

A Randomized Control Trial of Single VS Double drains in Modified Radical Mastectomy

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ABSTRACT

Background: Modified Radical Mastectomy is the most common procedure which is done for carcinoma breast in this part of the world. Normally MRM is done with two drains in which one is in the axillary area and the other is in the pectoral region so as to prevent seroma and hematoma formation. The drains are inserted to shorten the recovery period and reduce the incidence of seroma which is the most common post operative complication. The drainage of the pectoral region with a separate drain is still a controversial issue which needs to be settled.

Aim: To compare outcome of axillary drain versus axillary and flap drain in Modified Radical Mastectomy.

Methods: 64 patients who agreed to be the part of the study were randomly allocated into 2 groups of 32 each. Group I (n=32) had drain only inserted in the axilla while Group II (n=32) had drain inserted both in axilla and pectoral region. Surgeries were performed by 5-years-post-fellowship consultants. Flaps were made with the scalpel while axilla was dissected with the scissors. The size of the drain was constant with a constant negative suction pressure. The technique would be considered effective with a better outcome measured on the basis of less number of cases of seroma formation, less time and volume of drainage from the drain and complications.

Results: The seroma formation was the most common complication and it was found that 16 out of 32 in group I developed seroma while in group II 10 out of 32 had the same problem. Overall 26 patients out of 64 developed seroma which makes up 40.6% of patients while the volume of seroma was 165.7ml \pm 53.3 in group I and 143ml \pm 61.8 in Group II which is statistically insignificant. The mean of the volume of drainage was 312ml \pm 36 in group I while it was 297 ml \pm 28 in Group II which is statistically insignificant. The drain was placed inside for 5.7 \pm 2.1 days in group I compared to 4.8 \pm 1.5 days in Group II which is statistically insignificant. The rate of other complications in group I was 9.4% in which 2 out of 32 developed hematoma while one patient developed infection while in group II rate of other complications was 6.25 %. 1 patient out of 32 developed partial flap necrosis and another one developed hematoma.

Conclusion: MRM should be performed with drainage at pectoral region. There was significant difference in the percentage comparison of seroma formation as shown by the results of both groups.

Keywords: Radical mastectomy, axilla, hematoma formation

INTRODUCTION

Breast cancer is the most common cancer in women world over¹. The incidence of breast cancer has increased internationally as well as locally. According to some studies the incidence of breast cancer is expected to continue to increase for the next 10 years in Asia. Rates reported among Asian-Americans living in the United States is 1.5-4 times higher than the corresponding incidence rate in the women's respective countries of origin². Although various treatment modalities are offered and a multitude of adjuvant and neo adjuvant options are available with significant improvement observed in patient survival associated with Partial Mastectomy and radiotherapy PMR when compared with Modified Radical Mastectomy MRM³, MRM still has proved to be the procedure of choice in this part of the world⁴ and even in US and China it is the most undertaken procedure for breast cancer^{3,5}. Seroma formation is the most common complication which is postulated to be due to heavy body weight and extended radical mastectomy⁶, size of the tumor⁷, thermal trauma due to electrocautery dissection^{8,9}. Low pressure suction drainage^{8,10} preoperative intravenous steroids¹³, use of a buttress suture¹⁴ and ultrasound cutting devices⁷ and fibrin sealants^{11,12}, using scissors for dissection and ligatures for haemostasis³¹ are thought to decrease the rate of seroma formation. M. Akini Cetin et al showed that Patients with

hypertension were more likely to develop seroma after mastectomy (50% versus 11% in patients without hypertension), but no such difference was found with age, tumour size, total number of lymph nodes or metastatic lymph nodes¹⁵. Normally the MRM is done with two drains in which one in the axillary area and other in the Pectoral region so as to prevent seroma and hematoma formation. The drains are inserted to shorten the recovery period and reduce the incidence of seroma which is the most common post operative complication^{15,16,17}. However a few researchers conclude that placing a drain in MRM does not provide any additional benefit in preventing seroma formation¹⁸ drains themselves are associated with discomfort and prolonged hospital stay and no consensus is available in the literature on when is the optimal time to remove the drain and^{19,20,21}. Whether the pectoral area should be drained or not is still a controversy that needs to be sorted out as some surgeons advocate that the number of drains used after a mastectomy for breast cancer do not significantly affect the rate or amount of seromas¹¹, but the use of a single drain after mastectomy is significantly associated with less discomfort and shorter postoperative hospital stay^{22,23}. A systematic review of randomized controlled trials (RCTs) by Xiao-Dong He et al showed that insertion of a drain in the axilla following ALND in breast cancer surgery effectively decreased seroma formation,

volume of aspiration as well as the frequency of seroma aspiration without increasing the incidence of wound infection, but prolongs hospital stay³³.

At this time a very limited and scarce data is available in this respect but the rationale of the study is to determine the choice of procedure between a single axillary drain vs both axillary and pectoral drains on the basis of the post operative complications and recovery in Modified Radical Mastectomy.

