

Comparison of Mean Duration of Drain Removal in Quilting VS Non Quilting Wound Closure in Modified Radical Mastectomy

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ABSTRACT

Objective: To compare mean time for drain removal with quilting and non-quilting wound closure techniques in modified radical mastectomy.

Study Design: Single-centered prospective randomized control study

Place and Duration of Study: This study was conducted at the Department of General Surgery, Liaquat National Hospital, Karachi Study duration lasted for 1 year from April 2016 to March 2017.

Materials and Methods: All patients who had a Modified radical mastectomy during this period were included in this study. Total 72 patients were included. 36 Patients were enrolled either in Group-A (quilting) or in Group-B (no quilting). Quilting was done in group-A. 2 Radevac drains (flap drain & axillary drain) were placed in both groups. drains were removed when total drain output was 20cc or less per day. Final outcome was measured in term of total days of drain removal. Descriptive statistics were calculated. Stratification was done. Post stratification t test was applied. P-value ≤ 0.05 was considered as significant.

Results: Mean duration of flap drain removal in group-A was 8.52 ± 5.15 days and 10.41 ± 4.23 days in group-B. Mean duration of axillary drain removal in group-A was 12.91 ± 5.54 days and 17.55 ± 7.19 days in group-B. Mean total duration of drain removal was 14.63 ± 5.09 days in group-A and 18.38 ± 6.36 days in group-B. This mean difference of total duration of drain removal was found significant.

Conclusion: Quilting is an efficient method to significantly reduce the duration and volume of wound drainage.

Key Words: Drain Removal Time, Quilting, Non Quilting, Modified Radical Mastectomy.

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INTRODUCTION

Seroma is collection of serous fluid in dead space between subcutaneous flap and chest wall. This is one of most common and nauseate side effect of breast cancer surgery¹, with an unknown etiology. Incidence rate varies between 25 to 65 %² in mastectomy and axillary clearance and even some studies up to 85 %³ despite of multiple trial of difficult techniques to reduce this morbidity like drains of various types, adhesives etc have been used. Though not life threatening but this bothersome complication has both physical, psychological as well as financial burden on patient. It is associated with pain, heaviness at surgical site, swelling and morbidity of wound site infection and wound dehiscence⁴.

This all leads to multiple hospital outpatient clinic visits, delayed recovery time and delayed adjuvant treatments.⁵

Adjuvant treatment for breast cancer after most common procedure of modified radical mastectomy has significant role if given on time. Seroma and its effects i.e. prolong drain in place, delayed wound healing, secondary surgical site infection and pressure effect leading to flap necrosis is a commonest hurdle in start of adjuvant treatment.⁶

Multiple efforts yet not able to get exact pathogenesis of seroma. Common consideration is tissue acute inflammatory response secondarily to surgical assault^{5,6}. Different theories were given for its etiology like Orteli⁷ et al believed that it's due to fibrinolytic reaction, Petrek et al⁸ purposed number and extent of axillary lymph node dissection as a causative factor, Hashemi et al⁹ thought nature of surgery as a major factor. Mastectomy with axillary clearance has more rate of seroma production rather breast conservative surgery. But none of hypothesis is established as a known primary factor.

Due to unknown etiology different medical and surgical techniques were adopted to reduce this morbidity including use of steroids locally, chemical substances thromboxane, tranexamic acid and fibrin, use of

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seclerosent agent and octreotide. No technique has been rewarding and so could not adopted as a routine practice¹⁰.

Mechanical closure of dead space has been used in various areas by the Plastic Surgeons. The search of the method to decrease the dead space between skin and pectoralis major muscle gave an idea of a surgical technique modification for wound closure by mechanical closure of dead space, which showed significant reduction in time duration of drain removal, decrease repeated needle aspiration and decreased surgical site infection^{11,12} this include subcutaneous fixation of tissue with underlying muscle causing close approximation of space known as Quilting. Since patients want to have drain removed early and we also want to avoid residual seroma formation to decrease physical and psychological disturbance in the patients. There is no reliable data available in our country, this study was done to see the effectiveness of this quilting technique in post mastectomy patients.

