



Comparison between a Single Drain with Two Drains Following Modified Radical Mastectomy for Breast Cancer

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Abstract

Background: The primary modality for treatment of breast cancer is surgery that is mastectomy. In attempt to decrease morbidity the Modified Radical Mastectomy (MRM) was introduced. The complications following breast surgeries include wound infection, seroma, hematoma, chronic pain, venous thromboembolism, surgical dog ear, late sequel-breast fibrosis, lymphedema and recurrent cellulitis. Of these seroma poses a major threat. The aim of this study is to evaluate for seroma formation, post-operative pain, flap necrosis and quality of life in patient with single drain versus two drains following modified radical mastectomy for breast cancer.

Methodology: A single center randomized clinical study was conducted at PGIMER and Dr. RML Hospital, New Delhi from November 2015 to March 2017. A total 100 cases of carcinoma breast who met inclusion and exclusion criteria were selected by randomization table method for putting one drain or two drains.

Result: 20% (10 out of 50) of patients with double drain had seroma formation and 22% (11 out of 50) of patients with single drain had seroma formation. Chi-square analysis suggests that there was no significant difference in the incidence of seroma formation between two groups. Chi square value was 0.060 and p-value was >0.05. T-test analysis shows higher drain output is significantly associated with seroma formation. The p-value is 0.002 (P<0.05). Post-operative flap necrosis, numbness, lymphedema, VAS pain score and shoulder dysfunction shows no significant difference in between two groups (p-value >0.05).

Conclusion: Based on this study, one drain and two drain insertion techniques are equally effective methods to reduce seroma formation and associated complications after modified radical mastectomy. Thus we recommend insertion of a single drain as compare to double drain following modified radical mastectomy.

Keywords: Breast cancer; Modified radical mastectomy; Seroma formation

Introduction

The primary modality for treatment of breast cancer is surgery that is mastectomy. The radical mastectomy was originally described by Halsted [1] and was regarded as standard of care for every breast cancer patient. As this operation was associated with high morbidity [2]. In attempt to decrease morbidity the Modified Radical Mastectomy (MRM) was introduced and efficacy of both operations was equal while the morbidity was markedly decreased in MRM.

The complications following breast surgeries include wound infection, seroma, hematoma, chronic pain, venous thromboembolism, surgical dog ear, late sequel-breast fibrosis, lymphedema and recurrent cellulitis. Of these seroma poses a major threat [3,4].

Seroma formation is the most frequent post-operative complication seen after mastectomy and axillary dissection. The incidence of this seroma varies between 3% to 85% [5,6]. Seroma can cause ischemia, necrosis, and infection or wound dehiscence in pectoral and axillary flap. These complications and seroma reduces quality of life in patients [7].

Conversely patients undergoing MRM have a significant increased incidence of seroma formation when compared to those who have breast conservation surgery [8]. The number of removed lymph nodes probably does not influence seroma formation [9]. A randomized controlled trial by Purushotham et al. [10] demonstrated that sentinel lymph node biopsy is associated with significantly less seroma formation than that of conventional axillary dissection. Randomized trials have shown that the use of electrocautery for dissecting flaps is significantly associated with increased

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seroma formation when compared to that of scalpel dissection [11]. The use of drains after surgery for breast cancer is probably the most investigated and at the same time most controversial of all the techniques aimed at preventing or reducing the incidence of seroma formation. The use of closed suction drainage in the patient who underwent mastectomy accelerates wound healing and is also associated with a lower incidence of wound infection, necrosis and breakdown [12]. The influence of negative pressure causing skin flap opposition to the chest wall may facilitate wound healing reduce the incidence of wound infection, wound dehiscence or flap necrosis and prevent seroma formation [13]. There are however controversies correlating to the optimal suction pressure, number of drains, duration of drainage or in fact whether the drain should be used at all following breast cancer surgery. There are few studies to compare the use of single and multiple drains in breast surgery for breast cancer. Terrell and Singer [14] reported that the use of two drains (axilla and chest wall) is not superior to that of one drain in the axilla in preventing seroma formation in their 84 patients. Petrek et al. [15] randomized 65 patients undergoing axillary dissection or MRM for stage I or II carcinoma into one or four suction drains into the axilla. Both the groups had a drain in their chest wall dead space. The use of multiple drains in axilla conferred no advantage as they did not affect the amount and duration of drainage compared with single drain.

Our study was initiated to compare the use of a single drain with two drains following MRM in a controlled, randomized prospective setting. The primary aim of the study was to compare the seroma formation. The secondary was to compare the post-operative pain, flap necrosis, quality of life and to identify other factors that might affect seroma formation.

