

EVALUATING THE EFFICACY OF FLAP QUILTING SUTURES VS CONVENTIONAL SUTURES IN REDUCING POST-MODIFIED RADICAL MASTECTOMY SEROMA

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Abstract

Background: The incidence of breast cancer is increasing and is more common in India. Many women have breast cancer that is treated with modified radical mastectomy (MRM). This study aimed to assess the significance of the flap quilting technique in reducing fluid collection beneath the flaps and the complications that occur after a modified radical mastectomy. **Materials and Methods:** This single-centre prospective randomised controlled study included 50 patients treated at the Kanyakumari Medical College between 2019 and 2021. Fifty patients were randomly divided into Group A (flap fixation with quilting sutures) and Group B (without flap fixation). Patient data, examinations, investigations, and surgeries were obtained. Postoperative monitoring included fluid drainage, drain removal, and other complications. Patients were followed up for three weeks for seroma. **Result:** Group A had a significantly lower total drain volume (944±292.46 ml) than Group B (1415±261.61 ml), with earlier drain removal (9±2.2 days vs. 13±2.01 days). The most common age range in both groups was 41-50 years. Tumour stage IIA and carcinoma on the right side were similar between groups, with Group A showing smaller tumour sizes (2.0-3.0 cm) compared to Group B (3.0-4.0 cm). Group B had a higher incidence of seroma (26% vs. 0% in Group A) and a higher day-one drain volume, but no significant difference was observed in the volume drained on postoperative day 1 (p<0.05). **Conclusion:** This study suggests that flap fixation, a mechanical method, significantly reduces seroma risk during modified radical mastectomy, allowing for early drain removal and improving patient satisfaction.

INTRODUCTION

Breast cancer has been noted to have an increasing trend and is more common in India.^[1] Breast cancer is the most frequently diagnosed cancer in women worldwide. Despite public health initiatives, the incidence continues to rise, and globally, around 2 million women were diagnosed with breast cancer in 2018 as per one study.^[2] Breast cancer is responsible for over 36% of all oncological patients.^[3] It also forms the leading cause of death among women afflicted with cancer. The trends in India mirror the global data and are more profound. In particular, Indian statistics reveal an age-adjusted incidence of breast cancer of 25.8 per 100,000 females. While this is lower than the rate in a country like the UK which has an age-adjusted incidence of about 95 per 100,000; the mortality rate in the Indian population is

similar to that of the UK (12.7 as compared to 17.1 per 100,000).^[4]

As per the reports of Globocan (2012), India accounts for one-third of all breast cancer burden in the world, alongside the USA and China. Further, the incidence increased by 11.54% and mortality worsened by 13.82% as per the statistics recorded, and, the incidence in the peri-menopausal age group is increasing.^[5] The age-adjusted rate (per 100,000 women) was highest in Delhi (41), and then in decreasing order of frequency, Chennai, Bangalore and Thiruvananthapuram districts (37.9, 34.4 and 33.7 respectively).^[6] Sedentary lifestyle, breastfeeding patterns, urban location and body mass index have all been implicated as risk factors.^[7] The hours spent on household activities were directly protective in both rural and urban women, suggesting the direct effect of a sedentary lifestyle.^[8]

A 50% reduction in risk was noted with three or more pregnancies. However, a previous study established advancing age and obesity as key risk factors.^[9] The incidence is also increasing in rural India, and these patients tend to present later due to a lack of awareness at a much-advanced stage.^[10] These delayed presentations can explain why reports have stated that many women with breast cancer are treated with modified radical mastectomy (MRM) in India. Mastectomy is associated with a small number of serious consequences.^[11] Wound seroma, a collection of serous fluid containing plasma and possibly lymph fluid, is the most common consequence, with a reported incidence rate of 3%-85%. However, the pathogenesis of seromas remains unclear. The development of seroma is thought to be caused by several factors. Reducing complications related to mastectomy, which is almost the standard procedure for most cases of breast cancer, especially in India, can significantly impact the associated morbidity and mortality. Our study explored a technique for reducing the development of seroma.

Aim

This study aimed to assess the significance of the flap quilting technique in reducing fluid collection beneath the flaps and the complications that occur after a modified radical mastectomy.

MATERIALS AND METHODS

This single-centre prospective randomised controlled study included 50 patients treated at Kanyakumari Medical College between 2019 and 2021. This study was approved by the Institutional Ethics Committee before initiation, and informed consent was obtained from all patients.

Inclusion Criteria

Patients with carcinoma breast stage IIA and IIB over the age of 18 years, who needed modified radical mastectomy, and a signed permission form indicating their willingness to participate in the trial were included in this study.

Exclusion Criteria

Patients who underwent breast-conserving surgery, radiation for breast cancer, after neo-adjuvant chemotherapy, or carcinoma of the breast underwent a modified radical mastectomy, palliative surgery, toilet mastectomy, or full mastectomy, or refused to participate because they did not give their consent were excluded from the study.

