

A COMPARATIVE STUDY OF SEROMA FORMATION AFTER EARLY AND LATE REMOVAL OF DRAINAGE IN MODIFIED RADICAL MASTECTOMY MRM

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ABSTRACT

Background: Seroma following modified radical mastectomy is the most common wound complication. Various techniques are being practiced in the management of seroma, but whether early or late drain removal after mastectomy remains controversial. **Objective:** The aim of this study was to assess whether early drain removal after radical mastectomy influences the incidence of complications and quality of life. **Patients and Methods:** A Prospective Randomized Clinical Trial conducted for the period one year (May 2021 – May 2022) at Tishreen University Hospital in Lattakia-Syria. The study included two groups of women were compared: group I consisted of 22 women (47.8%) who underwent mastectomy and receive early drain removal, whereas group II consisted of 24 women (52.2%) who underwent mastectomy and received standard drain removal. Final outcome regarding complications and quality of life post-surgery were compared between two groups. **Results:** A total of 46 women with mean age of 50.1±9.4 years were included in the study. Seroma was occurred more frequently in group 1 (36.4% versus 25%, p:0.4). The rate of additional drainage tube insertion after drain removal didn't differ significantly between the two groups (27.3% in group 1 versus 16.7% in group 2, p: 0.3) with a mean number of drainage in group 1 (5.08±2.08) versus (1.9±1.31) in group 2, p: 0.5. Compared to late drain removal, early type reduced significantly hospital length of stay (1.77±0.7 versus 2.54±1.4, p:0.02), improved quality of life regarding the following variables; absence of shoulder pain post-surgery (81.8% versus 66.7%, p:0.01), limitation in daily activities and personal care (50% versus 79.2%, p:0.0001), nursing care needs at home after discharge (22.8% versus 91.7%, p:0.0001), restricted range of motion (27.3% versus 66.7%, p:0.0001), limitation in activities due to caring of wound (9.1 % versus 41.7 %, p:0.0001), and effects on social activities (18.2 % versus 54.2%, p:0.0001). **Conclusion:** The current study demonstrated favorable results in efficiency of early removal of drain to an early return to normal life without increasing complications.

KEYWORDS: Mastectomy, seroma, drainage, early, late.

INTRODUCTION

Breast cancer is the most common cancer of women in the world with continuous improvement in survival rates due to the early detection and management.^[1] Surgery represents the option for management of breast cancer which ranges from breast conserving treatment to more radical options.^[2] Modified radical mastectomy (MRM) is a legacy procedure that is rarely indicated.^[3] It is defined as a complete removal of breast and underlying fascia of the pectoralis major muscle with along with level I, II of axillary lymph nodes, and this resection was suggested to improve disease control.^[4]

Seroma represents the most common complication after MRM, which defined as collection of serous fluid in the dead space of post-mastectomy skin flap, axilla or breast.^[5] Responsible mechanism for the formation of seroma is poorly understood, but there are many factors that increased the occurrence such as extensive surgery, use of electrocautery for dissection, and presence of obesity. Formation of seroma predisposes to infection, flap necrosis, delayed wound healing, and wound dehiscence.^[6] There are two drains that used when MRM is performed to prevent seroma formation, one is placed beneath inferior mastectomy skin flap, and the another drain is placed into the axilla.^[7]

There is a paucity of evidence on optimal timing to remove drains, and several studies have evaluated advantages and disadvantages of early versus late removal due. Absence of the local studies prompted to conduct this study, therefore the aims of our study were: 1- to elucidate differences between the two techniques regarding the complications, 2- to determine quality of life of the two methods.

PATIENTS AND METHODS

This is a Prospective Randomized Clinical Trial of a group of women with breast cancer that required modified radical mastectomy attending department of general surgery at Tishreen University Hospital in Lattakia-Syria during one-year period (May 2021- May 2022). The exclusion criteria were presence of one of the following: patients who underwent conservative mastectomy, women who received radiation therapy before surgery, development of wound infection after surgery, and males with breast cancer. The following workup included history and physical examination were performed. The modified radical mastectomy procedure with level I and II lymph node dissection was done according to the standard recommendations and the wound was drained.

Patients assigned to group I who undergone to early drain removal (on third day after surgery), and group II who undergone late drain removal (after 7 days of surgery or when the volume of drained fluid is less than 50 ml on two consecutive days). Patients were followed up at regular intervals in the post-operative period regarding occurrence of seroma, volume of drained fluid, duration of hospitalization, and quality of life and the results were compared between two groups.

Ethical consideration: All patients were provided a complete and clear informed consent after discussion about the study. This study was performed following the Declaration of Helsinki.