Methods

The participants in this study are patients having carcinoma breast reporting to General Surgery Department of PGIMER and RML Hospital, New Delhi from November 2015 to March 2017. A total 100 patients of carcinoma breast who will meet the inclusion and exclusion criteria and will be selected by randomization table method for putting one drain or two drains.

Drain placement technique

One drain-one drain was placed in axillary area

Two drains-two drains were placed, one in axillary area and other one in pectoral area.

Inclusion criteria

All operable cases of carcinoma breast

Exclusion criteria

Inflammatory carcinoma, metastatic carcinoma and cases selected by randomization table for one drain and on table are indicated for two drains were also excluded from our study.

Randomization

Randomization was performed in the operating room with randomization table method (50 for one drain group and 50 for two drains group).

Surgery

Mastectomies were performed with diathermy. For axillary lymphadenectomy, all tissues inferior to the axillary vein, between the anterior border of latissimus dorsi and medial to the medial border of pectoralis minor up to the apex of the axilla was removed. The

pectoralis minor was retracted and not divided. The long thoracic, thoracodorsal nerve and intercostobrachial nerve was identified and preserved. Patients were randomized, if patient belonging to one drain group one drain was placed in axillary area and in patients belonging to two drain group two drains were placed one in axillary area and other in pectoral area. Breast mass was sent for pathological evaluation.

Follow-up

All patients were followed up on 1st, 3rd & 5th day and 4 weeks after the removal of drain. Drains were removed once daily output was <30 ml.

Outcomes variables

1. Seroma formation (no. of times aspiration required, aspiration done with needle)
2. Post-operative pain- VAS
3. Flap necrosis
4. Quality of life (in terms of)
 - Number of days required to attain normal physical activity
 - Incidence of post-op numbness, shoulder dysfunction or lymphedema
 - Incidence of post-op pain at drain site after one week of discharge of patient.

Statistical analysis

The statistical analysis was done using statistical software package SPSS v22.0. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean \pm SD. Normality of data was tested and if the normality was rejected then non parametric test was used. Continuous variables were compared using t-test/Mann-Whitney test and ordinal/nominal data was compared using Chi-square/Fisher's test. P-value <0.05 was taken as significant.

Results

The study was conducted from 1st November, 2015 to 31st March, 2017. A total of 100 patients were included in the study. The groups (single vs. double drain) results were compared regarding age, number of days required to remove drainage, volume of fluid (ml) drained, incidence of seroma formation, number of aspirations required, volume of seroma (ml) aspirated, VAS pain scale on various days and flap necrosis (Table 1) and found that there were no significant differences (p-value >0.05). The volume drained (with drainage system) and seroma formation showed that higher drain output is significantly associated with seroma formation (p-value <0.05) (Table 2). The comparison of single versus double drain groups regarding quality of life (in terms of) days required to resume physical activities, numbness, lymphedema, shoulder dysfunction, VAS pain scoring on week 1 after discharge (Table 3) showed that there were no significant differences (p-value >0.05).

Discussion

Seroma formation is the most frequent post-operative complication seen after mastectomy and axillary surgery with an incidence of 3% to 85%. Other complications are wound infection, wound dehiscence, hematoma, chronic pain, post-op numbness, shoulder dysfunction, lymphedema etc. many studies are conducted

Table 1: Comparison of single versus double drain groups regarding age, number of days required to remove drainage, volume of fluid (ml) drained, incidence of seroma formation, number of aspirations required, volume of seroma (ml) aspirated, VAS pain scale on various days and flap necrosis.

| | | Single drain, n=50 | Double drain, n=50 | p-value |
|---|--|--------------------|--------------------|---------|
| Age | | 47.54 ± 8.3 | 45.86 ± 9.3 | 0.344 |
| Number of days required to remove drain | | 5.70 ± 0.73 | 5.54 ± 0.78 | 0.296 |
| Volume of fluid (ml) drained | | 556.40 ± 46.59 | 552.20 ± 57.30 | 0.688 |
| Incidence of seroma formation | | 22% (11) | 20% (10) | 0.806 |
| Number of aspirations required on | 1st day | 0.02 ± 0.1 | 0.00 ± 0.0 | 0.32 |
| | Between 1 st - 3 rd day | 0.12 ± 0.4 | 0.08 ± 0.3 | 0.632 |
| | Between 3 rd and 5th day | 0.24 ± 0.6 | 0.16 ± 0.5 | 0.498 |
| | Between 5 th day and 4 th week | 2.10 ± 4.0 | 1.72 ± 3.5 | 0.619 |
| Volume of serosa (ml) aspirated | | 318.80 ± 44.48 | 312.20 ± 60.21 | 0.534 |
| VAS pain scale on | Day 0 | 54.8 | 46.1 | 0.117 |
| various days | | | | |
| (post-op) | Day 1 | 46 | 55 | 0.103 |
| | Day 2 | 47 | 54 | 0.201 |
| Flap necrosis | | 6 (12%) | 5 (10%) | 0.749 |

