

## A COMPARATIVE STUDY OF BREAST CONSERVATIVE SURGERY AND MODIFIED RADICAL MASTECTOMY IN EARLY BREAST CANCER

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### ABSTRACT

#### BACKGROUND

The improvement in the treatment of breast cancer is due to early diagnosis, better understanding of the natural history of this disease and therapeutic improvements over the years. There is a gradual shift away from radical surgery advocated by Halsted to the breast conservative surgery during the last few decades all over the world mainly influenced by the results of several large trials of lesser surgical procedures. The aim of the study is to compare the complications, duration of surgery and hospital stay, mental satisfaction of the patients, recurrence and survival of patients undergoing breast conservative surgery and modified radical mastectomy in early breast cancer.

#### MATERIALS AND METHODS

This was a cohort study of patients who presented with early breast cancer to the Department of General Surgery, Medical College Hospital, Calicut, between January 2007 and December 2008. Inclusion criteria were patients with early breast cancer, clinical stage I and II. All the patients were watched for different variables and were followed up for a period of five years.

#### RESULTS

Mean hospital stay of 7.47 days was there for BCS group while MRM group stayed for 9.4 days on an average. The 5-year disease-free survival rate in BCS group was 83.33% and that of MRM group was 86.66%. The five-year Distant Disease Free Survival Rate in BCS group was 86.66%. The same was 90% in MRM group. For mental satisfaction by visual analogue scale for BCS group, the mean came as 7.9333 with std. deviation of 1.14269 and std. error of 0.20863. In MRM group, the mean was 6.8333 with std. deviation of 1.26173 and std. error of 0.23036.

#### CONCLUSION

The 5-year disease-free survival and 5-year Distant Disease Free Survival Rate were comparable between BCS group and MRM group. Duration of hospital stay is less for the breast conservative surgery. There is significantly better mental satisfaction for the patients who underwent conservative surgery.

#### KEYWORDS

Breast Conservative Surgery, Modified Radical Mastectomy, Local Recurrence, Distant Metastasis, Mental Satisfaction. MeSH terms- Breast Carcinoma, Mastectomy, Modified Radical, Local Neoplasm Recurrence, Metastasis.

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#### BACKGROUND

The improvement in the treatment of breast cancer is due to early diagnosis, better understanding of the natural history of this disease and therapeutic improvements over the years. The surgical treatment provides a reasonable chance of curing for most of the early breast cancers. It mainly aims at dealing with potentially curable cancer confined to the breast and regional lymph nodes.<sup>1</sup>

The approach to operable breast cancer changed dramatically over the past century and so is the use of adjuvant therapy and presentation of the disease.

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Due to increasing awareness and improved diagnostic techniques and screening modalities breast cancer is nowadays diagnosed at an earlier stage.<sup>2</sup> During the 1970s, the Fisher propagated the idea that the disease in the majority of patients has already disseminated subclinically at an early stage before diagnosis. The Fisher attitude put an emphasis on systemic therapy than extensive surgery.<sup>2</sup>

There is a gradual shift away from radical surgery advocated by Halsted to the breast conservative surgery during the last few decades all over the world mainly influenced by the results of several large trials of lesser surgical procedures.<sup>3</sup> Conservative procedures refer to various treatment strategies that leave the breast largely intact with or without postsurgical radiation therapy and with or without axillary dissection.<sup>4</sup>

Several randomised studies compared different aspects of modified radical mastectomy and breast conservative surgery.<sup>3,5</sup> They all confirmed almost identical survival after these two treatment options. This study compares Breast Conservative Study (BCS) and Modified Radical Mastectomy

(MRM) in early breast cancer (T1 and T2, diameter up to 5 cm, N0 and N1, M0). Various aspects like age, HPR, adjuvant therapies, complications, recurrence, revision surgeries and how they fare after surgery were compared.

## MATERIALS AND METHODS

This was a cohort study of patients who presented with early breast cancer to the Department of General Surgery, Medical College Hospital, Calicut, between January 2007 and December 2008.

