC with improvement in the loco-regional control and survival. Addition of Hormonal therapy to this multimodality approach has improved overall survival.

Although incidence of LABC is low in developed world, it is common in India. Hence the present study aims to evaluate Clinical features, Investigations, various treatment modalities and the clinico-pathological correlation & outcome of various treatment modalities of LABC, with special emphasis on neo-adjuvant chemotherapy (NACT) in Indian setting.

MATERIAL AND METHODS:

STUDY DESIGN: A hospital based Prospective Nonrandomized Observational study of 57 patients of Locally Advanced Breast Cancer (LABC), conducted at Government Medical College and Hospital, Nagpur, Maharashtra, a Tertiary Care Centre in Central India, from September 2012 to November 2014.

AIM: To study the clinical features, investigations & various treatment modalities for Locally Advanced Carcinoma of Breast (LABC) and to study the outcome of treatment modalities for LABC.

INCLUSION CRITERIA: Consenting female patients in all age groups, presenting with LABC i.e. TNM Stage IIIB and IIIC with FNAC or histopathology proved malignancy.

EXCLUSION CRITERIA: Non consenting patients and patients lost to follow up.

PATIENT EVALUATION: A detailed history of all the patients of lump in breast followed by a thorough clinical examination of the breast and axilla was done. Lump size was measured clinically by Vernier's caliper. Patients with history and clinical examination suggestive of LABC were subjected to FNAC/ Biopsy of lump to confirm the diagnosis. All patients underwent baseline investigations (CBC, KFT-LF, ECG) and Metastatic work up (Chest X-ray, Ultrasonography of abdomen-pelvis, Skeletal X rays, Bone scan, CT scan).

All patients satisfying inclusion criteria in LABC group were included in study after taking written informed Consent.

Two Treatment protocols were Observed: Neoadjuvant chemotherapy → Surgery → Completion chemotherapy, Radiotherapy & Hormonal therapy. Surgery → Adjuvant chemotherapy, Radiotherapy & Hormonal therapy.

Choice of treatment protocols were dependant on Patient's choice, Surgeons choice and presenting factors like bleeding, foul smelling & infected ulcers (required surgery at earliest).

Chemotherapy was given in the form of either Neoadjuvant chemotherapy (NACT) or Adjuvant chemotherapy or both at 3 weeks interval with complete hematological and cardiac evaluation.

Following chemotherapy regimens were given in standard doses;

1. CAF- Inj Cyclophosphamide, Inj Adriamycin, Inj 5 – Fluorouracil.
2. TAC- Inj docetaxel, Inj Adriamycin, Inj Cyclophosphamide.
3. AC followed by T- Four cycles of -Inj. Cyclophosphamide, Inj. Adriamycin followed by Four cycles of Inj docetaxel.
4. CEF -Inj Cyclophosphamide, Inj Epirubicin, Inj 5 – Fluorouracil.
5. TEC- Inj docetaxel, Inj Epirubicin, Inj Cyclophosphamide.

In patients receiving NACT Clinical tumor response was graded according to World Health Organization Criteria for clinical tumor response:

- Complete clinical response (cCR): Absence of clinically palpable tumor,
- Partial clinical response (cPR): 50% or greater reduction in product of 2 maximum perpendicular diameters of tumor,
- Progressive disease (cPD): Increase in more than 25 % size of tumor,
- Stable disease (cSD): Response not meeting definition of cCR, cPR, cPD.

Feasibility for Breast Conserving Surgery (BCS) was checked for.

Loco-regional Surgical management consisted of either Modified Radical Mastectomy (MRM), Extended Simple Mastectomy, Simple Mastectmy or BCS (wide local excision, complete axillary dissection, post op radiotherapy) depending on feasibility and patient's` choice about type of surgery to undergo.

Adjuvant locoregional Radiotherapy was given to all patients as per standard guidelines. Adjuvant Hormonal therapy was given as standard dose of Tamoxifen (20 mg/day) for 5 years if not contraindicated.

STATISTICAL ANALYSIS: Continuous variables (age, tumor size, mean product, etc) were presented as mean+SD, categorical variables (gender, menstrual status, quadrant, Lymph node stage, etc) were expressed in actual number and percentages.

Tumor size and mean product were compared before and after chemotherapy by performing paired t-test. Categorical variables were compared by Chi square test. For small numbers, Fisher`s exact test was used applied wherever applicable. $P < 0.05$ was considered as statistical significance.

Statistical software STATA version 10.0 was used for statistical analysis.