Data is given as mean ± Standard Deviation (SD)

Table 2: The correlation between volume drained (with drainage system) and seroma formation.

| | Seroma formation (n=100) | | p-value |
|--------------------|--------------------------|---------------|---------|
| | No (n=79) | Yes (n=21) | |
| Mean drain out put | 546.20 ± 53.6 | 584.76 ± 30.4 | 0.002** |

Data is given as mean ± Standard Deviation (SD)

**higher drain output is significantly associated with seroma formation

Table 3: Comparison of single versus double drain groups regarding quality of life (in terms of) days required to resume physical activities, numbness, lymphedema, shoulder dysfunction, VAS pain scoring on week 1 after discharge.

| | Single drain, n=50 | Double drain, n=50 | p-value |
|---|--------------------|--------------------|---------|
| Days required to resume physical activities | 5.54 ± 0.7 | 5.54 ± 0.7 | 1 |
| Numbness | 2 (4%) | 2 (4%) | 1 |
| Lymphedema | 4 (8%) | 3 (6%) | 0.695 |
| Shoulder dysfunction | 6 (12%) | 5 (10%) | 0.749 |
| VAS pain scoring on week 1 after discharge | 47.1 | 53.8 | 0.189 |

Data is given as mean ± Standard Deviation (SD)

to look for the factors thought to contribute to seroma formation and the probable interventions that may be of help to reduce incidence. In a prospective study by Taylor et al. [16] on the results of surgery before and after implementing 'no drain policy' in a hospital in UK, there was no significant difference in occurrence of seroma, frequency of aspiration and wound infection in patients undergoing MRM surgery with or without drain insertion. In a retrospective study done by Saratzis et al. [17] have evaluated women undergoing MRM in three groups of one, two and three drains and results showed insignificant differences in volume of seroma produced among the three groups, however women with only one drain experienced less discomfort and hospital stay. A prospective randomized clinical trial done by Chintamani et al. [18] compared half vs. full vacuum suction drainage after modified radical mastectomy for breast cancer and result showed that half drainage system is better with reduced seroma and shorter hospital stay when compared with full suction drainage. In a clinical trial, Puttawibul et al. [19] compared one and two drains in patients undergoing MRM, their results revealed insignificant differences in seroma formation, volume of aspirated

liquid or complication after surgery. Another clinical trial by Terrell and Singer [14] compared insertion of an axillary drain with combined axillary and pectoral drains after MRM and results showed insignificant differences in complications between two groups. The study by Hashemi et al. [11] showed that seroma occurred in 35% of patients and the association of post-operative seroma formation was noted with modified radical mastectomy. No other factor was found to significantly affect the seroma formation after breast cancer surgery and they also concluded that there was no association between drain count and seroma formation, similar to our study. In a study by Akinci et al. [20] they concluded that hypertension and drainage flow rate greater than 40 ml/day for more than 7 days predict seroma formation following breast cancer surgery. Loo et al. [21] reported that presence of hypertension is a risk factor for seroma formation, particularly when the post-operative drainage exceeded 500 ml in the first three days. In our study we found that higher drain output is significantly associated with seroma formation. The p-value was <0.05 and therefore it should be further investigated. A randomized clinical trial done by Guneri et al. [22] they reported that seroma formation was higher in single drain group when compared with double drain group after mastectomies and also found that double drains groups have been shown to decrease seroma formation without increasing patient's discomfort and duration of hospital stay. Our randomized clinical study showed no difference between patient with one or two drains and according to results seroma formation occurred in 21% after MRM, with insignificant difference between the two groups and insertion of one or two drains made no difference in incidence of seroma formation. Also there is no significant difference in the incidence of other complications like flap necrosis, post-operative numbness, lymphedema, shoulder dysfunction and also no significant difference is seen in the days required to resume physical activities between two groups.

According to results it can be therefore being agreed that there is no need for the second drain after MRM, and the same results can be obtained by axillary drain alone.

Conclusion

In our study, according to obtained results, one drain and two

drains insertion techniques are equally effective methods to reduce the seroma formation and associated complications after modified radical mastectomy.

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