Inclusion criteria were patients with early breast cancer, clinical stage I and II (T1 and T2, diameter up to 5 cm, N0 and N1, M0). Patients with in situ lesions, stage other than I and II, those with positive margins after BCS and those who cannot be given radiotherapy were excluded from study.

Between January 2007 and December 2008, 30 patients underwent BCS (excision of the tumour with minimum one centimetre margin), complete axillary dissection and radiation therapy in our department. They were compared to an equal number of patients who underwent MRM. These patients were matched according to four baseline variables, which may have a significant association with local recurrence, distant metastasis and survival. These were age at diagnosis, axillary lymph node status, maximal diameter of the primary tumour and the use of neoadjuvant chemotherapy. The age of the patients was grouped in 10 years interval and matched accordingly. Axillary node status was matched as N0 or N1, maximal diameter of the tumour as T1 or T2 and whether taken or not taken neoadjuvant chemotherapy.

Patients in the BCS group underwent wide local excision of at least 1 cm margin. Patients in the MRM group underwent modified radical mastectomy. BCS group received radiotherapy to the breast in all cases. 50 Gy radiation was given in 25 cycles for each case. Radiation to the axilla was given according to the nodal status. Adjuvant chemotherapy was given to all cases.

All cases were watched for variables such as age, stage of disease, socioeconomic status, position of lump, presence of lymph nodes, tissue diagnosis, adjuvant chemotherapy, hospital stay, duration of surgery and wound complications.

They were called back and data were collected by referring medical records and interviewing them regarding their HPR, margins, adjuvant therapies, immediate and late complications, recurrence, revision surgeries and how they fare after surgery by visual analogue scale.

They were followed up for a period of five years. Patients underwent routine review and clinical examination every six months. Mammography of bilateral breasts or remaining breast (in case of total mastectomy) was done annually. Local recurrence was defined as any recurrence in the breast or chest wall or lymph nodes. These data was analysed and conclusions were made.

## RESULTS

There were 30 cases of breast conservative surgery, which was compared to other 30 cases, which underwent modified

radical mastectomy. They were followed up and data were collected. The mean period of follow up was 62 months. Comparing data of these patients, following observations were made.

The age, tumour size and nodal status of the patients included in this study are given in the Table 1. None of the patients had bilateral cancer. Seven patients underwent neoadjuvant chemotherapy. Majority of the patients were of poor socioeconomic status in both groups. In MRM, 80% of patients were of poor socioeconomic status and 20% of patients were of lower middle class. None were in upper middle class. Whereas in BCS group, 6.7% were in upper middle class and 63.3% were of poor socioeconomic status.

Variables	BCS	MRM
Mean Age	40.2	48.9
Minimum Age	21	28
Maximum Age	67	69
<b>Stage of the Disease</b>		
T1N0	4	4
T2N0	9	9
T1N1	2	2
T2N1	15	15
Neoadjuvant Chemotherapy	7	7
<b>Table 1. Age, Tumour Size and Nodal Status of the Patients</b>		

In this study, the commonest position of lump was upper outer quadrant. 46.7% cases in BCS group and 63.3% cases in MRM belonged to this site. In MRM group, 2 patients were of central group and BCS group had none in this position. Comparing these with chi-square test, p value came as 0.109.

In this study, the total duration of surgeries were compared. Mean duration of BCS was 87.5 minutes with standard deviation of 18.74 and std. error of 3.42. MRM took 91 minutes on an average with standard deviation of 12.21 and std. error of 2.23. By doing Student's t-test, p value of 0.395 was obtained (insignificant).

The hospital stay in the postoperative period was compared between two groups. Mean hospital stay of 7.47 days was there for BCS group while MRM group stayed for 9.4 days on an average. Significant p value of 0.007 was obtained by doing Student's t-test.

Immediate wound complications included in this study were seroma formation, wound infections, flap necrosis and wound gaping. Three patients in BCS group had wound complications compared to 2 patients in MRM group. Comparing these groups with chi-square test, the p value came as 0.64.