MATERIALS AND METHODS

This was a single-centered prospective randomized control study over a 1-year period was conducted at department of general surgery Liaquat national hospital, Karachi from April 2016 to March 2017. The non-probability consecutive sampling was used for sampling. By taking mean and standard deviation in group 1 (9 ± 3)¹¹ days and in group 2 (11 ± 3) days¹¹, power of study 80% than at least a sample of 36 in each group will be required. The total sample size will be 72 patients.

Total 72 patients were included. 36 Patients were enrolled either in Group-A (Quilting) or in Group-B (non Quilting). An informed consent was taken prior to induction in the study.

Patients selected for this study were who has Primary breast cancer up to stage III, planned for a mastectomy with axillary dissection with Nodal status N1 (clinically palpable mobile axillary nodes) or mastectomy with sentinel node biopsy and axillary clearance. Patients with Age group between 35-65 years, ASA 1 and ASA 2 with BMI < 35 Kg/m² were included in study. Patients BMI > 35 Kg/m², ASA 3 & 4, Prior breast surgery, Post neo-adjuvant patients, Stage 4 diseased patients, N2 & N3 nodal status (fixed axillary and supraclavicular node respectively). On histology greater than 10 axillary lymph node positive for metastasis and pregnant patients were excluded from study.

Modified Radical Mastectomy was the surgical procedure for carcinoma breast involving both breast removal along with axillary clearance. Quilting was done as a surgical method to approximate skin flaps with underlying tissues with interruptible absorbable sutures in multiple layers.

Drains were removed when drain out was 20 ml or less in the last 24 hours. Duration of drain removal was

noted as total number of days required to remove both drains

Mastectomy with axillary clearance was performed by consultant (with 20 years of experience) in breast surgery. Each patient enrolled in the study was eligible to be enrolled into either arm of the study following the opening of a sealed envelope which had a slip bearing the name of procedure (quilting or not) to be done. Quilting was done by suturing skin flaps with underlying muscle (pectoralis major) with interrupted vicryl 2/0 from cranial to caudal end of wound with 3cm between them, totaling some 3-5 rows for superior flap. Inferior flap was quilted with 1-3 rows from caudal to cranial fashion. In the Control group only simple wound closure by approximating flap with vicryl 2/0 and then skin closure. 2 Radevac drains (flap drain & axillary drain) were placed in both groups. Patient was followed post-operatively on every 3rd day until both drains were removed. Patient and one responsible attendant was taught to mark drain once in 24 hours with date. In case any patient forgot to mark drain then drain output from last OPD visit was measured and divided by number of days to get mean drain output of last 3 days. Results was compared on the basis of mean ml of drain output in total days. Drain was removed when the drain output was 20ml or less in 24 hrs. Final outcome was measured in term of total days, was calculated when both flap and axillary drain were removed. Group having less drain output in both drains and early drain removal showed better surgical technique.

Patients were divided in two groups, Group A (quilting) and Group B (non-quilting). Descriptive statistics were calculated using SPSS version 21. Qualitative variables were presented in terms of frequency and percentages. Quantitative variables were presented in term of mean and standard deviations. T test was applied to compare the mean duration of drain removal in two study groups. Stratification was done to see the effect of modifiers on outcome. Post stratification t-test was applied. P-value ≤ 0.05 was considered as significant.

RESULTS

Total 72 female patients with age between 35 to 65 years, who met the inclusion criteria were included in the study to compare mean time for drain removal with quilting and non-quilting wound closure techniques in modified radical mastectomy. Patients were divided in two groups, Group A (quilting) and Group B (non-quilting). 36 patients were included in each group.

The mean age of study subjects in Group A was 49.63 ± 8.60 years while mean age in Group B was 51.41 ± 9.79 years. The mean BMI for study subjects in group A was 25.30 ± 3.70 kg/m² while mean BMI for study subjects in group B was 25.45 ± 3.72 kg/m². Stratification was done to see the effect of modifiers on outcome. The mean duration of carcinoma in group A was 6.05 ± 7.83 months while in group B it was

34.33±5.90 months. Most of the study subjects were found with T2 stage in both groups while ASA-II was also found most common.

