



A COMPARATIVE STUDY OF COMPLICATIONS OF MRM (MODIFIED RADICAL MASTECTOMY) VERSUS BCS (BREAST CONSERVATION THERAPY) IN EARLY INVASIVE BREAST CANCER. A RESULT FROM SAVERA CANCER AND MULTISPECIALITY HOSPITAL PATNA, BIHAR.

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ABSTRACT **Background:** Early breast cancer patients admitted in the surgical oncology department of SaverA Cancer and Multispeciality Hospital. Patients were divided in two treatment arms; Arm A and Arm B. Arm A patient went through MRM and Arm B patients went through BCS. This study included prospective cases of 1 year from June 2019 to June 2020. **Method:** In all MRM group patients all breast tissue, skin, nipple areola complex and level 1, 2, 3 lymph nodes removed. In all BCS group patients lump was removed with an envelope of normal appearing breast tissue. In all resected specimens free surgical margin was ensured via histopathology reports (HPR). Patients were reviewed in early post operative period for complications and follow up done at the end of 1st, 3rd, 6th and 12th month for recurrence. **Result:** In treatment Arm A (MRM) 08 patients developed arm edema; 05 patients developed shoulder dysfunction; 07 patients developed flap necrosis; 07 patients developed arm dysesthesia. Whether in treatment ARM B (BCT) 04 patient had Seroma formation; 13 patients developed wound infection & wound contracture. Complications were reported in 35% of MRM group (35 out of 100 cases), while they were absent in 65% (65 out of 100). However, in the BCS group, complications were reported in 6.66% cases only (15 out of 100 cases), while were absent in 93.33% (75 out of 100). P value by statistical analysis being 0.283, the difference being statistically insignificant. Recurrence were present in 6.66% of MRM group (8/100) while they were absent in 92.34 % (92/100). However in BCS group recurrences were present in 3.33 % (3/100) and were absent in 97.67% (97/100). P value by statistical analysis being 1, the difference being statistically insignificant. Grading of complications has been captured from CTCAE Version 5.0 (Common Terminology Criteria for Adverse Events).

Conclusion: There is slight significant difference in the recurrence rate, whether the patient had undergone BCS or MRM based on our short term follow-up. However a long term follow-up is required.

KEYWORDS : NACT, BCS, lumpectomy, MRM, Complications i.e. stable disease, partial response, complete response, disease progression.

INTRODUCTION:

The attempt to preserve the breast without compromising survival brought up the use of Breast Conserving Therapy (BCT). This includes breast conserving surgery and breast radiotherapy. Although BCT and breast conserving surgery (BCS) are used interchangeably, strictly speaking BCT includes both BCS and breast radiotherapy. BCS is an important part of the breast- conserving therapy, which may be defined as a combination of conservative surgery for resection of the primary tumor with or without surgical staging of the axilla, followed by radiotherapy for the eradication of the residual microscopic disease of the breast, with or without adjuvant systemic therapy ^[1] Breast conserving surgery (BCS) followed by radiation therapy (RT) is standard therapy for low grade Breast Cancer. It is safe and preferred therapeutic procedure in all early detected breast cancers, because it provides the same level of overall survival as mastectomy. Besides that, BCS provides much better cosmetic effect, compared to radical treatments, a significant gain for patients, if tumors of grade I and II are considered. Breast conservation has become the standard of care in Western countries for early breast cancer. In India, especially in Bihar, BCT still not popular due to various reasons including advanced stage at presentation, cost of treatment, lack of appropriate equipments and facilities, physician's and patient's awareness Oncoplastic Breast Conservative Surgery: By using plastic surgical technique with aim of good cosmesis, oncoplastic BCS is emerging in current practice. Number of conditions must be fulfilled to treat a breast cancer with BCS ^[2]. There are number of factors that favor BCS: Smaller, monocentric tumors; Younger age; Treatment carried out in specialized institutions; Favorable physical factors; Localization of tumor; Patient compliance.

MATERIAL & METHOD:

Early breast cancer patients admitted in the surgical oncology department of SaverA Cancer and Multispeciality Hospital. Patients were divided in two treatment arms; Arm A and Arm B. Arm A patients went through MRM and Arm B patients went through BCS. This study included prospective cases of 1 year from October 2019 to September 2020.