The histopathological types of carcinoma obtained in this study are summarised in the Table 2. Majority of the patients had infiltrating duct carcinoma in both groups; 27 patients in each group.

Histopathological Types	BCS	MRM
Infiltrating Duct Carcinoma	27 (90%)	27 (90%)
Medullary Carcinoma	2 (6.7%)	1 (3.3%)
Metaplastic Carcinoma	1 (3.3%)	0
Mucinous Carcinoma	0	2 (6.7%)

**Table 2. Histopathological Types**

Eight patients in MRM group and seven patients in BCS group had histologically positive nodes in axilla and they received radiotherapy for the same. In BCS group, all patients received radiotherapy for chest wall while 26.7% of patients in MRM group received it for the axilla.

### Followup Data

The late complications of the surgery like chronic pain, lymphoedema, frozen shoulder and paraesthesia were compared between these two groups. Results are given in the Table 3. Although, BCS group had lesser number of complications, the results were not statistically significant.

Variables	BCS	MRM	p value
Chronic pain	3 (10%)	8 (26.7%)	0.688
Lymphoedema	3 (10%)	4 (13.3%)	0.688
Paraesthesia	3 (10%)	5 (16.7%)	0.448
Frozen Shoulder	0	0	

**Table 3. Late Complications After Surgery**

### Mental Satisfaction

Visual analogue scale was used to grade the mental satisfaction of the patients. They were asked to grade it from 0 to 10 according to their subjective feeling of well-being and satisfaction. In BCS group, the mean came as 7.9333 with std. deviation of 1.14269 and std. error of 0.20863. In MRM group, the mean was 6.8333 with std. deviation of 1.26173 and std. error of 0.23036. The t-test for equity of means was done and p value of 0.001 was obtained.

### Recurrence and Survival

Two patients in BCS group developed local recurrence. One patient underwent re-excision and the other patient underwent salvage mastectomy later. One patient in MRM group developed local recurrence. Four patients in BCS group (2 bone, 1 lung and 1 liver) and 3 patients in MRM group (1 bone, 1 lung and 1 liver) developed distant metastasis over the course of five years of follow up.

Comparing these groups with chi-square test, the p value came as 0.69. The 5-year Disease Free Survival Rate in BCS group was 83.33% and that of MRM group was 86.66%. The five-year Distant Disease Free Survival Rate was 86.66% in BCS group and 90% in MRM group. The overall survival rate also was 86.66% and 90%, respectively.

### DISCUSSION

Now, all over the world, the trend is towards conservative surgery for carcinoma breast. Today, breast conservation rates have increased up to 75%,<sup>6</sup> but when compared to mastectomies, the number of breast conservative surgeries done is less in our institution, which caters to the vast

population of northern Kerala. In this study, comparison was made between BCS and MRM for early breast cancer in various aspects.

In this study, 60 patients were included; 30 each from BCS and MRM groups. Inclusion criteria were patients with early breast cancer- T1 and T2 disease. They were followed up and following data was collected. The mean month of follow up was 62 months.

Reduction of the anaesthesia time is one of the goals of any modification of all surgical procedures. It is found that mean duration of BCS was 87.5 minutes while MRM took 91 minutes on an average. Thus, BCS is faster to perform than MRM as per these observations. The increased duration in MRM maybe due to the complexity of the procedure. The difference between the duration between these two groups is not statistically significant.

Hospital stay of the patients following a surgery should be reduced for minimising total cost of the treatment. There was a significant difference between the hospital stay of the two groups as per this study. Mean hospital stay of 7.47 days was there for BCS group, while MRM group stayed for 9.4 days on an average. BCS proved to be better for duration of hospital stay. The difference between the duration between these two groups is statistically significant (0.007). The reported postoperative hospital stay following breast cancer surgery in the UK about a decade ago was 5 to 7 days.<sup>7</sup> The cause for prolonged duration of hospital stay maybe due to our habit of delayed removal of drain. Dalberg et al<sup>8</sup> in a large multicentre Swedish randomised trial showed that early removal of drain shortened the hospital stay without risking high incidence of seroma formation and other wound complication.