Methods

Fifty patients who met the selection criteria were randomised into two groups: group A (25 patients) with flap fixation through quilting sutures and group B (25 patients) without flap fixation with an equal number of patients in each group (randomised by computer-based software).

In group A, wounds were closed in two layers using 2/0 vicryl for subcutaneous tissue and 2/0 ethilon for skin after a modified radical mastectomy. In group B, without flap fixation, the wound was closed using multiple rows of intermittent 2/0 Vicryl to secure the

skin flap to the pectoralis major muscle, followed by skin closure with 2/0 Ethilon. All patients had two 14F suction drains placed in the axilla and front of the pectoral muscles.

Information was gathered on a predetermined proforma that included the patient's personal information, history, general and local examinations, clinical findings, corresponding investigations, and type of surgical procedure. Anaesthetic fitness was obtained, and all patients received the same preoperative antibiotics. Surgery was performed in a standard operating room, with strict aseptic precautions. All the surgeries were performed by the same surgeon.

All patients were evaluated intraoperatively for the duration of surgery and postoperatively for complications such as surgical site infections, seroma formation, flap necrosis, and duration of postoperative hospital stay. The patients were monitored for three weeks postoperatively.

The drain volume was measured on the first postoperative day and removed when the output was < 30 ml in 24 h. The total drain volume was recorded, and the patients were followed for three weeks. Seroma and surgical site complications were noted and antibiotics were administered postoperatively. In addition, patients were followed up for three weeks postoperatively for seroma.

Statistical Analysis

Data were presented as mean, standard deviation, frequency and percentage. Continuable variables were compared using the independent sample t-test. Categorical variables were compared using the Pearson chi-square test. Significance was defined by P values less than 0.05 using a two-tailed test. Data analysis was performed using IBM-SPSS version 21.0 (IBM-SPSS Science Inc., Chicago, IL).

RESULTS

In group A, the highest percentage of patients was in the 41-50 years range, 15 (60%). In group B, the highest percentage of patients was also in the 41-50 years range 9 (36%). In both groups, the tumour was more commonly located on the right side in group A, 15 (30%), and group B, 17 (34%). Tumour stage IIA was slightly more common in both groups [group A, n=13 (26%); group B, n=14 (28%)]. In group A, the most common tumour size was 2.0-3.0 cm (12 patients). [Table 1]

In group A, 60% of the patients had a day-one drain volume > 150 ml compared to 70% in group B. There was no statistically significant difference in the volume drained on postoperative day 1 (p=0.47). The incidence of seroma was 0% in group A and 26% in group B, with a significant difference (p=0.009). The comparison of wound complications showed no wound in group A, but 4% of the patients in group B had wound complications, with 96% having no complications. The difference in wound complications between the two groups was not statistically significant (p=0.312) [Table 2].

The total drain volume (944±292.46 ml) was higher in group A than in group B (1415±261.61 ml). The duration of drain removal was 9 days in group A and

13 days in group B, and the difference was statistically significant ($p < 0.0001$) [Table 3].

Table 1: Demographic and clinical characteristics of groups.

		Group A	Group B
Age in years	≤ 40	6 (24%)	8 (32%)
	41 -50	15 (60%)	9 (36%)
	51 -60	3 (12%)	3 (12%)
	> 60	1(8%)	5 (20%)
Site of the tumour	Right	15 (30%)	17 (34%)
	Left	10 (20%)	8 (16%)
Stage of the tumour	IIA	13 (26%)	14 (28%)
	IIB	12 (24%)	11 (22%)
Size of the tumour (cm)	2.0-3.0	12	9
	3.0-4.0	8	8
	4.0-5.0	5	8

Table 2: Comparison of drain volume and seroma incidence between groups

		Group A	Group B	P value
Day one drain volume (ml)	< 100	2 (8%)	1 (4%)	0.47
	100-150	8 (32%)	5 (20%)	
	> 150	15 (60%)	19 (70%)	
Seroma- incidence	Present	0	6(26%)	0.009
	Absent	25(100%)	19 (76%)	
Wound complications	Present	0	1 (4%)	0.312
	Absent	25 (100%)	24 (96%)	

Table 3: Comparison of total drain volume and drain removal day between groups

	Mean		P value
	Group A	Group B	
Total drain volume	944±292.46	1415±261.61	< 0.0001
Drain removal day	9±2.2	13±2.01	< 0.0001

DISCUSSION

The era of breast conservative surgery is here to stay, with more and more centres progressing towards the adoption of BCS as standard protocol, one cannot ignore the place of the classical modified radical mastectomy or MRM which is still the most frequently performed procedure in our setting for breast cancer. A multifactorial cause for this can be established: delayed presentation, poor follow-up, and patient factors such as age and preference actively contribute to this picture. Even in women with early breast cancer in tertiary centres, the rate of performing breast conservative surgery or BCS approaches is only 35% in various studies.^[12] Regardless of how advanced the disease is, MRM remains the most frequently performed procedure for breast cancer. Hence, it is important to understand various complications and ways to combat them effectively. These include seromas, surgical site infections, blood loss, loss of flap viability, recurrence, and lymphoedema. Of these, seroma is the most commonly encountered complication.^[13] According to Woodworth et al., the incidence of seroma ranged from 10%-81%.^[14] Axillary dissection for breast cancer seroma is a severe condition that is now regarded as a sequela rather than a complication. Many studies have recommended the obliteration of extra space via flap fixation to lower the incidence of seroma development, with mixed results.