OBSERVATIONS AND RESULTS: During the study period 57 patients of LABC (TNM- Stage IIIB & IIIC) diagnosed by clinical evaluation and proved by cytology or biopsy, were included in the study after their due consent.

All 57 patients presented with history of lump in breast.

Patients in the study had age ranging from 32 to 86 years. Maximum i.e. 35.09% patients were in age group of 41- 50 years with mean age of presentation being 51.42 years and median age of presentation was 50 years.

More than half of the patients were post-menopausal i.e. 32 patients (56.14%). Rest 25 patients (43.86%) were pre- menopausal.

Duration	No. of patients	Percentage
≤1 month	04	07.02
>1-6 months	28	49.12
>6-12 months	19	33.33
>12 months	06	10.53
Total	**57**	**100**

Table 1: Duration of presentation to hospital after development of symptoms

Almost half of patients, 28(49.12%) presented to hospital within 1 to 6 months of development of symptoms. Maximum duration of presentation was 36 months. Mean duration of presentation after development of symptoms was 7.88 months with a median of 6 months (table 1).

Left side was involved in 29(50.88%) and Right side in 28(49.12%) patients. Upper outer (22 i.e. 38.59%) and central (18 i.e. 31.58%) quadrants were mostly involved by the tumor mass, followed by lower outer quadrant which was involved in 7(12.28%) patients. Lower inner and Upper inner quadrant were involved in 6(10.53%) and 4(7.02%) patients. Large tumors however involved more than one quadrant.

Tumor size	No. of Patients	Percentage
<2cm	0	0.0
2-5cm	12	21.05
5-10cm	34	59.65
>10cm	11	19.30
Total	57	100

Table 2: Breast lump size at presentation

Table 2 Tumor sizes were graded on the basis of maximum dimension size at presentation. 34(59.65%) patients had tumor size between 5–10 cm. Average size of the lump was 7.68cm.

Tumor stage	No. of patients	Percentage
T2	02	03.51
T3	02	03.51
T4	53	92.98
T4a (Chest wall fixity alone)	01	01.75
T4b (Skin involvement alone)	42	73.69
T4c (Both 4a & 4b)	10	17.54
T4d (Inflammatory carcinoma)	00	00.00

Table 3: Tumor Stage

Both skin involvement and chest wall fixity together was found in 10(17.54%) patients. Hence overall skin involvement was observed in 52(91.23%) patients. (Table-3)

Stage	No. of Patients	Percentage
Stage IIIB	48	84.21
T4 N0 M0	08	14.03
T4 N1 M0	34	59.65
T4 N2 M0	06	10.53
Stage IIIC Any T, N3 MO	09	15.79
Total	**57**	**100**

Table 4: Shows the TNM staging

After clinical examination, all the patients were investigated and tissue diagnosis was obtained in every case. FNAC was done in all 57 patients. FNAC confirmed diagnosis in 54 patients and was inconclusive in 3 patients in whom the diagnosis was confirmed by biopsy. Thus sensitivity of FNAC in our study was 94.73%. Biopsies were done in 3 patients of whom 2 had undergone incisional biopsy and 1 patient had undergone Trucut Biopsy. Biopsy was thus conclusive in 100 % cases. Distant metastasis was ruled out.

Treatment Protocol	No. of Patients	Percentage
NACT → Surgery → Completion chemotherapy + Radiotherapy + Hormonal therapy	32	56.14
Surgery → Adjuvant chemotherapy + Radiotherapy + Hormonal therapy	25	43.86
Total	**57**	**100**

Table 5: Treatment Protocol

Post-operative radiotherapy was given in all patients of both the groups. Out of 57 patients, 32(56.14%) were given NACT before surgery. Rest 25(43.86%) were primarily subjected for surgery followed by Adjuvant chemotherapy.

CAF was the primary chemotherapy regimen in maximum, 37(64.91%) patients. Taxane based regimens TAC and AC→T were used in 8(14.04%) and 9(15.79%) patients respectively. While 2(3.51%) patients received TEC & 1(1.75%) received CEF regimen. 3 patients of CAF regimen were converted to AC→T regimen during chemotherapy treatment.

No. of cycles	No. of patients	Percentage
02	03	09.37
03	14	43.75
04	08	25.00
05	02	06.25
06	05	15.63
Total	32	100

Table 6: number of chemotherapy cycles received pre-operatively

Out of 32 patients, 14 (43.75%) received 3 cycles of NACT, whereas 8(25%) patients received 4 cycles and 2(6.25%) patients received 5 cycles. However 5(15.63%) patients received all 6 cycles pre-operatively. Average number of NACT cycles in our study was 3.75 with a median of 3.