Statistical Analysis

Statistical analysis was performed by using IBM SPSS version 20. Basic Descriptive statistics included means, standard deviations (SD), median, Frequency and percentages. To examine the relationships and comparisons between the two groups, chi-square test was used. Independent t student test was used to compare 2 independent groups. All the tests were considered significant at a 5% type I error rate ($p < 0.05$), β : 20%, and power of the study: 80%.

RESULTS

The baseline characteristics of the participants were as shown in (Table 1). Ages range from 30 to 73 years (mean 50.1 ± 9.4 years) and the age group 50-60 years represented the most frequent age group (67.4%) followed by the group 40-50 years (13.1%), older than 60 years (10.8%) and 30-40 years (8.7%). Patients were divided according to body mass index (BMI) as follows:

normal in 7 cases (15.2%), overweight in 29 cases (63%), and obese in 10 cases (21.7%). Diabetes mellitus was detected in 16 cases (34.8%).

Table 1: Demographic characteristics of the study population.

Variable	Result
Age (years)	50.1 ± 9.4 (Range 30-73)
Age groups	
30-40	4 (8.7%)
40-50	6 (13.1%)
50-60	31 (67.4%)
>60	5 (10.8%)
BMI	
Normal	7 (15.2%)
Overweight	29 (63%)
Obesity	10 (21.7%)
Diabetes mellitus	
Present	16 (34.8%)
Absent	30 (65.2%)

Patients were classified according to the time of drain removal into two groups: early in 22 cases (47.8%) and late in 24 cases (52.2%). The demographic characteristics were compared between the two groups as shown in table 2.

There was no significant difference between two groups regarding age (53.36 ± 9.5 in group I versus 51.94 ± 8.6 , $p: 0.2$). Age groups were compared between two groups (group 1 versus group 2); 30-40 years (4.5% vs. 12.5%), 40-50 years (9.1% vs. 16.7%), 50-60 years (72.7% vs. 62.5%), and > 60 years (13.6% vs. 0%), $p: 0.09$. There was no significant difference between two groups regarding BMI (27.63 ± 3.9 versus 27.67 ± 3.2 , $p: 0.9$). BMI groups were compared between two groups (group 1 versus group 2); normal (22.7% vs. 8.3%), overweight (59.1% vs. 66.7%), and obese (18.2% vs. 25%), $p: 0.3$. Diabetes mellitus was present in 6 cases (27.3%) group 1 versus 8 cases (33.3%) in group 2, $p: 0.8$.

Table 2: Demographic characteristics of the study population by comparison of the two group.

Variable	Group 1 Early 22(47.8%)	Group2 Late 24(52.2%)	P value
Age(year)	53.36±9.5	51.94±8.6	0.2
Age groups			
30-40	1(4.5%)	3(12.5%)	0.09
40-50	2(9.1%)	4(16.7%)	
50-60	16(72.7%)	15(62.5%)	
>60	3(13.6%)	0(0%)	
BMI	27.63±3.9	27.67±3.2	0.9
Normal	5(22.7%)	2(8.3%)	0.3
Overweight	13(59.1%)	16(66.7%)	
Obesity	4(18.2%)	6(25%)	
Diabetes mellitus			
Present	6(27.3%)	8(33.3%)	0.8
Absent	16(72.7%)	16(66.7%)	

The duration of hospitalization was significantly longer in group 2(2.54±1.4 versus 1.77±0.7, p0.02). Occurrence of seroma was observed among 8 patients (36.4%) in group 1 versus 6 cases (25%) in group 2 without significant difference, p:0.4. Of all 22 patients in group

1, 6 patients (27.3%) needed reinsertion of a drain, versus 4 patients (16.7%) in group 2, p: 0.3, with a mean number of drainage 5.08±2.08 versus 1.9±1.31 in group 2,p:0.5.

Table 3: Outcome of by comparison of the two group.

Variable	Group 1 Early 22(47.8%)	Group2 Late 24(52.2%)	P value
Duration of hospitalization (day)	1.77±0.7	2.54±1.4	0.02
Seroma			
Present	8(36.4%)	6(25%)	0.4
Absent	14(63.6%)	18(75%)	
Drain re-insertion	6(27.3%)	4(16.7%)	0.3
Number of drainage	5.08±2.08	1.9±1.31	0.5

Table (4) shows the number of answers, in percentages, for each question after surgery. When QOL among the groups was compared, no significant differences were observed between the two groups regarding the pain at the site of breast in which 22.7% and 4.6% of the patients in group 1 were experienced mild and severe pain in the site of surgery versus 33.3% and 4.2% in group 2, p:0.2, as well as disturbances of sleep in which 77.3% of the patients in group 1 experienced of sleep problems after surgery versus 75% in group 2, p: 0.8.

activities(present in 18.2 % of the group 1 versus 54.2% in group 2, p:0.0001).

