



RESEARCH PAPER

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Comparison of Postoperative Complications of Breast Conserving Surgery Versus Modified Radical Mastectomy in Early Breast Carcinoma

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Abstract

Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death in female's worldwide. Carcinoma of breast is potentially curable disease when treated at early stage. Metastatic breast cancer is essentially incurable disease in spite of the clinical benefits of chemotherapy. Modified radical mastectomy (MRM) or even breast-conserving surgery (BCS) combined with radiotherapy, could achieve local recurrence rates and overall survival rates similar to more invasive approaches. In our study we compared the postoperative complications of BCS and MRM in Early Breast Carcinoma by examining a total of 160 women with stage I and stage II breast carcinoma. We also computed the rate of common complications such as seroma formation and wound infection. This can be helpful in deciding the better technique in terms of less complication rate.

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Introduction

Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death in female's worldwide, accounting for 23% (1.38 million) of the total new cancer cases and 14% (458,400) of the total cancer deaths in 2008 (Jemal *et al.*, 2011). About half of the breast cancer cases and 60% of the deaths are estimated to occur in economically developing countries (Jemal *et al.*, 2010; Jemal *et al.*, 2011).

In Pakistan multicentric studies have revealed that breast cancer is the most common malignant tumor and accounts for approximately 25% of all malignant tumors in the female population (Siddiqui *et al.*, 2000).

Carcinoma of breast is potentially curable disease when treated at early stage, which is still confined to the breast, but when it involves the regional lymph nodes, the survival rate will be less and once it spreads beyond regional lymph nodes, cure becomes impossible. Metastatic breast cancer is essentially incurable disease in spite of the clinical benefits of chemotherapy. With standard therapy such women have a median survival of the two years after documentation of metastasis (Parveen *et al.*, 2011).

The introduction of widespread mammographic screening, better imaging techniques, improved patient awareness and breast self-examination have all contributed to an increase in early diagnoses. Accordingly, survival rates have improved and an increasing number of patients present with operable disease. Surgery, therefore, continues to play a prominent role in the curative management of breast cancer.

Breast cancer surgery has changed dramatically over recent decades. Radical mastectomy was introduced over 100 years ago and required an en bloc removal of the breast, the muscles of the chest wall and the axillary lymph nodes. During the second half of the 20th century, more limited operations were promoted, based on suggestions that less radical surgery might be just as effective as the more

extensive operations then performed. During the 1970s, the first randomized clinical trials were conducted with the goal of determining that less invasive surgery, such as the modified radical mastectomy or even breast-conserving surgery (BCS) combined with radiotherapy, could achieve local recurrence rates and overall survival rates similar to more invasive approaches (Krekel *et al.*, 2013). For early-stage breast cancer, Breast conserving surgery is now accepted as a viable alternative to modified radical mastectomy and can be safely offered to most breast cancer patients, provided that additional radiotherapy is administered. When following national guidelines, over 75% of breast cancer patients qualify for breast-conserving treatment, and this is now the accepted care standard for the increasing number of women with early-stage breast cancers.

In a study showing patient undergoing modified radical mastectomy 20% developed seroma formation and 16.6% developed wound infection (Bhatty *et al.*, 2004).

In another study patients undergoing Breast conserving surgery, 6.67% developed seroma and 3.3% developed wound infection (Kayani *et al.*, 2008).

As there is dearth of data at national and international level on comparing complications associated with above two procedures.

In our study we will discuss the common complications such as seroma formation and wound infection, which are two most common post-operative complications of these 2 procedures. By knowing this we can provide base line data to our population.

This can be helpful in deciding the better technique in terms of less complication rate.

Original study

Objective

To compare the postoperative complications of Breast

Conserving Versus Modified Radical Mastectomy in Early Breast Carcinoma (Stage I and Stage II).

Operational definitions

Breast conserving surgery

In Breast conservation surgery resection of the primary breast cancer with a margin of at least 1cm of normal-appearing breast tissue was removed. Separate incision for Axillary Lymph node was given if lymph node were palpable.

