Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 14, Issue 9S (2025)
https://www.jneonatalsurg.com

OPEN ACCESS

Comparative Study Between Free Disease Interval of Modified Radical Mastectomy Versus Conservative Breast Surgery in Patients with Triple-Negative Breast Cancer

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Cite this paper as: Ahmed Zaki Ghareeb, Adel Morad Abdallah, Ahmed Sobhi Mahmoud, Emad M Mostafa, (2025) Comparative Study Between Free Disease Interval of Modified Radical Mastectomy Versus Conservative Breast Surgery in Patients with Triple-Negative Breast Cancer. *Journal of Neonatal Surgery*, 14 (9s), 903-908.

ABSTRACT

Background: Breast cancer is a significant concern in modern research due to its mortality and associated psychological aspects. In recent years, breast conservation surgery (BCS) and modified radical mastectomy (MRM) have been widely used in the treatment of early-stage breast cancer. This study aims to compare the free disease interval of modified radical mastectomy (MRM) versus conservative breast surgery (Lumpectomy) in patients with triple-negative breast cancer stage I and stage II. **Methods:** In this retrospective-based record comparative study, 100 triple negative (invasive ductal carcinoma confirmed through histopathology) breast cancer females' stage I and stage II were enrolled, the study was conducted at 6 October University Hospital. This study compares free disease interval (3-5 years) of modified radical mastectomy and conservative breast surgery. The study record was over a period from 2015 to 2022.

Results: There was a significant positive correlation between age and metastatic patients ($r = 0.329$; $P < 0.010$*). There was a significant positive correlation between metastatic patients and grade II, III & IV ($r = 0.777$, $P < 0.0001$; $r = 0.433$, $P < 0.0001$). There was a significant positive correlation between metastatic patients and stage Tmic/ T1a/ T1b, T1c, and T2 ($r = 0.624$; $P < 0.010$*; $r = 0.517$; $p < 0.0001$; $r = 0.494$, $p < 0.0001$). There was a significant positive correlation between metastatic patients and lymph nodes N0 and N1 ($r = 0.497$; $P < 0.010$*; $r = 0.195$, $p < 0.044$*).

Conclusion: modified radical mastectomy and conservative breast surgery in triple-negative breast cancer female patients, both techniques represent successful rates, however; conservative breast surgery had a higher successful rate than modified radical mastectomy.

Keywords: *Mastectomy; Conservative Breast Surgery; Triple Negative Breast Cancer*

1. INTRODUCTION

Triple-negative breast cancer (TNBC) is a term that has been applied to cancers that lack expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2).[1] TNBC is a very heterogeneous disease. Lehman et al., in 2011, divided TNBC into six different subtypes: basal-like 1 (BL1); basal-like 2 (BL2); mesenchymal (M); immunomodulatory (IM); mesenchymal stem-like (MSL); and luminal androgen receptor (LAR). [2]

In particular, triple-negative breast cancers (TNBCs), which account for approximately 10% to 17% of all patients with breast cancer, present poorly differentiated tumors lacking expression of ER, PR, and HER2 on immunohistochemical analysis; they are characterized by a high proliferation rate and increased aggressiveness compared with other subtypes be Because endocrine and HER2-targeted therapies cannot offered, conventional cytotoxic chemotherapy followed by adjuvant RT is the standard of care for patients with TNBC. The paucity of therapeutic options emphasizes the urgent need to optimize the current locoregional management of patients with TNBC and reduce their risk of locoregional recurrence (LRR).[3]

Breast-conserving surgery (BCS) including radiotherapy (RT) has been demonstrated in numerous clinical trials to provide at least an equivalent prognosis to mastectomy (M) in breast cancer. These trials did not account for specific breast cancer subtypes such as triple-negative breast cancer (TNBC). [4]

This study aims to compare the free disease interval of modified radical mastectomy (MRM) versus conservative breast surgery (Lumpectomy) in patients with triple-negative breast cancer stage I and stage II.

Patients and Methods

In this retrospective-based record comparative study, 100 triple negative (invasive ductal carcinoma confirmed through histopathology) breast cancer females' stage I and stage II were enrolled, the study was conducted at 6 October University Hospital. This study compares free disease interval (3-5 years) of modified radical mastectomy and conservative breast surgery. The study record was over a period from 2015 to 2022.

Inclusion Criteria: Patients more than 25 years old, All the included patients are females, Patients with a history of previous triple-negative breast cancer and a Confirmed diagnosis of triple-negative breast cancer.

Exclusion Criteria: Patients with known hereditary breast cancer syndromes and Patients with concurrent malignancies or having cancer at any other of the body site or unfit for the surgery.