In our study, 50 patients with breast cancer who underwent MRM were divided into two groups (group A and group B, each with 25 women) to assess the total drain volume, drain removal time, seroma development, and wound complications. Both groups were similar in terms of age, cancer stage, and tumour size. The incidence of seroma was 0% in group A and 26% in group B, with a significant difference ($p=0.009$). There were no statistically significant differences in complications.

Inwang et al., study found the number of patients diagnosed with seroma through clinical examination was recorded, and any complications, including infection, cellulitis, or necrosis, were monitored at the wound site and drainage time ($p > 0.001$; significant).^[15] In Eldin et al., study the average number of days for drain removal was 9 in group A whereas 13 was in group B. The flap-fixation approach greatly reduced the total volume of fluid evacuated ($p < 0.001$; significant) in the current investigation.^[16]

The formation of seroma during MRM was initially assumed to be an acute inflammatory exudate,^[17] but Wu et al. soon showed a VEGF-mediated cascade of post-traumatic stress responses that resulted in seroma formation.^[18] One theory stated that the direct effect of surgical trauma caused the lymphatic channels to open up. Other theories postulated attribute seroma development to the dead space that is present due to the unique anatomy of the region. It was also thought that frequent arm movements

disrupting flap securing could be causative.^[19] Kumar et al. noted that the incorporation of quilting led to longer operative time and more blood loss, but also lesser seroma aspiration, shortened hospital stays, early initiation of chemotherapy and better return to function of shoulder mobility.^[20]

Pramegia et al. used a different approach to study IL-6 levels. They enrolled 39 patients, 20 of whom were assigned to a quilting group. They noted a statistically significant reduction in both seroma formation and IL-6 levels, thus establishing the advantage of quilting. The average differences in total seroma volume and IL-6 levels between the two groups were 399.25 mL ($p=0.000$) and 3160.75 mL ($p=0.000$), respectively. The results of linear regression showed that the total time needed for wound closure ($p=0.029$; 95% CI: 183.291–592.605) and the quilting technique ($p=0.018$; 95% CI: 1727.971–8101.730) both had a statistically significant effect on the change in seroma volume, as well as IL-6.^[21]

Meena et al. included 72 patients in a randomised controlled trial that spanned 2 years. In their study, there was no significant reduction in seroma formation ($p=0.233$).^[22] However, they noted no increase in postoperative complications with quilting and suggested that it may still be a viable option for reducing seromas. A randomized controlled trial by Eliav et al. on over 2000 patients noted a statistically significant reduction in seroma formation ($p < 0.001$, RR 0.367 [95% CI 0.25, 0.539]; I² = 63.56%) as well as drain duration ($p = 0.015$) with the introduction of quilting compared to conventional closure methods.^[23]

Similar results were noted in a randomised controlled trial by Khater et al., who studied 120 patients. They noted that the incidence of seroma was lower at 20% in comparison with the conventional group with 78.3%, as well as reduced drain duration (9 days vs 11 days) and drain volume as well (710 ml vs 1160 ml) ($p < 0.0001$).^[24] Morarasu et al. included close to 3500 patients from 21 studies in their systematic review and meta-analysis. The study group showed significantly lower rates of seroma ($p < 0.00001$), total drainage volume ($p < 0.0001$), days to drain removal ($p < 0.00001$), and length of hospital stay ($p < 0.00001$), with no increased incidence of complications.^[25]

Hence, the results of various studies closely mirrored those of our study. The introduction of a harmonic scalpel in axillary dissection is said to reduce seroma; however, it is not a commercially viable option in our setup and the learning curve is steep.^[26] The introduction of quilting is a simpler and more cost-effective mechanism to reduce the incidence of seromas, which can have a shorter learning curve and appreciable reduction in mortality and morbidity.

CONCLUSION

The current prospective investigation found that mechanical obliteration of the dead space by flap

fixation considerably reduces the risk of seroma development. However, because the sample size of the present study was small, a larger sample size may be required before any further conclusions can be drawn. Despite the limited sample size in this study, mechanical obliteration of the dead space by flap fixation in patients is still recommended. Flap fixation is a beneficial approach for decreasing seroma development during modified radical mastectomy, allowing early drain removal, and improving patient satisfaction.

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