Modified radical mastectomy

In this surgical procedure breast was completely removed with the underlying pectoralis minor and some of the adjacent lymph nodes. The pectoralis major was not excised.

Seroma

Accumulation of serous fluid following breast conserving surgery or modified radical mastectomy was checked by watery or bloody discharge or swelling of the wound.

Wound infection

Infection of wound was checked by any one of the following such as redness of wound margin or pus discharge up to 7 days.

Stage I breast cancer

Tumors which was ≤ 2 cm and limited to breast

Stage II breast carcinoma

Tumors which was >3 cm and <5 cm, or with ipsilateral non matted lymph nodes.

Hypothesis

Breast conservative surgery has fewer complications as compared to Modified radical mastectomy.

Material and methods

Study design

Randomized Control trial.

Setting

Study was conducted at Bolan Medical Complex

hospital, Quetta.

Duration of study

Six months from January 2013 to June 2013.

Sample size

By taking the prevalence of seroma that is 6.67% in Breast conserving Surgery and 20% in Modified radical mastectomy, Power of study = 80%, Level of significance 95%, at least 80 patients were required in each group.

Sampling technique

Non-Probability Consecutive sampling technique

Inclusion criteria

1. Patients with Stage I and stage II Breast Carcinoma
2. Tumor size should be less as compared to size of the breast
3. Tumor size ≤ 5 cm
4. No evidence of relapse since primary treatment
5. No other malignant diagnosis;
6. Age >35 and <75 years at the time of the survey.
7. Pts having diabetes and hypertension will be included

Exclusion criteria

1. Multi centric Tumor
2. Pregnancy (Radiation is Contraindicated)
3. Tumor size more as compared to breast
4. Central breast tumor
5. Positive surgical margins are also an absolute contraindication.
6. Prior Radiotherapy to breast
7. Associated diffuse micro calcifications which appear malignant on Mammogram.

Data collection procedure

Collection of data was started after approval of Synopsis by CPSP and after discussing with the Ethical committee at Bolan Medical Complex hospital Quetta. The patients were recruited from OPD. History was taken in detail. Thorough physical examination was performed. Informed consent was taken for surgery. Patient was included according to

inclusion and exclusion criteria. Patients were randomly allocated into two groups by lottery methods. Patients were prepared for surgery. Surgery was performed by Senior Consultant.

After Operation patient was followed for 7 days and final outcome was noted on 7th day postoperatively and was recorded on approved Performa.

Data analysis

Data was analysed through SPSS version 17. Mean and standard deviation were calculated for age and weight. Frequency and percentages were calculated for complication (seroma and wound Infection) in both groups. Chi-square test was applied to compare

the complications in both groups. Stratification with respect to age, weight, gender, diabetes and hypertension was done. Post stratification Chi-square test was applied. P-Value ≤ 0.05 was taken as significant.

Results

A total of 160 women with stage I and stage II breast carcinoma were included in this study. Patients were equally divided into two groups. Eighty women were operated with breast conservative surgery and other 80 were treated with modified redical mastectomy.

Most the women were above 50 years of age women as presented in figure 1.

Table 1. Comparison demographic variables between groups.

Variables	Breast Conserving Surgery n=80	Modified Redical Mastectomy n=80	P-Value
Age (Years)	56.06±9.18	57.9±6.96	0.15
Weight (kg)	64.88±5.71	65.7±6.59	0.39

Independent sample t test used to compare mean differences between groups.

Table 2. Comorbidities with respect to groups.

Variables	Breast Conserving Surgery n=80	Modified Redical Mastectomy n=80	Total
Hypertension			58(36.3%)
Yes	33(41.3%)	25(31.3%)	102(63.8%)
No	46(58.8%)	55(63.8%)	
Diabetic Mellitus			39(24.4%)
Yes	20(25%)	19(23.8%)	121(75.6%)
No	60(75%)	61(76.3%)	

The average age of the women was 56.98±8.18 years. Average age and weight of the women were not statistically significant between groups as shown in table 1. Regarding stage of disease, stage I carcinoma was found in 94(58.8%) and stage II was observed in

66(41.3%) cases. Stage of carcinoma with respect to groups is presented in figure 2. Hypertension was commonly observed in 58(36.3%) cases and diabetic mellitus was 39(24.4%) women (table 2).