PATIENT AND METHODS

Inclusion criteria: Females having Carcinoma breast diagnosed from FNAC or Trucut Biopsy

Exclusion Criteria:

- Stage IV
- Pt. on anticoagulants and steroids
- Pre operative radiotherapy and chemotherapy
- Hypertension
- NIDDM
- IHD

Data Collection: The study which was a randomized control trial was conducted in Surgical Unit I of Sir Ganga Ram Hospital, Lahore from 1st Nov 2009 to 31st April 2010. Once the study was approved by the ethics review committee all the patients meeting the inclusion criteria as mentioned above were recruited from the Breast clinic Surgical OPD .The informed consent was taken followed by a random allocation by a blind observer using a sealed envelope into one of the two groups Group I and Group II. In Group I only the axillary drain was placed while in Group II both axillary and the flap drain were placed but the operating surgeon was not aware of the choice of procedure till he was about to place the drains after the surgery. The operative techniques were performed in a uniform fashion in all the patients by the same group of surgeons which included only the consultants 5 years post fellow ship. Sharp cutting by the scalpel was used in the entire procedure as the use of electrocautery to create skin flaps in mastectomy reduced blood loss but increased the rate of seroma formation [24] except the axillary area which was cleared by the scissors. A uniform gauge suction drain was placed as a standard drain in all the procedures. Every day drainage output was recorded and totaled till the time of removal of the drain and then discharging the patient after keeping the complete record of the duration of the post operative stay, seroma formation, total volume of discharge from the drain and the duration of the drainage. The wound dressing was opened on the third day post op to detect any other complications like infection, hematoma and flap necrosis .The drain was removed after the output went down to 30 ml/day.[25] and any output of more than 40ml/day for 7 days predicted the seroma formation [15]. This group was especially followed up in the OPD for the complication of seroma formation. Ultrasonography was done to confirm any seroma formation if there was a clinical suspicion so as the other patients were also followed up in order to assess the recovery and any other complications. Seroma was aspirated from the axillary and pectoral regions. Patients with shoulder stiffness were referred to physiotherapy department and other complications were dealt accordingly.

Data Analysis: Data was analyzed using computer soft ware SPSS version 11. The variables like seroma formation, volume of drainage and duration of drainage are presented by calculating mean and S.D. Two groups are being compared by applying student’s t- test. P value <0.05 will be considered significant.

RESULTS

As shown in the Table I and Figure I pathological staging of these patients that majority of them were T3 lesions in TNM Staging. The mean age for the group one was 49 yrs with a standard deviation of ±13.2 yrs while group II was 47 yrs with standard deviation of ±9.2 yrs which is comparable to Hashemi et al²⁸ 46.3±11.9 while Di G H⁵ found the median age to be 51 yrs. As described in the Table II the seroma formation was the most common complication and it was found that 16 out of 32 patients in group I developed seroma, 5 in pectoral region and 11 in the axilla, while in group II 10 out of 32 patients developed the same problem in which 2 were in pectoral while 8 were in axilla. The Percentage of seroma formation was 50% in Group I while it was 31.25% in Group II. The overall percentage of seroma formation was 40.6%.The volume aspirated from the seroma was 165.7ml ±53.3 in group I compared to 143ml ±61.8 in Group II which is statistically insignificant. The mean of the volume of drainage collected in the suction drains was 312ml ±36 in group I compared to 297ml ±28 in Group II which is statistically insignificant. The drain was placed inside for 5.7±2.1 days in group I compared to 4.8±1.5 days in Group II which is statistically insignificant. The rate of other complications in group I was 9.4% in which 2 patients out of 32 developed hematoma while one patient developed infection while in group II it was 6.25%. 1 patient out of 32 developed partial flap necrosis and another 1 developed hematoma

Table 1: Staging of Breast Cancer in two groups

Staging	Group I	Group II
T1N1M0	2	1
T2N0M0	5	4
T2N1M0	7	7
T3N0M0	10	9
T3N1M0	8	11
Total	32	32

Table 2: Seroma formation in both groups with Percentage

	Seroma at Pectoral	Seroma at axilla	%age
Group I	5	11	50
Group II	2	8	31.25
Total	7	19	40.6

Table 3: Time and volume of drainage

	Group I	Group II	P value
Time of drainage (days)	5.7 SD±2.1	4.8 SD±1.5	.061
Volume of drainage(ml)	312 SD±36	297 SD±28	.076
Volume of seroma	165.7SD±53.3	143SD±61.8	.139

Table 4: details of complications in both groups

Complications	Group I	%	Group II	%
Hematoma	2	6.25	1	3.125
Wound Infection	1	3.125		
Flap Necrosis			1	3.125
Total	3	9.375	2	6.25