Sample size: 200 breast cancer patients on each arm:- Arm A [MRM] = 100 pts and Arm B [BCS] = 100 pts

Treatment allocation procedure: Through randomization

A) INCLUSION CRITERIA

1. Patients with early breast cancer stage I and II, T1N0M0/ T2N1M0. Diameter up to 5 cm.
2. Those who give written informed consent.
3. Age groups 18 plus and upto 65 years.

B) EXCLUSION CRITERIA

1. Patient in advanced stage of breast cancer/ MBC.
2. Neoadjuvant (NACT) chemotherapy patients.
3. Patients not willing to give written consent.
4. Lactating patients.
5. Elderly age group (65 onwards).

METHODOLOGY:

In treatment ARM A (MRM) patients all breast tissue, skin, nipple areola complex and level 1, 2, 3 lymph nodes removed. In treatment ARM B (BCS) patients lump was removed with an envelope of normal appearing breast tissue. In all resected specimens free surgical margin was ensured via histopathology reports. Patients were reviewed in early post operative period for complications and followed at the end

of 1st, 3rd, 6th and 12th month for recurrence.

1. Informed consent has been taken from all the patients recruited in the study.
2. All patients in study had undergone a detailed history taking including general examination.
3. All participants counseled about randomization. There are two arm treatments
 - a) Arm A Modified Radical Mastectomy (MRM)
 - b) Arm B Breast Conservative Surgery(BCS)
4. Patient's confidentiality i.e. name, address, contact details, ethnicity, and race will be Kept confidential as per GCP norms.

RESULTS:

Recurrence were present in 8.66% of Treatment Arm A (MRM group) (8 out of 100) while they were absent in 92.34 % (75 out of 100). However in Treatment Arm B i.e. BCS group recurrences were present in 20.00 % (20 out of 100) and were absent in 80.00% (80 out of 100). P value by statistical analysis being 2.283, the difference being statistically insignificant.

Fig. 1.1 Classification of participants on complications & recurrences Arm A (MRM)

Treatment Arm A (MRM)	Complications	Total No. of Pts = 100	%
100 Patients on this arm	Arm edema	8/100	8.00%
	Shoulder dysfunction	5/100	5.00%
	Flap necrosis	7/100	7.00%
	Arm dysesthesia	7/100	7.00%
	Recurrence	8/100	8.00%
		Total = 35 events/100 pts	35.00%

Fig. 1.2 Classification of participants on complications & recurrences Arm B (BCS)

Treatment Arm B (BCS)	Complications	Total No. of Pts = 100	%
100 Patients on this arm	Seroma formation	4/100	4.00%
	Wound infection and wound contracture	13/100	13.00%
	Recurrence	3/100	3.00%
		Total = 20 events/100 pts	20.00%

DISCUSSIONS:

Complications were present in 35.00% of MRM group (35 out of 100 cases), while they were absent in 65.00% (65 out of 100). However, in the BCS [3-5] group, complications were reported in 20.66% cases only (20 out of 100 cases), while they were absent in 80.33% (80 out of 100). P value by statistical analysis being 0.283, the difference being statistically quite significant. According to visual analogue scale the mean of mental satisfaction score in MRM group is 6.66, while in BCS group mean of mental satisfaction score is 7.60. P value by statistical analysis being 0.013, the difference is statistically significant. Similar results were demonstrated by a study at Athens University Medical School – 'Laiko' General Hospital, Athens, Greece who concluded that those undergoing breast-conserving surgery were more satisfied and reported a lower impact on their self-esteem and sexual life versus those who only had MRM/ Mastectomy [6-8]. Also in a multicentre randomized clinical trial in 1980 by EORTC-BCCG significant benefit in body image and satisfaction with treatment was observed in the BCS patients. Very slight significant difference was observed in rate of recurrence between the two groups [9].

CONCLUSION:

There is remarkable significant difference in the recurrence rate, whether the patient had undergone BCS or MRM based on our One year follow up (short term follow-up). However a long term follow-up is required. Complications has been observed and captured as per grading scale of CTCAE version 5.0.

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