Table 3. Comparison of post-operative complication between groups.

Post-Operative Complication	Breast Conserving Surgery n=80	Modified Redical Mastectomy n=80	Total	P-Value
Seroma Formation				0.001
Yes	11(13.8%)	29(36.3%)	40(25%)	
No	69(86.3%)	51(63.8%)	120(75%)	
Wound Infection				0.009
Yes	16(20%)	31(38.8%)	47(29.4%)	
No	64(80%)	49(61.3%)	113(70.6%)	

Chi-square test applied.

In this study, Post-operative complication seroma formation was developed in 25% (40/160) case and 29.4% (47/160) developed wound infection. Rate of seroma formation was significantly low in patients underwent breast conserving surgery as compare to modified redical mastectomy (13.8% vs. 36.3%;

$p=0.001$) similarly rate of wound infection was also significantly low in patients underwent breast conserving surgery as compare to modified redical mastectomy (20% vs. 38.8%; $p=0.009$) as presented in table 3.

Table 4. Comparison of post-operative complication between groups for ≤ 55 years of age women.

Post-Operative Complication	Breast Conserving Surgery n=32	Modified Redical Mastectomy n=31	Total	P-Value
Seroma Formation				0.039
Yes	5(15.6%)	12(38.7%)	17(27%)	
No	27(84.4%)	19(61.3%)	46(73%)	
Wound Infection				0.011
Yes	5(15.6%)	14(45.2%)	19(30.2%)	
No	27(84.4%)	17(54.8%)	44(69.8%)	

Chi-square test applied.

Table 5. Comparison of post-operative complication between groups for above 55 years of age women.

Post-Operative Complication	Breast Conserving Surgery n=48	Modified Redical Mastectomy n=49	Total	P-Value
Seroma Formation				0.010
Yes	6(12.5%)	17(34.7%)	23(23.7%)	
No	42(87.5%)	32(65.3%)	74(76.3%)	
Wound Infection				0.201
Yes	11(22.9%)	17(34.7%)	28(28.9%)	
No	37(77.1%)	32(65.3%)	69(71.1%)	

Chi-square test applied.

Age stratification analysis showed that rate of complications (seroma formation and wound infection) was significantly low in patients underwent breast conserving surgery as compare to modified

redical mastectomy in below and equal to 55 years of age women. Rate of seroma formation was significant between groups ($p=0.01$) as shown in table 4 while wound infection was insignificant between groups ($p=0.201$) in above 55 years of age women (table 5).

Table 6. Comparison of post-operative complication between groups for ≤ 65 kg weight of women.

Post-Operative Complication	Breast Conserving Surgery n=45	Modified Redical Mastectomy n=36	Total	P-Value
Seroma Formation				0.17
Yes	6(13.3%)	9(25%)	15(18.5%)	
No	39(86.7%)	27(75%)	66(81.5%)	
Wound Infection				0.004
Yes	7(15.6%)	16(44.4%)	23(28.4%)	
No	38(84.4%)	20(55.6%)	58(71.6%)	

Chi-square test applied.

Stratification analysis of weight of women showed that rate of complications seroma formation was insignificant while wound infection was significantly low in patients underwent breast conserving surgery as compare to modified redical mastectomy in below and equal to 65 kg weight of women (table 6) while

rate of seroma formation was significant ($p=0.003$) and wound infection was insignificant in patients underwent breast conserving surgery as compare to modified redical mastectomy in above 65 kg weight of women (table 7).

Table 7. Comparison of post-operative complication between groups for above 65kg weight of women.