	Pre chemotherapy	Post chemotherapy
Mean of product of dimensions of lump	55.88	20.12
Median of the product of dimension of lump	31.56	6.07
SD	59.608	39.319
95 % C.I. of difference	20.121 – 51.391	
t-value	4.664	
p-value	<0.001, Highly significant	

Table 7: Decrease in Breast Lump size after NACT

In our study, it was observed that the lump size (product of two maximum diameters in cm) was reduced to more than half of the original size of presentation after NACT. It was found that reduction in lump size was statistically highly significant as evident from paired t- test ($t=4.664$, $p<0.001$).

Clinical response	No. of patients	Percentage
Ccr	04	12.50
cPR	22	68.75
cSD	05	15.63
cPD	01	03.12
Total	**32**	**100**

Table 8: Response to NACT

Table 8 shows that total 26 (81.25%) patients were responder to NACT {cCR(4)+cPR(22)}. Thus Objective Response (OR) was 81.25 %.

However pathological complete response (pCR) was seen in only 2 of the 32 down staged patients i.e. 6.25 %.

Out of 32 patients who received NACT, clinically lymph nodes were palpable in 28(87.50%) patients before chemotherapy. After chemotherapy nodes were palpable in 14(46.87%) patients.

Lymph nodal response to chemotherapy was assessed by Chi-square test and it was inferred that response was significant ($p < 0.05$).

Parameter		Responders (cPR+cCR)	Non-responders (cPD+cSD)	p-value
Age (years)	≤50	16 (80%)	4 (20%)	0.815
	>50	10 (83.33)	2 (16.67%)	
Size (cm)	≤7.5	17 (89.47%)	2 (10.53%)	0.15
	>7.5	09 (69.23%)	4 (30.77%)	
Menstrual status	Pre menstrual	11 (78.57%)	3 (21.43%)	0.732
	Post menstrual	15 (83.33%)	3 (16.67%)	

Table 9: Neoadjuvant chemotherapy response assessment on the basis of age, tumor size and menstrual status

Partial and complete responders clubbed together were labeled as Responders and the patients with static disease and disease progression as Non-responders. Response to chemotherapy was compared on the basis of age, pre chemotherapy size of tumor, menstrual status in an attempt to predict the response of chemotherapy on basis of these parameters.

As seen in table 9, the response to NACT in tumor <7.5 cm was better than in tumor >7.5cm, 89.47% and 69.23% respectively however was not statistically significant on applying Chi square test. Age & menstrual status were also not significantly associated with response as evident from the above table.

Surgery- MRM (Modified Radical Mastectomy) was performed in maximum, 51(89.48%) patients. While 3(3.51%) patients underwent ESM (Extended simple mastectomy), SM (Simple mastectomy) was performed in rest 3(3.51%) patients. None underwent BCS. Feasibility of BCS was assessed in downstaged patients. Out of 32, 4(12.5%) patients were feasible to undergo BCS but none opted for when involved in decision making.

Infiltrating ductal carcinoma was the most common histopathological subtype which was found in 51(89.48%) patients. Invasive lobular and Metaplastic carcinoma was found in 2(3.51%) patients each.

Margins	NACT followed by surgery		Surgery followed by Adjuvant chemotherapy	
	No. of patients	Percentage	No. of patients	Percentage
Positive	06	18.75	09	36
Negative	26	81.25	16	64
Total	32	100	25	100

Table 10: Margins in histopathological specimen

Out of total 57 patients histopathological margins for malignancy were positive in 15 (26.31%) and negative in 42(73.68%) patients. In neoadjuvant chemotherapy group (total 32 patients) margins were positive in 6(18.75%) patients and negative in 26(81.25%) patients. Surgery followed by adjuvant chemotherapy group (total 25 patients) showed 9(36%) margin positivity and 16(64%) margin negativity.

Average no of axillary lymph nodes identified in histopathological specimen of axillary dissection was 11.91 with less than half (5.52) were positive for malignant metastatic deposits.

DISCUSSION:

1. **Age distribution:** In our study mean age is 51.42 years and median age of presentation is 50 years.

   Mean age of the patients in the study by Bhattacharyya et al. (2014)[2] was 46 years, by Raina V et al. (2011)[3] was 48 years with a range of 22 to 85 years. Median age in the study by Cance et al. (2002)[4] was 44 year, by Swain et al (1987)[5] was 42 years.

