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ORIGINAL ARTICLE

Comparison of axillary Exclusion versus No Exclusion on seroma formation after Modified Radical Mastectomy.

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ABSTRACT… Objective: To determine the effectiveness of axillary exclusion technique versus no axillary exclusion in Modified Radical Mastectomy in terms of mean drain output. **Study Design:** Randomized Control Trial. **Setting:** Department of Surgery, Allied Hospital Faisalabad Pakistan. **Period:** 8th August, 2018 to 8th February, 2019. **Methods:** A request for authorization was made to the Hospital Ethical Review Committee. The research had 60 individuals in all who were admitted. General Surgery Department from outside the Allied Hospital in Faisalabad. For the sixty patients receiving modified radical mastectomy, written informed consent was obtained. A computer-generated database of random numbers was used to split them into two equal groups of thirty patients each at random. Following a modified radical mastectomy, group A received axillary exclusion, but group B did not. Total volume of accumulated fluid) following a modified radical mastectomy. After surgery, until the drain was removed, the total quantity of fluid collection in the drainage bag was recorded and compared across groups. Data was input into a template form. **Results:** In our study, the mean + SD was determined as 43.73+5.64 years in Group B. Of the two groups, 63.33% (n=19) in Group A and 70% (n=21) in Group B were between 41 and 70 years old, while 36.67% (n=11) in Group A and 30% (n=9) in Group B were between 20 and 40 years old. (First Table-I). Following a modified radical mastectomy with drainage, axillary exclusion procedures were compared with no exclusion, and the results indicated that the mean total drainage output (+SD) in Group B was 642.1 ml (+117.06). (Table-II). The total volume of seroma fluid drained between the two groups was significantly lower, as indicated by the p value of <0.001. **Conclusion:** In comparison to individuals who do not undergo axillary exclusion, we find that axillary exclusion procedures considerably reduce drainage expense in patients undergoing modified radical mastectomy.

Key words: Axillary Exclusion, Breast Cancer, Drain Output, Modified Radical Mastectomy.

INTRODUCTION

The uncontrolled growth of the cells of the breast tissue is defined as breast cancer. The cells continue to grow abnormally result in a malignant tumor in the breast[1] Since 2008, the estimated incidence of breast cancer has increased by more than 20%, while mortality has calculated to 14%. It is the cause of death in every fourth woman[2] that based on burden of breast cancer in Pakistan, it has been reported as the most common cancer and is claimed to account for 34.6% of total cancer cases in women.[2]

Current literature shows that the rated of surgery, chemotherapy and radiation therapy vary across different countries and institutions indicating the need for greater use of standardized cancer treatment guidelines, Surgery, primarily modified radical mastectomy is the most common form of therapy described.[3] It allows for both for both the removal of the main tumor mass and glandular tissue which are suspected of infiltration and multifocality of the process and a sentinel axillary lumph node removal. Most common post – surgical complications following MRM are the formation of a hematoma, the infection of the surgical wound and the formation of a seroma.[4]

A seroma is a collection of serous fluid that accumulation in dead space and presents as a fluctuant swelling beneath a wound. There are number of mechanisms have been suggested

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that contribute to seroma formation and the etiology is likely to be multifactorial. Seroma is reported to occur in 15- 81%[5] of patients after node dissection. It can require repeated aspirations and the risk of wound increase dehiscence, prolonged pain, infection, reduced limb mobility and prolonged time off work, impairing the quality of life. However, prolonged stay of the drain is a frequent use of discomfort for the patients, and needed to drain the seroma.[1] Several trials used the adhesive glues and sclerosing agents to reduce the post mastectomy seroma. However a recent study of meta-analysis showed that such a preventive techniques are still not convicined.[2] If it is believed that the lymphatics disruption in the axillary fossa is main etiology, it follows that obliterating this space will minimize fluid collection .axillary exclusion is a technique have a objective to obliterate dead space there by excluding axilla from the rest of wound after axillary clearance and minimize collection. More importantly, this technique has a beneficial that reduces clinically apparent seroma after drain removal, however reducing the consequences of anxiety of the patient and add morbidity. The technique involves suturing the superior mastectomy skin flap down to the free edge of pectoralis major, lateral chest wall using a continuous 2/0 vicryl stitch then placing 4-6 interrupted sutures between pectoralis major and minor to reliably exclude the axillary fossa from the remainder of the mastectomy cavity. Pressure dressing is applied to all wounds.14F Handy vac suction drain is placed at surgery in all clients with the tip placed with in mastectomy cavity, the total drain outputs are recorded.[3] According to one study conducted in Egypt, the total mount and the mean of the study group was 1476.2ml ±518ml while the mean of the control group was 4525.6ml ± 97..6ml. The result showed significant reduction in the total amount of the drain output p<0.001.[6]