Post-Operative Complication	Breast Conserving Surgery n=35	Modified Redical Mastectomy n=44	Total	P-Value
Seroma Formation				0.003
Yes	5(14.3%)	20(45.5%)	25(31.6%)	
No	30(85.7%)	24(54.5%)	54(68.4%)	
Wound Infection				0.42
Yes	9(25.7%)	15(34.1%)	24(30.4%)	
No	26(74.3%)	29(65.9%)	55(69.6%)	

Chi-square test applied.

Table 8. Comparison of post-operative complication between groups for hypertensive cases.

Post-Operative Complication	Breast Conserving Surgery n=33	Modified Redical Mastectomy n=25	Total	P-Value
Seroma Formation				0.014
Yes	4(12.1%)	10(40%)	14(24.1%)	
No	29(87.9%)	15(60%)	44(75.9%)	
Wound Infection				0.012
Yes	7(21.2%)	10(40%)	17(29.3%)	
No	26(78.8%)	15(60%)	41(70.7%)	

Chi-square test applied.

Stratification analysis for patients with hypertensive and diabetic were also presented in 6 to 9. Rate of complications seroma formation and wound infection was observed significant in patients with and without hypertensive. Similarly rate of seroma formation was insignificant and wound infection was observed

significant for diabetic women while rate of seroma formation was significant and wound infection was insignificant in patients underwent breast conserving surgery as compare to modified redical mastectomy for non-diabetic women as presented in table 8 and 9.

Table 9. Comparison of post-operative complication between groups without hypertensive cases.

Post-Operative Complication	Breast Conserving Surgery n=47	Modified Redical Mastectomy n=55	Total	P-Value
Seroma Formation				0.023
Yes	7(14.9%)	19(34.5%)	26(25.5%)	
No	40(85.1%)	36(65.5%)	76(74.4%)	
Wound Infection				0.035
Yes	9(19.1%)	21(38.2%)	30(29.4%)	
No	38(80.9%)	34(61.8%)	72(70.6%)	

Chi-square test applied.

Discussion

Breast conserving surgery and Modified radical mastectomy are the most commonly performed procedures in patients with CA Breast (Porter *et al.*, 1998) because it is a peripheral soft tissue organ,

many wound complications related to breast procedures are relatively minor and frequently are managed on an outpatient basis. Like every surgical procedure there is significant rate of morbidity and mortality.

Table 10. Comparison of post-operative complication between groups for diabetic cases.

Post-Operative Complication	Breast Conserving Surgery n=20	Modified Redical Mastectomy n=19	Total	P-Value
Seroma Formation				0.93
Yes	4(20%)	4(21.1%)	8(20.5%)	
No	16(80%)	15(78.9%)	31(79.5%)	
Wound Infection				0.015
Yes	4(20%)	11(57.9%)	15(38.5%)	
No	16(80%)	8(42.1%)	24(61.5%)	

Chi-square test applied.

Table 11. Comparison of post-operative complication between groups without diabetic cases.

Post-Operative Complication	Breast Conserving Surgery n=60	Modified Redical Mastectomy n=61	Total	P-Value
Seroma Formation				0.0005
Yes	7(11.7%)	25(41%)	32(26.4%)	
No	53(88.3%)	36(59%)	89(73.6%)	
Wound Infection				0.111
Yes	12(20%)	20(32.8%)	32(26.4%)	
No	48(80%)	41(67.2%)	89(73.6%)	

Chi-square test applied.

The morbidity includes early and late complications. Early complications include hemorrhage, hematoma, seroma, wound infection, skin flap necrosis,

paresthesia, edema of arm, and muscle paralysis. Late complications include shoulder stiffness, brachial plexopathy and psychosexual disturbances.