One of the factors, which influence the hospital stay includes immediate wound complications. Incidence of wound complications was comparable in two groups with no statistical significance. Pyfer B et al<sup>9</sup> analysed 11645 patients and found that SM group had significantly higher wound complications, bleeding, infections and overall complications than the BCS group.

Majority of the patients had infiltrating ductal carcinoma in both groups; 90% patients in each group. In BCS group, 2 patients had medullary and one had metaplastic carcinoma. In MRM, group 2 patients had mucinous and one had medullary carcinoma. The pattern of histopathology is similar in two groups. In one study by El-Marakby,<sup>10</sup> 82% patients had infiltrating duct carcinoma, 4% had intraductal carcinoma, 5% had invasive lobular carcinoma, 3% had mixed ductal and lobular, 2% had medullary and 2% had cribriform carcinoma.

In this study, at the end of follow up period late complications like pain, paraesthesia, lymphoedema and shoulder pain were analysed and following observations were made. Frozen shoulder was not seen in either group. This may be due to small sample size of this study. MRM group had slightly increased number of delayed complications, but it is not statistically significant. Thus, incidence of delayed complications is comparable between two groups.

In this series, visual analogue scale was used to grade the mental satisfaction of the patients. In BCS group, the mean came as 7.9333. In MRM group, the mean was 6.8333. This difference is statistically significant as per Student's t-test (0.001). Many patients in BCS group had fear for recurrence. This maybe the reason for the low score in some patients. For many patients in MRM group undergoing mastectomy was traumatising, but the fear of the carcinoma made them considering mastectomy especially in young patients. Surprisingly, many of the patients were not that much concerned of the cosmetic outcome of the breast conservative surgery.

A number of clinical studies in early breast cancer have shown the advantages of breast conserving surgery with an improved body image and a diminished psychological morbidity.<sup>11,12</sup> In a study involving 266 BCS patients, the cosmetic outcome was reported as excellent/good by 73% of the patients (self-assessment) vs. 43% as assessed by the oncologist ( $p < 0.001$ ).<sup>13</sup> In this study, also there is definite decrease in psychological morbidity as per the data of the analysis of mental satisfaction of the patients who underwent BCS.

In this study, two patients in the BCS group and one patient in the MRM group had local recurrence. In one study, the probability of having recurrent tumour was significantly higher in the group that received breast conserving therapy than in the radical mastectomy group.<sup>14</sup> It varied from 14.3% to 39.2% during a period of twenty years of follow up. In our study, 2 (6.67%) patients with BCS had local recurrence during a period of 5 years of follow up. Breast irradiation decreased the likelihood of a recurrence in the ipsilateral breast cancer in BCS group of patients.<sup>15</sup> The benefit of radiation therapy was independent of the nodal status.<sup>15</sup>

In this study, the 5-year Disease Free Survival Rate in BCS group was 83.33% and that of MRM group was 86.66%. The overall survival rate was 86.66% and 90%, respectively. Several randomised studies in Europe and North America that address various aspects of conservative treatment of breast cancer have accumulated an experience of 10 or more years of follow-up. All of them confirm that breast conserving local therapies and more radical surgical therapies yield similar rates of survival.<sup>3</sup> Furthermore, the National Cancer Institute's early breast cancer trial comparing lumpectomy, axillary dissection and radiation with modified radical mastectomy has accumulated a median potential 10-year follow-up. At 10 years, there was no difference between the two groups in overall survival (66% for the mastectomy patients and 65% for the BCT patients;  $P = 0.11$ ) or in their distant metastasis-free rates (66% for the mastectomy patients and 61% for the BCT patients;  $P = 0.24$ ).<sup>16</sup>