By conducting this study, we can assess and evaluate the total average amount of seroma fluid formed and drained post operatively and effect of axillary exclusion on reduces the drain output, lessen psychological burden of long time drain, post operative visits for drain follow up and complications related to seroma(formation after breast cancer surgery)

Sampling Size

By using WHO sample size calculator for two mean:

Anticipated population mean=1476.2[6]

Test Value of population mean= 4525.6[6]

Patients with diagnosed stage 2 or 3 breast carcinoma having no distant metastasis and planned for mastectomy.

2. Female patients aged above between 20-70 years

Exclusion Criteria

1. Patients with history of previous breast surgery ,chemotherapy or breast irradiation
2. Patients having co-morbid factors like morbid obesity, poorly controlled diabetes and hypertension.
3. Patients arranged for conservative breast surgery or palliative surgery (for advanced breast cancer)
4. Patients with known collagen disease or diffuse small vessel disease.
5. Patients with a history of long term use of steroids and with deranged clotting profile.

Data Collection Procedure

The total number of patients were sixty that included in the study and they admitted in General Surgery Department from outdoor of Allied hospital Faisalabad. Permission was sought from hospital ethical review committee (48ERC/FMU/2023-24/436). written informed consent was taken from all the sixty patients. Undergoing modified radical mastectomy after they were explained about the nature, benefits and draw backs of the procedure. They were randomly divided into two equal groups. Group A (underwear axillary exclusion) and Group B (did not undergo axillary exclusion) of 30 patients of each individual by using computer generated random number table.

All patients were kept nil per oral from midnight .Standard general anesthesia was given to all the patients. In Group A modified radical mastectomy

was done bleeding points were secured, axillary exclusion was done by suturing superior mastectomy flap to free edges of pecpotoralis major and lateral chest wall with vicryl 2/0 and by interrupted sutures between pecpotorilis major and minor muscles. 14F closed suction drain was placed in mastectomy cavity outside obliterated axillila in Group B (control mastectomy was done in same manner but axillary exclusion was not done, instead wound was closed by convention method at the edges nd one closed suction drain ws placed.

In the postoperative period all the patients were observed for amount of fluid drained till the removal of drain. Drain was removed when fluid drainage ceased to 30 ml in last 24 hours. Patients were discharged on third postoperative day with instructions for home drain care, assisted by regular vistis in surgical OPD for recording of total drainage volume before drain removal. Data was entered in a pre-designed preformat attached.

Data Analysis

All the data was transferred to SPSS version 20 and analyzed accordingly. Mean and standard deviation was calculated for all quanitative variables like age and the total drain amount. Independent sample t-test was applied. P-VALUE <0.05 was taken as significant. Effect modifiers like age was controlled by stratification. Post-stratification t-test applied.

RESULTS

A total of 60 cases (30 in each group) fulfilling the inclusion/exclusion criteria were enrolled to compare axillary exclusion versus no exclusion after mofified radical mastecomy in terms of mean drain output.

Age distribution of the patients was done, it showed that 36.67%(n=11) in Group-A and 30%(n=9 in Group-B Were Between 20-40 Years of Age Whereas 63.33%(n=19) in Group-A and 70% (n=21) in Group B were between 41-70 years of age, mean+SD was calculated as 43.73+5.64 years in Group-A and 43.96+6.17 years in Group–B, (Table-I Comparison of axillary exclusion technique with no exclusion after modified radical mastectomy was done, it showed that the mean of the total drain output (+SD) in Group A was 556.2ml(+66.78) and whereas in Group B was 642.1ml (+117.06). p value was <0.001 showing a significant reduction in the total amount of the seroma fluid drained between the between the two groups. (Table-II)