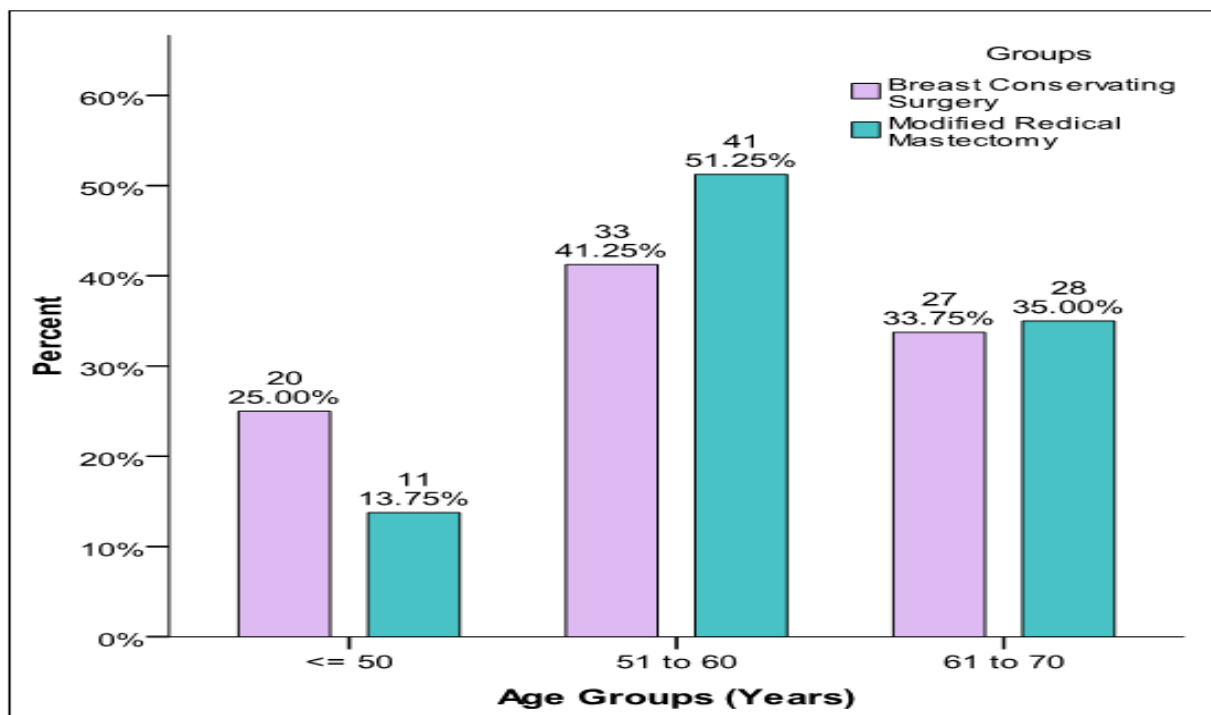


Fig. 1. Age distribution of the patients with respect to groups.

The most common complication in our study was wound infection which occurred in 29.6% of our patients. The literature shows the incidence of wound infection in 3.6% of patients in a study by Lanng and Hoffmann, 2002. In another study by Lefebvre D *et al*, 2000 the overall wound infection rate was 3.51%. In our study the rate of wound infection was significantly low in patients underwent breast

conserving surgery as compare to modified redical mastectomy. The increased number of wound infection in our patients, was due to factors associated with patients and hospital, like malnutrition, improper hygiene of patient, improper sterilization, the drain and wound care. These patients were treated with antibiotics according to culture and sensitivity report and sterilized daily dressing.