Ethical Considerations: The study protocol was submitted to the relevant institutional review board (IRB) approval or ethics committee for review and approval before initiation to ensure that the study is conducted in accordance with ethical guidelines and regulations. The OCU REC was organized and operated according to guidelines of the International Council on Harmonization (ICH) and the Islamic Organization for Medical Science (IOMS), the United States Office for Human Research Protection and the unites states Code of Federal Regulations and operates under federal wide assurance (FWA) No. 00017858.

All the patients studied were subjected to:
All the included data collected from a variety of sources, medical records, and pathology reports from 6 October University Hospital. Demographic Data, Medical History, **and** Physical examination included changes or differences in the shape, size, or thickness of the breasts. differences in skin color, temperature, and texture in the breasts, such as redness, increased warmth or dimpling of the skin and rashes, or any nipple changes such as inversion, deviation, and bloody discharge and examination of axillary lymph nodes (5 groups) with supraclavicular lymph nodes may be mobile and firm in early stage or Fixed and hard in late stage. TNBC History: stages (regional, I or II), diagnosis negative for both estrogen (ER) and progesterone (PR) hormone receptors as well as human epidermal growth factor receptor 2 (HER2). Treatment Outcomes: Treatment was evaluated based on the medical record which included ultrasound record results, mammogram, true cut incision, histopathological exam, and stagging at the time of diagnosis. The diagnosis of TNBC was confirmed by biopsies and resected surgical samples through histopathological investigations. In addition, the free disease interval in each method was analyzed, and cosmetic outcomes and psychological outcomes were assessed.
Statistical Analysis: Analysis of data was performed using SPSS for Windows version 23 for statistical analysis. Categorical variables were described by **number and percentage** (N, %), whereas continuous variables were described by mean and standard deviation **(Mean, SD)**. **The chi-square test** and Fisher exact test are used to compare between categorical variables and compare between continuous variables by **t-test** and ANOVA. **A two-tailed p < 0.05** was considered statistically significant. All analyses were performed with the **IBM SPSS 21.0** software.

Results

Table (1) - Demographic Data and Patient Characteristics

Data	**MRM (N = 47)**	**Conservative (N = 53)**	**Test of Sig.**	**P value**
Age				
Mean±SD	49.42±10.32	47.21±9.15	2.262	>0.309
Min - Max (Median)	25 - 71 (49)	25 - 63 (48.5)		
Menpausal Status				
Pre (N%)	24 (51%)	20 (37.5%)	2.364	>0.124
Post (N%)	23 (49%)	33 (62.50%)		
Family History				
-ve (N%)	45 (95.70%)	47 (88.60%)	2.351	>0.504
+ve (N%)	2 (4.30%)	6 (11.40%)		
Marital status				
Married (N%)	32 (68%)	43 (81%)	2.131	**<0.0004***
Single (N%)	3 (6.50%)	1 (1.90%)		
Divorced (N%)	4 (8.50%)	5 (9.5%)		
Widowed (N%)	8 (17%)	4 (7.60%)		
Comorbidities				
No Comorbidities (N%)	21 (44.60%)	26 (49.40%)	2.068	1.000
DM (N%)	5 (10.60%)	12 (22.80%)		
HTN (N%)	11 (23.40%)	13 (24%)		
IHD (N%)	5 (10.60%)	2 (3.80%)		
Smoking (N%)	3 (6.40%)	0 (0%)		
Hysterectomy (N%)	2 (4.30%)	0 (0%)		

Table (1) - shows that; The mean age of MRM was 49.42±10.32 years old, minimum and maximum of 25 to 71 with a

median age of 49 years old and a mean age of 47.21±9.15 years old, minimum and maximum of 25 to 63 with a median age 48.5 years old, there were non-significant differences between MRM and conservative breast surgery regarding age (p > 0.309). There were non-significant differences between MRM and conservative breast surgery regarding family history (p > 0.504). There were significant differences between MRM and conservative breast surgery regarding marital status (p < 0.0004*). There were non-significant differences between MRM and conservative breast surgery regarding comorbidities (p > 1.000).