In another study by Lize Wang et al,<sup>17</sup> the 6-year local recurrence-free survival (LRFS) rates were 98.2% in the BCT group and 98.7% in the MRM group ( $P=0.182$ ), respectively. Disease Free Survival (DFS) rates in BCT and MRM groups were 91.3% and 86.3% ( $P < 0.001$ ), respectively, whereas the Distant Disease Free Survival (DDFS) rates in BCT and MRM groups were 93.6% and 87.7% ( $P < 0.001$ ), respectively. Ten year Recurrence Free Survival (RFS) and 20-year Overall Survival (OS) based on intent to treat did not reveal significant differences in outcome between BCS vs. mastectomy,  $p=0.95$  and  $p=0.10$ , respectively in a trial conducted by Danish Breast Cancer Cooperative Group (DBCG).<sup>2</sup> Comparison of local recurrence and survival rates of the patients in this study with that of other major studies are summarised in Table 4.

Trial	Period	Follow up (years)	Treatment		Local Recurrence %	Overall Survival %
			Type	Patients (n)		
Present study	2007-08	5	BCT	30	6.7 at 5 y	86.6 at 5 y
			MRM	30	3.3 at 5 y	90 at 5 y
Van Dogen et al <sup>16</sup> (EORTC 10801)	1980-86	13.4	BCT	448	19.7 at 10 y	65.2 at 10 y
			MRM	420	12.2 at 10 y	66.1 at 10 y
Fisher et al <sup>15</sup> (NSABP B-06)	1976-84	20	BCT	628	2.7 at 20 y	46 at 20 y
			MRM	589	10.2 at 20 y	47 at 20 y
Veronesi et al <sup>14</sup> (NCI Milan)	1973-80	20	BCT	352	8.8 at 20 y	58.3 at 20 y
			MRM	349	2.3 at 20 y	58.8 at 20 y
Lize Wang et al <sup>17</sup> (Peking University Cancer Hospital, China)	2000-09	6	BCT	873	1.8 at 6 y	DFS <sup>a</sup> - 91.3 at 6 y
			MRM	873	1.3 at 6 y	DFS- 86.3 at 6 y
Blichert-Toft et al <sup>2</sup> (DBCG-82TM)	1983-89	20	BCT	404	13 at 20 y	53.7 at 20 y
			MRM	389	21 at 20 y	49.1 at 20 y
Poggi et al <sup>18</sup> (U.S. National Cancer Institute)	1979-87	18.4	BCT	121	22 at 20 y	53 at 20 y
			MRM	116	0 at 20 y	58 at 20 y

**Table 4. Summary of Trials Comparing Breast Conserving Therapy with Mastectomy**

<sup>a</sup> Disease Free Survival

Conservative approach in early breast cancer surgery is now a days a widely accepted treatment option though there are still controversies when compared to mastectomy. In this study, the outcomes of both BCS and MRM were comparable except for hospital stay, need of radiotherapy and mental satisfaction of patients. Hospital stay was less for the BCS group, which can be considered as a definite advantage of the conservative surgery. There was significantly better mental satisfaction for the patients who underwent conservative surgery, which along with the decrease in hospital stay is a strong indicator patient compliance.

Though statistically insignificant, following findings were also obtained; more middle class patients in BCS group, decreased duration of surgery for BCS group and more patients in MRM group complained of chronic pain. All other findings were comparable between the two groups including the position of the lump, wound complications and late complications.

This study has many limitations like small sample size, lack of randomisation and less period of follow up. In order to achieve higher levels of evidence, RCTs comparing traditional mastectomy and breast conservative surgery would be desirable.<sup>19</sup>

## CONCLUSION

The 5-year Disease-Free Survival and 5-year Distant Disease Free Survival Rate were comparable between BCS group and MRM group. Duration of hospital stay is less for the breast conservative surgery. There is significantly better mental satisfaction for the patients who underwent conservative surgery. Wound complications, late complications and duration of surgery were comparable between the two groups. Thus, BCS has the advantage of less hospital stay and better mental satisfaction against the need for radiotherapy with comparable disease free survival.

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