On the other hand, there were significant differences between two groups regarding the following statements: shoulder pain in the same side of surgery (absent in 81.8% in group 1 versus 66.7% in group 2, p:0.01), limitations in daily activities (present in 50% of the group 1 versus 79.2% in group 2, p:0.0001), need for nursing care at home (present in 22.8% of the group 1 versus 91.7% in group 2, p:0.0001), limited range of motion (present in 27.3% of the group 1 versus 66.7% in group 2, p:0.0001), restriction of activities due to wound care(present in 9.1% of the group 1 versus 41.7% in group 2, p:0.0001), and effects on social

Table 4: Quality of life post-operative by comparison of the two group.

Question	Group 1 Early 22(47.8%)	Group2 Late 24(52.2%)	P value
Pain in breast area after surgery			
No	16(72.7%)	15(62.5%)	0.2
Yes			
Mild	5(22.7%)	8(33.3%)	
Severe	1(4.6%)	1(4.2%)	
Ipsilateral shoulder pain post-surgery			
No	18(81.8%)	16(66.7%)	0.01
Yes			
Mild	4(18.2%)	6(25%)	
Severe	0(0%)	2(8.3%)	
Limitations in activities of daily living or personal care			
No	11(50%)	5(20.8%)	0.0001
Yes			
Mild	10(45.4%)	13(54.2%)	
Severe	1(4.6%)	6(25%)	
Need for nursing services for post-operative care at home			
No	17(77.2%)	2(8.3%)	0.0001
Yes			
Mild	4(18.2%)	20(83.3%)	
Severe	1(4.6%)	2(8.3%)	
Disturbances of sleep quality after surgery			
No	5(22.7%)	6(25%)	0.8
Yes	17(77.3%)	18(75%)	
Limited range of motion(walking, driving)			
No	16(72.7%)	8(33.3%)	0.0001
Yes			
Mild	4(18.2%)	10(41.7%)	
Severe	2(9.1%)	6(25%)	
Limitations in activities due to wound care			
No	20(90.9%)	14(58.3%)	0.0001
Yes			
Mild	1(4.55%)	7(29.2%)	
Severe	1(4.55%)	3(12.5%)	
Limitations in social activities			
No	18(81.8%)	11(45.8%)	0.0001
Yes			
Mild	3(13.6%)	8(33.3%)	
Severe	1(4.6%)	5(20.8%)	

DISCUSSION

This Randomized Clinical Trial of radical mastectomy in 46 women assessed prevalence of seroma occurring after surgery in early versus late removal of drain and final outcome regarding quality of life. This study showed the main findings: First, patients were of a wide range of ages and there were no significant differences between two groups regarding age, BMI, presence of diabetes mellitus. Second, seroma and re-insertion of drain were observed more frequently in early group with higher number of drainage in this group but without significant difference ($p > 0.5$). Third, duration of hospitalization was significantly shorter in early removal group ($p: 0.02$). Finally, quality of life was better in early removal group regarding shoulder pain, limitation of daily activities, need for nursing care, motion, wound care and

continuing social activities. These findings are comparable with results of previous studies.

Dalberg et al (2004) demonstrated in a study conducted in 247 women who underwent modified radical mastectomy from five hospitals during four years that early removal of drain was associated with more seromas formation and shorter duration of hospitalization without any increasing in wound complications.^[8]

Vos et al (2018) demonstrated in a study conducted in 99 women who underwent breast cancer surgery that early removal was associated significantly with improved quality of life, lower duration of home nursing care and volume of fluid drained ($p < 0.05$). There were no significant differences between two groups regarding

wound healing and the rate of infection which was slightly lower in early removal.^[9]

Shima et al (2021) demonstrated in meta-analysis study (7 studies) included women who underwent breast surgery that formation of seroma in early drain removal group was significantly higher than in late group, without significant differences between two groups regarding surgical site infection. In addition to, early removal of drain was associated significantly with shorter duration of hospitalization.^[10]

On the other hand, Barton et al (2006) showed in a study performed in 24 women who underwent modified radical mastectomy that early drain removal was associated with higher rates of complications, whereas patients in late removal had lower rates of seroma aspirations, drain re-insertion, and fewer physician office visits.^[11]

In summary, there appears to be good evidence in favor of early drain removal due to clinical benefit regarding quality of life and decreasing of hospital stays without significant complications.

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