Table (2) - Tumor Stages, Grades, Size and Lymph Nodes

Data	MRM (N = 47)	Conservative (N = 53)	Test of Sig.	P value
Stage			2.201	**0.002***
Tmic /T1a/T1b (N%)	12 (25.50%)	23 (43.40%)		
T1c (N%)	15 (31.90%)	18 (33.90%)		
T2 (N%)	20 (57.40%)	12 (22.70%)		
Tumor Size (cm)			2.205	**0.004***
T1 (<2) (N%)	20 (42.55%)	17 (32.10%)		
T2 (2 - 5) (N%)	27 (57.45%)	36 (67.90%)		
Tumor Grade			2.202	**0.0039***
I (N%)	31 (65.90%)	27 (50.90%)		
II (N%)	15 (31.90%)	23 (43.40%)		
III and IV (N%)	1 (2.20%)	3 (5.70%)		
Lymph Node			2.085	**0.0004***
N0 (N%)	18 (38.30%)	21 (39.70%)		
N1 (N%)	29 (61.70%)	32 (60.30%)		

Table (2) - shows that; The stages of the MRM group represented Tmic /T1a/T1b stage 25.50%, T1c stage 31.90%, and T2 stage 57.40%, the stages of conservative breast surgery represented Tmic /T1a/T1b stage 43.40%, T1c stage 33.90% and T2 stage 22.70%, there was significant differences between MRM and conservative group regarding tumor stage (P <0.002). There were significant differences between the MRM and conservative group regarding tumor size (P <0.004). There were significant differences between the MRM and the conservative group regarding tumor size (P <0.0039). There were significant differences between MRM and the conservative group regarding lymph nodes (P <0.0004).

Table (3) - Type of Surgery, Neoadjuvant & Adjuvant Treatment

Data	MRM (N = 47)	Conservative (N = 53)	Test of Sig.	P value
Type of Surgery			2.137	0.302
LT. Side	20 (42.50%)	28 (52.80%)		
RT. Side	27 (57.5%)	17 (32.20%)		
RT & LT Side	0 (0%)	8 (14.40%)		
Adjuvant & Neoadjuvant Therapy (Chemo/Radio)				
Neoadjuvant & adjuvant (N%)	38 (80.90%)	36 (67.90%)	2.134	1.000
Adjuvant (N%)	9 (19.10%)	17 (32.10%)		

Table (3) - showed that; There were non-significant differences between the MRM group and conservative breast surgery regarding the type of surgery (P > 0.302). The Adjuvant & neoadjuvant therapy (chemo +/- Radio) represented MRM 80.90% and adjuvant only 19.10%, There were non-significant differences between the MRM group and conservative breast surgery regarding Adjuvant & neoadjuvant Therapy (P > 1.000).

Table (4) - Year of Diagnosis and Surgery, Follow-up and Update

Data	MRM (N = 47)	Conservative (N = 53)	Test of Sig.	P value
Year of Surgery			2.093	1.000
2017	1 (2.12%)	3 (5.70%)		
2018	6 (12.80%)	5 (9.50%)		
2019	6 (12.80%)	6 (11.40%)		
2020	14 (29.80%)	21 (39.70%)		
2021	20 (42.50%)	18 (33.70%)		
Last follow-up Update			2.405	1.000
2020	5 (10.70%)	9 (16.90%)		
2021	7 (14.80%)	11 (20.75%)		
2022	9 (19.20%)	8 (15.10%)		
2023	8 (17%)	6 (11.40%)		
2024	18 (38.30%)	19 (35.85%)		
Follow-up			2.052	1.000
Free	32 (68.08%)	39 (73.58%)		
Recurrence	0 (0%)	6 (11.32%)		

Metastasis				
Bone	10 (21.27%)	4 (7.54%)		
Liver	1 (2.12%)	2 (3.77%)		
Lung	4 (8.51%)	2 (3.77%)		

Table (4) - showed that; There were non-significant differences between MRM and conservative breast surgery group regarding year of surgery (P > 1.000). There were non-significant differences between MRM and the conservative breast surgery group regarding the last follow-up update (P > 1.000). There were non-significant differences between MRM and the conservative breast surgery group regarding follow-up (P > 1.000).

Table (5) - Relation between recurrence & metastasis cases in MRM and BCS with therapy

Recurrence, Mets / Therapy	MRM (N = 15)	BCS (N = 14)
Neoadjuvant	5 (33.33%)	4 (28.57%)
Non	10 (66.66%)	10 (71.42%)

Table (5) - showed that; In MRM metastasis patients there were 5 (33.33%) patients from a total of 15 patients who received neoadjuvant therapy. In BCS Recurrence, metastasis patients there were 4 (28.57%) patients from a total of 14 patients who received neoadjuvant therapy**.**

Table (6) - Relation between recurrence & metastasis cases in MRM and BCS with Stages

Recurrence, Mets / Stages	MRM (N = 15)	BCS (N = 14)
Tmic /T1a/T1b (N%)	0%	0%
T1c (N%)	6 (40%)	4 (28.57%)
T2 (N%)	9 (60%)	10 (71.43%)

Table (6) - showed that; In MRM metastasis patients there were 6 (40%) patients in stage T1c and 9 (60%) in stage T2. In BCS recurrence, metastasis patients there were 4 (28.57%) patients in stage T1c and 10 (71.43%) in stage T2.