The mean duration of flap drain removal in group A was 8.52±5.15 days while for group B it was 10.41±4.23 days. The mean duration of axillary drain removal for study subjects in group A was 12.91±5.54 days while in group B it was 17.55±7.19 days. In our study mean total duration of drain removal was 14.63±5.09 days in group A while in group B it was 18.38±6.36 days. Comparison of mean was done through t-test. P-value < 0.05 was taken as significance. The results showed that there was significant mean

difference of total duration of drain removal in study groups (p=0.007). Stratification with respect to age, ASA status, BMI, stage and duration of carcinoma was done to control the effect of these factors on outcome (total duration of drain removal) among two study groups. Significant mean difference of total duration of drain removal in study groups for patients age>50 years (p=0.007), patients with ASA-II (p=0.037), patients with BMI≥25 kg/m² (p=0.040) and duration of carcinoma≤3 months (p=0.013) was observed. Post stratification t-test was applied. P-value ≤ 0.05 was considered as significant.

Table No.1: Descriptive statics of parameters Age,BMI , duration Of cancer , ASA

Parameters		Mean + SD	Median	Range	Minimum	Maximum
Age (years)	Group A (n =36)	49.63 ±8.60	50	30	35	65
	Group B	51.41 ±9.79	52.00	30	35	65
BMI Kg/m	Group A	25.30±3.70	25.30	13.20	18.60	31.80
	Group B	25.45±3.72	26.00	12.80	19	31.80
Duration of cancer (months)	Group A	6.05± 7.83	7.83	35	1	36
	Group B	4.33±5.90	2.00	23	1	24
duration of removal of flap drain (Days)	Group A	8.52 ± 5.15	7.50	23	2	25
	Group B	10.41±4.23	10.00	17	3	20
Duration for removal of axillary drain (Days)	Group A	12.91±5.54	11.50	24	3	27
	Group B	17.55±7.11	17.00	25	3	28
Mean total duration of drain removal	Group A	14.63±5.09		18	9	27
	Group B	18.38±6.36	18	20	8	28

RESULTS

Mean of total duration of drain removal		Mean	Median	Range	minimum	maximum	p-value < 0.05* significant
In patients with ASA-I (n=44)	Group A	14.12±4.93	13.00	18	9	27	0.208**
	Group B	16.31±6.08	15.00	19	9	28	not significant
In patients with ASA-II (n=28)	Group A	15.81±5.51	15.00	17	9	26	0.037*
	Group B	20.07±6.00	22.00	19	8	27	significant
In patients with age <50 years (n=37)	Group A	14.25±5.25	12.50	18	9	27	0.349**
	Group B	16.00±5.96	16.00	19	8	27	Not significant
In patients with age >50 years (n=35)	Group A	15.12±5.03	14.00	15	10	25	0.007*
	Group B	20.53±6.06	22.00	18	10	28	Significant
In patients with BMI <25 kg/m ² (n=27)	Group A	14.80±5.69	13	18	9	27	0.094**
	Group B	18.91±6.57	18.50	16	10	26	Not significant
In patients with BMI ≥25 kg/m ² (n=45)	Group A	14.52±4.77	14.00	17	9	26	0.040*
	Group B	18.12±4.77	17.00	20	8	28	significant
In patients with T1 stage (n=6)	Group A	18.25±4.34	18.50	8	14	22	0.058**
	Group B	27.00±1.41	27.00	2	26	28	Not significant
In patients with T2 stage (n=42)	Group A	14.28±5.56	12.00	17	10	27	0.060**not significant
	Group B	17.76±6.04	17.00	19	8	27	significant
In patients with T3 stage (n=24)	Group A	14.00±4.19	15.00	13	9	22	0.092** not significant
	Group B	14.08±6.61	19.00	17	9	26	significant
Days	Group A	14.63±5.09	13.50	18	9	27	0.007*
	Group B	18.38±6.36	18.00	20	8	28	significant

DISCUSSION

Seroma is most common worrisome sequel that disturb both patient and surgeon with multiple visits that delay

starting the adjuvant therapy and cause great patient's discomfort with possibility of increased surgical site infection

After breast surgery there is collection of serous fluid between skin flaps and muscles. This is due to axillary dead space^{13,14}. Manifold research work is done to identify cause but no conclusive pathogenesis is identified the one of the most likely cause for the accumulation of seroma is damage to axillary lymphatic channels¹⁵. However, fluid analysis showed contradictory results for lymphatic fluid and inflammatory exudate. Other proposed risk factors are high BMI, large breast size, smoking, extensive axillary nodal disease.^{16,17}

In our study patients with BMI greater than 25, duration of cancer less than 3 months and ASA II has high rate of seroma formation rather low BMI, ASA I, age less than 50 years and carcinoma greater than 3 months.