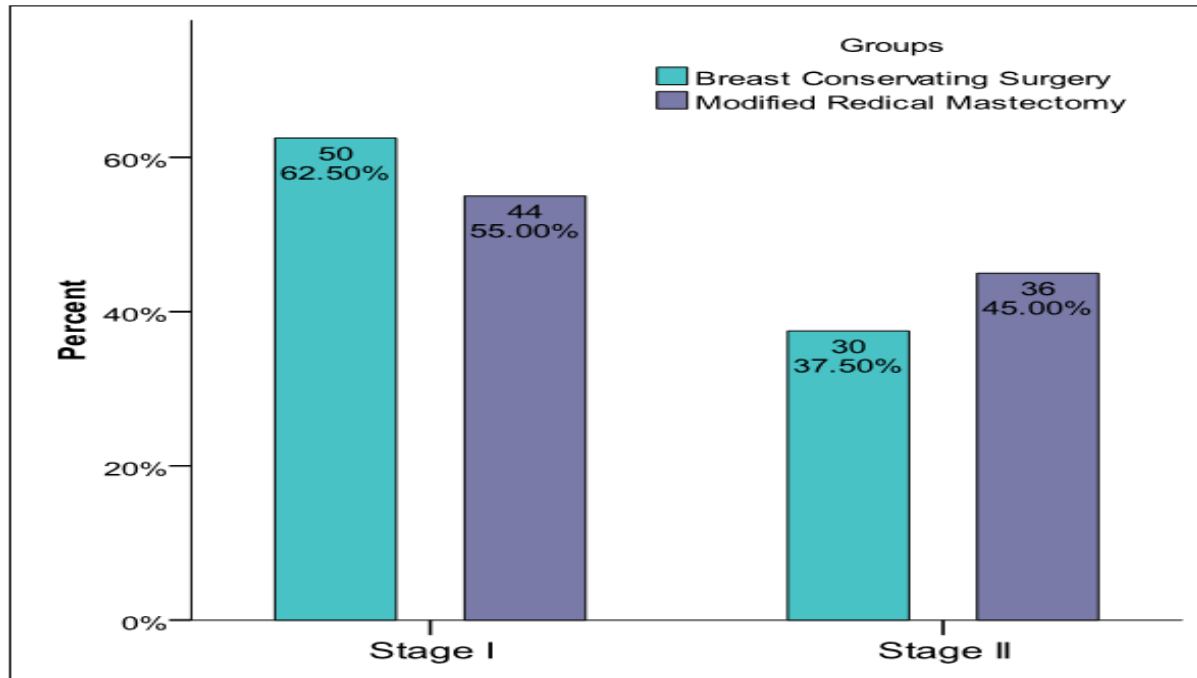


Fig. 2. Early breast carcinoma stages.

Use of preoperative antibiotic coverage to minimize infection rates has been evaluated in multiple retrospective as trials and in prospective, randomized, controlled trials.

These studies have yielded disparate results many have shown that a single dose of a preoperative antibiotic (usually a cephalosporin, administered approximately 30 minutes preoperatively) effectively reduces wound infection rates by 40% or more (Platt *et al.*, 1990; Platt *et al.*, 1993), and the meta-analysis by Platt *et al.*, 1993 revealed that antibiotic prophylaxis reduced wound infection rates by 38%, despite the selection bias of antibiotics being used predominantly in higher-risk cases. In our study seroma formation which was observed in 25% patients, while in literature the published rate of seroma formation varies between 4.2% and 89% in

un-drained axilla and as high as 53% in drained axilla (Talbot and Magarey, 2002). Woodworth *et al.*, 2000 observed seroma 2.5 to 51%. The overall seroma rate was 15.8% in study by Gonzalez EA *et al.*, 2003.

In our study it was observed that the rate of seroma formation was significantly low in patients underwent breast conserving surgery as compare to modified redical mastectomy. Seroma formation under the skin flaps of axillary or mastectomy wounds impairs the healing process; therefore, drains are usually left in place to evacuate postoperative fluid collections. Most breast cancer surgery is performed in the outpatient setting, and patients must be instructed about proper drainage catheter care. After 1 to 3 weeks, the skin flaps heal and adhere to the chest wall, as evidenced by diminished drain output. The seroma formation can be prevented by insertion of suction drain deep to

mastectomy flaps in the axilla (Cameron *et al.*, 1988).

Conclusion

Wound infection and Seroma formation are the most common complications found in patients with Breast surgery that can be detected early through proper postoperative care. It was evident in our study that Breast conservative Surgery has few or less complications as compared to modified radical mastectomy.

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Abbreviations

Breast-conserving surgery (BCS).

Modified radical mastectomy (MRM).

Radiation therapy (RT).