Table (7) - Correlation between metastasis and Demographic Data and Tumor characteristics

Recurrent Cases	Correlation (rs)	P Value
Age	0.329	0.010*
Grade		
I	0.096	0.468
II	0.777	<0.001**
III & IV	0.433	<0.001**
Stage		
Tmic /T1a/T1b	0.624	<0.001**
T1c	0.517	<0.001**
T2	0.494	<0.001**
Lymph Node		
N0	0.497	<0.001**
N1	0.195	0.044*

Table (5) - showed that; There was a significant positive correlation between age and metastatic patients (r = 0.329; P <0.010*). There was a significant positive correlation between metastatic patients and grade II, III & IV (r = 0.777, P <0.0001; r = 0.433, P <0.0001). There was a significant positive correlation between metastatic patients and stage Tmic/ T1a/ T1b, T1c, and T2 (r = 0.624; P <0.010*; r = 0.517; p <0.0001; r = 0.494, p <0.0001). There was a significant positive correlation between metastatic patients and lymph nodes N0 and N1 (r = 0.497; P <0.010*; r = 0.195, p <0.044*)

Discussion

Triple-negative breast cancer (TNBC) refers to a subtype of breast cancer that is negative for estrogen receptor (ER), progesterone receptor (PR), and HER-2 expression. TNBC accounts for approximately 10–20% of all breast cancer patients and is highly heterogeneous **(Guo et al., 2021).**[5]

This study aims to compare the free disease interval of modified radical mastectomy (MRM) versus conservative breast surgery (Lumpectomy) in patients with triple-negative breast cancer stage I and stage II.

There were non-significant differences between MRM and conservative breast surgery regarding age (p > 0.309), menopausal status (p > 0.124), family history (p > 0.504), and comorbidities (p > 1.000).

Another previous study **Gammal et al.**[6] was conducted on 20 patients, 10 patients treated with MRM, and 10 patients

treated with CBS. Their age ranged between 41-65 years in the CBS group compared with 45-70 years with a mean age. In the CBS group 6 (60 %) of patients were married compared with 4 (40 %) in the MRM group of patients. There was no statistically significant difference in this age, marital status, comorbidities, and distribution.

There were significant differences between the MRM and conservative group regarding tumor stage (P <0.002), tumor size (P <0.004), tumor grade (P <0.0039) and lymph node (P <0.0004).

Another previous study **Gammal et al.**[6] in the CBS group, 6 (60 %) of patients were affected on the left side compared with 5 (50 %) in the MRM group of patients. There was no statistically significant difference in this distribution. In the CBS group tumor size was < 2 cm in 6 (60 %) of patients w compared with 5 (50 %) in the MRM group of patients. (2-5) cm in 4 (40%) and 4 (40%) in CBS and MRM groups respectively. One patient in MRM had (> 5) cm tumor size. A statistical correlation was found (p-value: 0.047). In the CBS group, tumor grade II was found in 3 (30 %) of patients compared with 2 (20 %) in the MRM group of patients. Tumor grades III and IV were present in 7 (70%) and 8 (80%) in the CBS and MRM groups respectively. This was a statistically significant difference (p-value: 0.001). In the CBS group, N 0 was presented in 7 (70 %) of patients compared with 8 (80 %) in the MRM group of patients. N1 was in 3 (20%) and 2 (20%) in CBS and MRM groups respectively. N2 presented in only one patient in the CBS group. This was a statistically significant difference (p-value: 0.022).

There were non-significant differences between the MRM group and conservative breast surgery regarding type of surgery (P > 0.302) and Adjuvant & neoadjuvant therapy (P > 1.000), year of surgery (P > 1.000).

Additionally, on locoregional treatment of TNBC patients has been limited by relatively small sample sizes and has demonstrated inconsistent outcomes. **Guo et al.**[5] identified a total of 1325 patients with TNBC who underwent CBS or mastectomy and found that the five-year LRR-free survival and distant metastasis-free survival rates were higher in the CBS group.

A study **Tutt et al.**[8] including 1,138 TNBC patients who were treated with CBS, mastectomy alone, or mastectomy plus RT showed that for 775 T1-2N0- 1M0 TNBC patients, the adjusted risks of mortality in the three groups were not significantly different.

However, **Chen et al.**[9] their study consisted of 11,514 TNBC patients, constituting a larger cohort and a wide range of patients from the SEER database, and provided more convincing evidence that CBS+RT may not be contraindicated for TNBC patients. Additionally, the primary outcomes of BCSS and OS can represent the ultimate effects of different surgical types.