Other supposed causative factor is electrocautery dissection that increases seroma production due to thermal trauma.¹⁹ which causes activation of pro inflammatory cytokines. Diathermy is regularly used for adequate hemostasis and to reduce operating time. Comparison of electrocautery and an ultrasonic dissector showed that ultrasonic dissector appears to produce smaller volumes of pro-inflammatory cytokines and also has a reduced incidence of seroma formation.²⁰ Quilting is not a new idea. However most of these studies were non randomized. Suturing of skin flap to underlying muscle leads to abolition of dead space and causes early approximation of subcutaneous tissue with chest wall. This all leads to less fluid production and early removal of drains. As prolong drain insitu also causes increase fluid production due to tissue reaction. So, quilting not only reduce dead space but also helps in early removal of drain which is another causative factor for fluid production.²¹

Khater et al¹¹ explained the incidence of seroma in the quilting group was 20% versus 78.6% in the control group and significantly reduced the mean duration of drainage from 11 days in the control group to 9 in the intervention group ($P < 0.001$) A similar figure was reported by Sakkary MA¹² explained it with an overall incidence of 20% in the intervention group versus 50% in the control group ($P = 0.047$). and significant reduction in duration of drain removal from 13.4 to 5, $P < 0.001$ with a mean decrease from 2017.8mL in the control group to 524.8 in the intervention group ($P < 0.001$). Coveney EC²² and his coworkers described an closed suction drainage was significantly less ($P < 0.05$) in the group that had flaps sutured, 272 +/- 46 ml vs 393 +/- 39 ml. Also fewer patients in the flap sutured group developed seromas, 5 (25%) vs 17 (85%) chi 2 = 12.2 $P < 0.001$. a significant difference 25% in the suture group versus 85% in the control group.

In recent trial by Ten Wolde²³ and his coworkers in 2014 showed decrease of seroma from 80.5% in the control group to 22.5% in the quilting group ($P < 0.01$) also had significant reduction in total drainage volume

(from a mean of 1160 to a mean of 710) with a decrease of mean number of aspirations from 4.86 to 2.40 ($P = 0.015$) and the volume of aspirations from 1660mL to 611mL ($P = 0.05$). Seroma has significant association with extent of surgery i.e. mastectomy has great incidence of seroma rather than breast conservation. Similarly extensive axillary dissection and number of nodes removal is directly proportional to amount of seroma.

Purushothamet al. demonstrated in a controlled randomized study that the incidence of seroma was significantly lower with sentinel lymphnode (SLNB) axillary approach than with conventional axillary dissection²⁴.

Previous work in the literature have compared the effect of quilting versus conventional closure with drainage after mastectomy for breast cancer on patient outcome. However, these studies have limited impact due to small sample sizes, single centered and absence of randomization. Breast cancer surgeons appear to currently still favor conventional wound closure with drainage, although current evidence suggests better patient outcomes with quilting suture.²⁵

Quilting give a large advantage over non-quilting in decreasing medical cost and improving the outcome by early hospital discharge ,less outpatients visits .It also helps in early start of adjuvant therapy by early drain removal and decreasing surgical site infection. Though it is also associated with prolong operative time and some surgeon yet not preferred this technique due to time shortage and fear of drain entrapment or formation of pockets which can lead to infection. No data is available on these queries and there was no such complication noted during our study trial.so, additional operative time may be not considered as important obstacle of performing flap fixation any more for breast cancer patients.

CONCLUSION

Quilting is an effective method in modified radical mastectomy to significantly reduce the postoperative seroma formation in addition to significantly reducing the duration and volume of fluid drainage in the drains by causing obliteration of dead space. Therefore, quilting of flaps is recommended as a routine step at the end of any mastectomy.

Author's Contribution:

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