   The average age of breast cancer patients, at presentation, has been reported to be 50–53 years in various population-based studies conducted in different parts of our country while a significant proportion of Indian breast cancer patients are younger than 35 years of age.[6]
2. **Menstrual status:** In our study 56.14% were in postmenopausal group. This is in concordance with study by Bhattacharyya et al. (2014)[2] (57.40%) and Raina V et al. (2011)[3] (56.5%.)
3. **Duration of presentation to hospital after development of symptoms:** In our study Mean duration of presentation after development of symptoms was 7.88 months with a median of 6 months as compared to 5 months in the study of Raina V et al. (2011).[3]

   Patient factor was the major cause of delay and lack of awareness about disease compounded with financial difficulty, i.e. inability to afford cost of treatment, led to neglect of disease by the patient herself and also by the relatives. Next common cause of advancement was treating doctors showing neglect by not referring the patient for treatment to a specialized center and trying to treat LABC with alternative pathies.
4. **Chemotherapy regimens:** In our study purely Anthracycline based chemotherapy regimens (CAF/CEF) were used in 61.4% patients while remaining patients received both taxanes and anthracyclines comparable to study by Bhattacharyya et al. (2014)[2]

5. **Number of NACT cycles:** Median number of NACT cycles in our study was 3 with a range from 2 to 6. In the study by Bhattacharyya et al. (2014) [2] median number of cycles was 6. Most of the studies (Raina V et al[3],Gupta et al[7], Vishwambharan et al[8], Egwuonwu et al[9], Deo et al. (2003)[10]) used 3 to 6 chemotherapy cycles pre-operatively, which is comparable to our study.

6. **Response to NACT:**

Study	No. of patients	cCR	cPR	SD	Progressive
Bhattacharyya et al. (2014)[2]	148 (IIIA included)	27 (18.2%)	92 (62.2%)	19 (12.8%)	10 (6.8%)
Raina V et al. (2011)[3]	128	17 (13.3%)	91 (71.1%)	13 (10.2%)	7 (5.5%)
Gupta et al. (2011)[7]	91	19 20.8 %	39.56%.	-	-
Vishwambharan et al. (2005)[8]	-	13%	73%	13%	1%
Deo et al. (2003)[10]	50	14%	52%	-	-
NSABP trial (1997)		36%	44%	-	-
Present study	57	4 (12.5%)	22 68.75%.	1 (3.12%)	5 (15.63%)

In the present study results are comparable to most of the studies, whereas some studies had a higher rate of complete clinical response. This could be due to the fact of different lump sizes in the studies with comparatively larger average tumor size (7.68 cm) in our study and newer chemotherapeutic agent used in other studies. Also many studies included Stage IIIA along with IIIB and IIIC, while our study purely includes Stage IIIB and IIIC only.

Total objective response: Our study showed an Objective Response (cCR + cPR) rate of 81.25%. OR is reported as 80.4% by Bhattacharyya et al. (2014)[2], 84.4% by Raina V et al. (2011),[3] 60.36% by Gupta et al. (2011)[7], 86% by Vishwambharan et al. (2005),[8] 66% by Deo et al. (2003),[10] 80% in NSABP B18 (1997) which included 608 patients showed that patients who received 4 cycles of doxorubicin and cyclophosphamide pre operatively.

Total objective response in the present study was comparable to most of the published studies.

Pathological Response: Our study showed a complete pathological response (pCR) in 2 out of 32 total patients i.e. 6.25% pCR which was 16.2% by Bhattacharyya et al. (2014)[2], 7.8% by Raina V et al. (2011)[3], (6.67%) by Vishwambharan et al. (2005)[8], 4% by Deo et al. (2003)[10] reported 4% pathological complete response out of 50 patients treated with neoadjuvant chemotherapy.

Most of the published studies had a higher complete pathological response compared to the present study; this could be due to the higher rates of cCR and the smaller initial lump size in the published reports.

When we tried to assess the response to chemotherapy on the basis of age, initial tumor size and menstrual status no statistically significant difference was found. Hence with the small sample size in the present study we can say that it is difficult to predict the response of chemotherapy with respect to these parameters.

With overall clinical response of 81.25%, neoadjuvant chemotherapy is an effective treatment option for patients with Locally Advanced Breast Cancer.

7. **Surgery:** In our study MRM (Modified Radical Mastectomy) surgery was performed in maximum, 51(89.48%) patients. While rest 10.52% patients underwent ESM (Extended simple mastectomy) and SM (Simple mastectomy).