Stratification for data shows that between 20-40 years of age Group0 A had 493.5ml (+23.27), whereas Group B had 575.3ml(+54.04) mean drain output, p value was 0.0002 while between 41-70 years of age , Group A had mean output 595.2ml (+56.27), and Group B 670.7ml (+125.85)p value was 0.021. (Table-III)

Age	Group A N=30		Group B N=30	
	No of Patients	%	No of Patients	%
20-40	11	36.67	9	30
41-70	19	63.33	21	70
Total	30	100	30	100
Mean*+-SD		47.73+-5.64		43.96+-6.17

Table-I. Age distribution of the patients N=60

Gropus	Total Drain Output			P-Value
	Mean (ml)	±SD	Range	
Group A (n=30)	556.2	66.78	460-660	0.0009
Group B (n=30)	642.1	117.06	495-855	
Total	599.13	103.95	460-855	

Table-II. Comparison of total drain output in two groups (n=60) t-statistics:3.491; significant level p<0.05

Gropus	Total Drain Output			P-Value
	Mean (ml)	±SD	Range	
Group A (n=11)	493.5	23.27	460-535	0.0002
Group B (n=9)	575.3	54.04	495-638	

Table-III. Stratification of drain output with regard to age AGE:20-40 (n=20) t-statistics:4.551; significant level p<0.05

DISCUSSION

A seroma is an accumulation of serous fluid that develops under the skin flaps or in the axillary dead space and is a common side effect after mastectomy. Seroma and its sequelae form the mainstay of complications in breast cancer surgery, varying from increased susceptibility to infection, skin flap necrosis, persistent pain and wound dehiscence. Prolonged stay of the drain needed to drain seroma fluid is a frequent cause of discomfort for the patient.

This study was planned to find out a better surgical technique to lessen the psychological and financial burden of seroma. The technique which shows better results may be adopted for practice in future for the early recovery of the patients.

In our study, out of 60 cases (30 in each group) 36.67%(n=11) in Group–A and 30%(n=9) in Group-B were between 20-40 years of age whereas 63.33%(n=19) in Group-A and 70%(n=21) in Group-B were between 41-70 years of age, mean+SD was calculated as 43.73+5.64 years in Group-A and 43.96+17 years in Group-B. Comparison of axillary exclusion technique with no exclusion after modified radical mastectomy was done. It showed that the mean (+SD) of the total drain output in Group A was 556.2ml (+66.78) and whereas mean output in Group-B was 642.1ml(+117.06). p value was <0.001 showing a significant reduction in the total amount of the seroma fluid drained between the two groups.[8]

The results of our study can be compared with a randomized controlled trial done by Faisal M. et al. on 64 patients that took place in Surgery Department,Suez Canal University Hospital, Ismailia, Egypt. Their results showed a significant reduction in the total amount of the drain output with the mean of the total amount in the study group after axillary exclusion (1476.2 ml +97.6 ml);p<0.001.

In one study, Roman M et al.[4] observed that the duration and volume of postoperative fluid formation are significantly longer and higher for the patients who had a modified radical mastectomy with Axillary dissection than those who had a breast conserving surgery. Seroma is reported to occur in 15-81% of patients after node dissection, the most likely cause for the formation of seroma is the disruption of lymphatic channels in the axilla. It is supported by many studies. Petrek et al.[5] in a prospective randomized trial showed that the most significant influencing factors in the causation of seroma were the number and the extent of axillary dissection,an RCT of Purushotham et al.[9] has demonstrated that sentinel LN biopsy is associated with significantly less seroma formation than conventional axillary dissection.

In our study we have considered that the largest potential dead space is the empty axillary apex after axillary dissection and indeed that seroma formation is contributed significantly to by disruption of axillary lymphatics, so it follows that excluding this space by closure from rest of wound might prove useful. Halsted suggested that the obliteration of dead spaces facilitated surgical recovery. Different methods were used for obliterating the dead space. such as Pressure wound dressing fibrin glue, tissue adhesive and sclerotherapy agents. Pressure wound dressing has no effect on reducing the amount of the seroma Yet, the effects of chemical agents are not clear. Some studies report no advantage of using fibrin glue and because of the pain, the use of tetracycline for obliteration and sclerotherapy has been abandoned.