Fig. 1: Patient presentation with staging of breast cancer

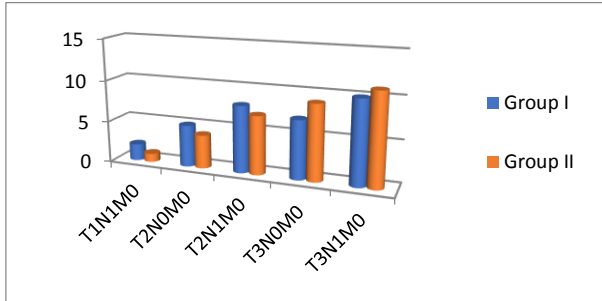


Fig. 2: Seroma formation in Group I

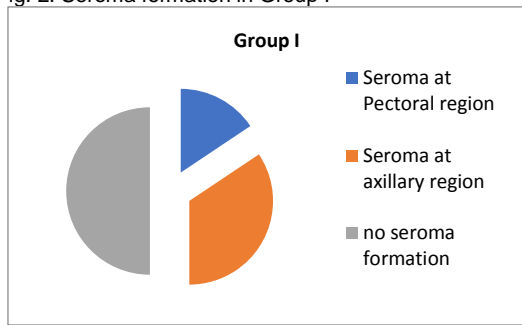
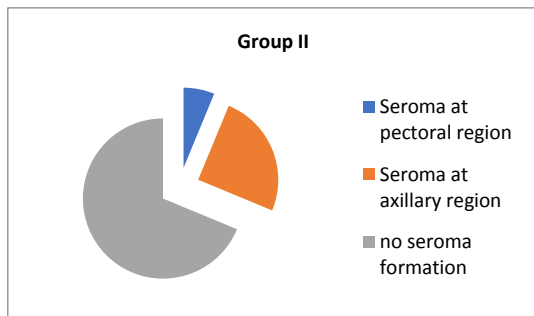


Fig.3: Seroma formation in Group II



DISCUSSION

If we analyze the staging of the breast cancer, it was almost same in both the groups. The same standard procedure of Modified Radical Mastectomy was done in both the groups and even the operating surgeon was not aware of the Group he was operating upon until he was about to place the drains. The mean time for the drainage during which the drain remained inside was 5.7±2.1 days in group I while it was 4.8± 1.5 days in Group II which was not statistically significant. The mean of the volume of drainage collected in the suction drains was 312ml ±36 in group I while it was 297ml±28 in Group II which was statistically insignificant. The mean age for the group I was 49 yrs with a standard deviation of ±13.2 yrs while in group II it was 47

yrs with standard deviation of ±9.2 yrs which is comparable to Hashemi et al²⁸ 46.3±11.9 while Di G H⁵ found the median age to be 51 yrs

During the follow up period, the drains were removed and the patients were sent home and were advised to return to the OPD in a week time. It was shown that 16 out of 32 patients in Group I (50%) and 10 out of 32 patients in Group II developed seroma (31.25%). The overall percentage of seroma formation was 40.6%. The mean volume aspirated from the seroma was 165.7ml ±53.3 in group I compared to 143ml ±61.8 in Group II which is again statistically insignificant.

Puttawibul P²⁵, Tejler²⁷, Hashemi²⁸ have reported seroma formation to be the most common complication and it was found to be 36 %, 36.5% & 35% respectively which is comparable to our study which showed a rate of 40% seroma formation, but higher than that of Irsala Bhatti et al¹⁶ Gonzalez²⁹ & Unalp H R et al¹⁴ which reported figures of 20% and 19.9% respectively but surprisingly Nadkani MS et al³⁰ has reported it to be as high as 90%. Melih Akinci¹ et al study showed that as compared to the single drain, double drains have been shown to decrease ultrasonography confirmed seroma formation without increasing patients' discomfort and duration of hospital stay after mastectomies³². So seroma formation was the most common complication while Safdar Husain shah et al⁴ argued the wound infection to be the most common complication. In other complication 3 patients developed hematoma, 2 in group I while 1 in Group II. All the patients recovered conservatively which is also comparable to the study conducted by Tejler²⁷ and Puttawibul P²⁵. 1 patient in group I developed wound infection while 1 patient from the group II developed flap necrosis.

Hence in our study it was found that surgery without a drain in pectoral area was no different than the ones with the drain in pectoral area. However the percentage of seroma formation was higher in the Group I of 50% as against 31.25% of Group II. Hence the drainage of the axilla is still important as it reduces the rate of seroma formation this was comparable to the results reported by Saratzis A²² while Jain P K¹¹ suggests that drains do not prevent seroma formation, and are associated with a longer postoperative stay and higher pain scores after surgery for breast cancer

CONCLUSION

The results of the RCT show insignificant difference between both the Groups with respect to volume of seroma, volume and time in which the drains remained inserted but showed higher percentage of seroma formation with the single axillary drain. so MRM should be performed with drainage of the pectoral region.

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