   In our study 4 (12.5%) patients out of 32 downstaged were feasible to undergo BCS. However BCS was not done in any of those feasible as they opted for MRM when involved in decision making. Reasons for low feasibility of BCS in chemotherapy responders were excessive scaring at previous ulcer site, multifocality detected on mammography, incomplete regress of skin changes even after chemotherapy response.

   In the study by Bhattacharyya et al. (2014)(2) Breast conserving surgery was possible in 28.4% cases while 64.9% patients underwent modified radical mastectomy.

   In study by Gupta et al. (2011)(7) Surgery performed was modified radical mastectomy (MRM) for all 110 (100%) patients.

   These results are comparable to our study. Higher Feasibility of BCS in some studies could be due to inclusion of stage IIIA patients, which were not included in our study.

8. **Histopathology:** In our study infiltrating ductal carcinoma was the most common histopathological subtype which was found in 89.48% patients comparable to other studies. {2, 3, 4}

   In our study histopathological margins for malignancy were positive in 15(26.31%) and negative in 42 (73.68%) patients. Margin positivity was comparatively less in NACT group than in patients with having primary surgery.

   In the study by Bhattacharyya et al. (2014)[(2)] margins were positive in 8.1% patients.

   Higher positive margins in our study could be due to larger average tumor size, non-inclusion of Stage IIIA patients and primary surgery followed by adjuvant chemotherapy treatment protocol in some patients.

9. **Number of axillary lymph nodes identified in histopathology:** In our study median number of axillary lymph nodes identified on histopathology was 12.5 with 4 (Median) among them positive for metastatic deposits comparable to other studies (2, 3).

CONCLUSIONS: Locally Advanced Breast Cancer in the Indian scenario is an outcome of Neglect due to patient and system factors. These factors offer an excellent opportunity to plan a

community-oriented preventive strategy for the general population and practitioners to decrease the incidence of LABC.

Early detection and timely intervention can improve outcome. Smaller tumors responded better to NACT although not statistically significant. Neo-adjuvant Systemic Therapy is effective in management of Locally Advanced Breast Cancer (LABC) as effect of chemotherapy is statistically significant in down staging the disease with added advantages of in vivo testing the sensitivity of chemotherapeutic agents, early management of micrometastasis and feasibility of BCS.

Patients presenting LABC constitute a diverse group for which a variety of treatment modalities should be instituted with coordinated treatment planning among surgeons, medical oncologists and radiation oncologists.

However limitations of the study are small sample size, short follow up, and lack of survival analysis. A randomized controlled trial with larger sample size and longer follow-up is necessary.

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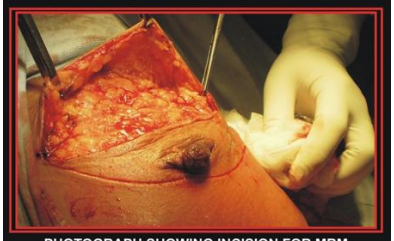
RESPONSE TO NEOADJUVANT THERAPY

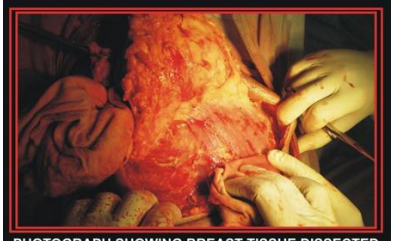
LUMP AT DIAGNOSIS

PATIENT SHOWING COMPLETE CLINICAL RESPONSE

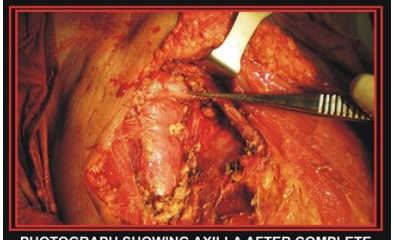
MODIFIED RADICAL MASTECTOMY



PHOTOGRAPH SHOWING INCISION FOR MRM



PHOTOGRAPH SHOWING BREAST TISSUE DISSECTED FROM PECTORALIS MAJOR



PHOTOGRAPH SHOWING AXILLA AFTER COMPLETE DISSECTION

SKIN INVOLVEMENT

PHOTOGRAPH SHOWING PEAU DE ORANGE APPEARANCE

PHOTOGRAPH SHOWING NIPPLE DEVIATION DUE TO CENTRAL QUADRANT LUMP INVOLVING SKIN

ORIGINAL ARTICLE

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