There were non-significant differences between MRM and the conservative breast surgery group regarding the last follow-up update (P > 1.000). There were non-significant differences between MRM and the conservative breast surgery group regarding follow-up (P > 1.000).

A study by **Houshyari et al.**[7] reported that since December 2014, a median follow-up time was 71 months (range 48 - 192 months), 11 cases (1.68%) of local recurrence were shown in the BCT group and seven patients (1.07%) of local recurrence were shown in MRM group during the five years of follow up. Thus the 5-year local recurrence-free survivals were 98.32% in the BCT group and 98.93% in the MRM group. There were not any significant local recurrence differences between the BCT group and MRM group based on the log-rank test 5-year local recurrence analysis, (P = 0.173, RR = 1.13, 95% CI = 1.05 - 1.22). Then patients in the BCT group did not show more local recurrence than the MRM group. In the BCT group, 68 patients (10.38%) were diagnosed with distant metastasis during the 5-year follow up and 121 patients (18.47%) had a distant recurrence in the MRM group. Thus the 5-year-distant recurrence-free survival was 89.62% in the BCT group and 81.53% in the MRM group. We found a significant difference between the two groups as distant recurrence-free survival based on log-rank test analysis (P < 0.001, RR = 1.78, 95% CI = 1.58 - 1.98).

Luo et al.[10] showed that BCT patients had worse LR, inferior 5-year DFS, and inferior 5-year OS than MRM cases as stage I, II, and III of breast cancer; in the present study, We showed 5-year DFS and 5-year OS in both groups were compatible, that were inconsistent with Yuan et al.'s study.

Wang et al.[11] in July of 2000 showed the 10-year local recurrence rates were 20% in the BCT patients and 12% in the MRM cases (P = 0.01). These findings were inconsistent with our study which found the 5-year LR rates were 1.68% in the BCT cases and 1.07% in the MRM patients (P = 0.173). They also showed that the 10-year OS rates in the BCT and MRM groups were 66% and 65% (P = 0.011), respectively.

There was a significant positive correlation between age and metastatic patients (r = 0.329; P <0.010*). There was a significant positive correlation between metastatic patients and grade II, III & IV (r = 0.777, P <0.0001; r = 0.433, P <0.0001). There was a significant positive correlation between metastatic patients and stage Tmic/ T1a/ T1b, T1c, and T2 (r = 0.624; P <0.010*; r = 0.517; p <0.0001; r = 0.494, p <0.0001). There was a significant positive correlation between metastatic patients and lymph nodes N0 and N1 (r = 0.497; P <0.010*; r = 0.195, p <0.044*).

Another previous study **Gammal et al.**[6] Overall Survival was investigated in patients with TNBC treated with mastectomy compared with those receiving CBS. Kaplan-Meier analysis was used to generate Overall Survival for these two surgical types. The analysis indicated that patients with CBS had better survival than patients with mastectomy in Overall Survival (P < 0.001). In the Multivariate analysis, excellent survival was identified in the CBS group when compared with the mastectomy group (HR, 0.579; 95%CI, 0.488 to 0.687; P < 0.001, for Overall Survival).

A study by **Houshyari et al.**[7] reported that The five-year DFS rate was 87.94% and 80.46% in the BCT and MRM groups,

respectively. We observed a significant difference between the two groups as the five-year DFS based on the log-rank test analysis (P < 0.001). Then patients in the BCT group showed better DFS than the MRM group. In the BCT and MRM groups, the five-year OS rate was 89.31% and 83.02%, respectively. We showed a significant difference between the two groups as the five-year OS based on log-rank test analysis (P = 0.041). Then patients in the BCT group showed better OS than the MRM group.

Conclusion

In conclusion, from our study on October 6 University Hospital data, regarding modified radical mastectomy and conservative breast surgery in triple-negative breast cancer patients, both techniques represent a successful rate, however; conservative breast surgery was at a higher successful rate than modified radical mastectomy. Therefore, CBS is a preferable choice for TNBC patients if given adequate Adjuvant & neoadjuvant treatment.

Recommendations

One of the strengths of the present study rests on the sizable number of triple-negative breast cancer patients on the 6th of October University Hospital database, which ensures the strength and objectivity of our conclusions.

Limitations

However, concerning the TNBC subtype, the early peaks of recurrence and mortality occur within the first 5 to 10 years after diagnosis. Additionally, information on adjuvant or neoadjuvant chemotherapy is not The Aim of our study and probably variables According to tumor biology we are still not aware that may exert a certain influence on our results.

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