Actually, closure of the dead space especially in the axilla was recommended by van Bemmel et

al. Ideal wound closure should minimize lymph spillage and serum oozing, provide a means of holding skin flaps securely to the chest wall structures, obliterate dead space, and allow rapid removal of fluid as it forms. Many studies have provided evidence that the technique used for axillary exclusion and axillary space obliteration by suturing the upper mastectomy flap to the pectoralis major to muscle and lateral chest wall by continuous suture and suturing the pectoralis major to the pectoralis minor by interrupted sutures that was carried out in our study decreases postoperative seroma. Similar technique was used by A Khater et al.in A Randomized study and by El-Sisi et al.[10] and they found that the total amount of fluid drained was significantly less ($P<0.001$; highly significant)in both studies. Similarly N.Chand et al.[3] has also shown that reliably excluding the axillary fossa from the remainder of the mastectomy wound can considerably reduce post-operative drainage volume (reduction of over 65%, $p<0.001$) and more importantly, this technique significantly reduces clinically apparent seromas after drain removal.[11]

However, the results of our study in agreement with other above studies justify the hypothesis of our study that "Axillary exclusion is an effective technique in reducing total drain outputs after Modified Radical Mastectomy in patients of Breast carcinoma."[12]

CONCLUSION

We concluded that the axillary exclusion technique significantly reduces drain output in patients following modified radical mastectomy as compared to those who do not undergo axillary exclusion.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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REFRENCES

1. Benevento R, Santoriello A, Pellino G, Sciaudone G, Candilio G, De Fatico G et al. **The effects of low-thrombin fibrin sealant on wound serous drainage, seroma formation and length of postoperative stay in patients undergoing axillary node dissection for breast cancer. A randomized controlled trial.** Int J Surg. 2014; 12:1210-5.

2. Khater A, Elnahas W, Roshdy S, Farouk O, Senbel A, Fathi A et al. **Evaluation of the Quilting technique for reduction of postmastectomy seroma: A randomized controlled study.** Int J Breast Cancer. 2015; 2015:1-6.

3. Chand N, Aertssen A.M.G, Royle G.T **Axillary "exclusion"—A successful technique for reducing seroma formation after mastectomy and axillary dissection.** Adv Breast Cancer Res. 2013; 2:1-6.

4. Roman M, Nogaret JM, Fils JF, Bourgeois P. **Seromas and punctures after complete axillary node dissection for breast cancer: Differences between mastectomy and lumpectomy.** J Surgery. 2015; 3(2):7.

5. Sakkary MA. **The value of mastectomy flap fixation in reducing fluid drainage and seroma formation in breast cancer patients.** World J Surg Oncol. 2012 Jan 11; 10:8.

6. Faisal M, Abu-Elela S, Mostafa W, Antar O. **Efficacy of axillary exclusion on seroma formation after modified radical mastectomy.** World J Surg Oncol. 2016; 14:39.

7. C.Ozaslan, K.B.Yilmaz, L.Dogan, C.Atalay, M.Altinok. **Effect of mechanical closure of dead space on seroma formation in modified radical mastectomy.** Turk J Med Sci. 2010; 40(5):751-55.

8. Van Bemmel AJ, van de Velde CJ, Schmitz RF, Liefers GJ. **Prevention of seroma formation after axillary dissection in breast cancer: A systematic review.** Eur J Surg Oncol. 2011; 37:829-3.

9. Purushotham AD, Upponi S, Klevesath MB, Bobrow L, Millar K, Myles JP, etal. **Morbidity after sentinel lymph node biopsy in primary breast cancer: Results from a randomized controlled trial.** J Clin Oncol 2005; 23:4312-21.

10. El-Sisi AA, Mohamed AMF, Amer NF. **Dead space obliteration for reducing seroma formation after mastectomy and axillary dissection.** Menoufia Med J. 2015; 28:69-73.

11. A.J.M Van Bemmel C.J.H. Van de velde, R.F .Schmitz, G.J.Liefers. **Prevention of seroma formation after axillary dissection in breast cancer: A Systematic review.** Eur J Surg Oncol. 2011 Oct; 37(10):829-35.

12. H Turner EJ, Benson JR, Winters ZE. **Techniques in the prevention and management of seromas after breast surgery.** Future Oncol. 2014; 10:1049-63.

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3	Shaheer Sultan	Manuscript designing, Data collection.	
4	Feryal Qaisar	Statistical analysis.	
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6	Faisal Bilal Lodhi	Proof reading.	