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# Mastectomy Flap Quilting Sutures versus Conventional Dual-Drain Closure for Reduction of Seroma after Modified Radical Mastectomy

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## ABSTRACT

**Background:** Seroma after modified radical mastectomy (MRM) is the most common complication, which is reported to cause longer drainage, delayed wound healing, and higher morbidity in the patient. **Objective:** To compare the mastectomy flap quilting suture technique versus the conventional mastectomy with respect to seroma formation. **Study Design:** Prospective randomized controlled trial. **Settings:** Department of Surgery, Allied Hospital, Faisalabad Pakistan. **Duration:** One year from 01-11-2023 to 31-10-2024. **Methods:** This was a prospective randomized controlled trial of 120 female patients with breast carcinoma at stage II-III who were treated at MRM at Allied Hospital, Faisalabad. Group A (60 patients) received quilting sutures and an axillary drain, and Group B (60 patients) received conventional closure and dual drains. Seroma was clinically evaluated at 4-week follow-up and analyzed using SPSS v25 ( $p < 0.05$ ). **Results:** Groups were comparable for age (mean  $49.85 \pm 6.91$  vs.  $51.5 \pm 5.6$  years;  $p = 0.249$ ), tumor size ( $4.20 \pm 0.91$  vs.  $4.40 \pm 0.85$  cm;  $p = 0.209$ ), stage ( $p = 0.658$ ), and neoadjuvant chemotherapy ( $p = 0.854$ ). Seroma was significantly lower in Group A (13.3%) versus Group B (28.3%) ( $p = 0.043$ ). The benefit was most pronounced in Stage II disease (10.9% vs. 27.1%;  $p = 0.046$ ) and intermediate-sized tumors 3.5-4.4 cm (5.0% vs. 38.5%;  $p = 0.008$ ). **Conclusion:** Quilting sutures are an effective method of reducing post-MRM seroma, especially in Stage II disease and intermediate tumor size. Simple, reliable, and cost-effective, this technique should be performed routinely in MRM, particularly in high-risk patients.

**Keywords:** Modified radical mastectomy, Seroma, Quilting sutures, Flap fixation, Breast cancer, Dead space obliteration, Axillary drain.

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## INTRODUCTION

Breast cancer is the most prevalent type of cancer among women worldwide. With an age-standardized incidence of about 50 per 100,000 women, it is the leading cancer among women in Pakistan, as per the GLOBOCAN 2020 statistics,<sup>1</sup> and the late presentation is due to lack of access to organized screening programs as well as socio-cultural barriers to early medical consultation.<sup>2</sup>

In low and middle-income countries like Pakistan, MRM is the most common surgical treatment of breast cancer, because its presentation is usually late in the disease course, leading to its surgery in most of the tertiary centres.<sup>3</sup> MRM includes the whole breast, the skin overlying the breast, the nipple-areola complex, and axillary lymph node clearance. The large dead spaces under the mastectomy flaps and inside the axilla are an anatomic risk for seroma formation, the most common

postoperative complication after MRM, which has been reported at rates of 3% to 72%.<sup>4,5</sup>

Clinically significant seromas require repeated needle aspirations, delay drainage, delay wound healing, delay initiation of adjuvant therapy, increase the risk of infection, and impose a psychological and economic burden on the patient.<sup>5</sup> The pathophysiology of seroma is due to the disruption of axillary lymphatic channels, resulting in persistent lymphorrhea, surgical inflammatory reaction causing protein-rich exudate, and dead space preventing fibroblastic adhesion for obliteration.<sup>4</sup>

Traditionally, closed-suction drainage is used, consisting of two drains (an axillary and a pectoral). The quilting suture technique (systematic interrupted sutures that anchor the skin flap to the underlying pectoral fascia) mechanically eliminates dead space, provides conditions for fibroblast ingrowth, and makes the pectoral drain unnecessary and is therefore better for

eliminating accumulated fluid (suction is not completely redundant, as dead space is still removed).<sup>7,8</sup>

Multiple RCTs and meta-analyses have confirmed the advantage of quilting sutures over traditional drainage in reducing seroma formation,<sup>8,9,10</sup> but there is a lack of local data for comparison. A comparison of quilting with a single axillary drain with the conventional dual-drain closure for the prevention of seroma formation after MRM was thus made in the present RCT in a tertiary centre in Faisalabad, Pakistan.

## METHODS

The study was a prospective, randomized, controlled trial conducted in the Department of Surgery, Allied Hospital, Faisalabad, a tertiary academic hospital affiliated with Punjab Medical College and Faisalabad Medical University, for a period of 12 months, following approval from the Ethical Review Committee (ERC) of Faisalabad Medical University N0-48/ERC/FMU/2022-23/323, dated 05-10-2023. All participants gave written informed consent

Female patients of age 20 to 70 years with histologically confirmed (FNAC or Tru-cut biopsy) stage II -III breast carcinoma who were planned for MRM with ALND.

Mastectomy without axillary dissection, patients wanting to have a breast conserving surgery, inoperable disease and patients with recurrent breast cancer after a mastectomy were excluded from the study.

Sample size was determined using a WHO sample size calculator, based on expected seroma proportions in groups A and B of 23% and 58%, respectively, as reported in the literature<sup>11</sup> (90% power at 95% confidence level), a sample size of 120 patients was calculated (60 patients in group A and 60 patients in group B).

Patients in Group A (n = 60) were sutured with quilting sutures and axillary drains, while patients in Group B (n = 60) were closed by conventional sutures and pectoral and axillary drains.

Surgery was performed by the same surgical group using a uniform method. For Group A (quilting), after mastectomy and ALND, two rows of interrupted 2-0 Vicryl quilting sutures were placed along the inferior and medial borders of the skin flaps to anchor the skin flaps to the pectoral fascia, thus preventing the dead space between the skin and fascia from being formed. One 18 Fr closed-suction drain was inserted into the axilla. There was no pectoral drainage. In Group B (conventional), the skin was closed with non-absorbable sutures, and the deeper layers with absorbable sutures. Two 18 Fr closed suction drains (axillary and pectoral) were inserted. Histopathological examination of lymph nodes for metastasis was performed on all resected specimens. Some patients were discharged within 48 hours of drain removal. Follow-up was done in the outpatient departments for four weeks. Any fluid accumulation, identified clinically in the dead space under the mastectomy flaps or in the axilla, regardless of whether or not it was aspirated, was considered seroma.

The data were analyzed using SPSS 25. Quantitative variables were presented as mean  $\pm$  SD, and qualitative variables as

frequencies and percentages. Stratification was used for effect modifiers: age, tumor size, stage, and NACT. An independent-samples t-test was used to compare continuous variables between groups after confirming normality. The post-stratification chi-square test was used, and Fisher's exact test (when it applied to the data). P values < 0.05 were deemed statistically significant.

## RESULTS

### Baseline Characteristics

The study population comprised 120 females aged 20-70 years. The mean age in Group A and Group B was  $49.85 \pm 6.91$  years and  $51.5 \pm 5.6$  years ( $p = 0.249$ ). Most patients in both groups were aged 41-60 years (Table 1). Mean tumor size in Group A and Group B was  $4.20 \pm 0.91$  cm and  $4.40 \pm 0.85$  cm ( $p = 0.209$ ) (Table 2). The tumors were mainly located in the outer half (65.0% in both groups). Stage II disease predominated in both groups (76.7% vs. 80.0%;  $p = 0.658$ ). 45.0% (Group A) and 43.3% (Group B) ( $p = 0.854$ ) received Neoadjuvant chemotherapy. All baseline characteristics were well-balanced across groups.

**Table 1: Comparison of age**

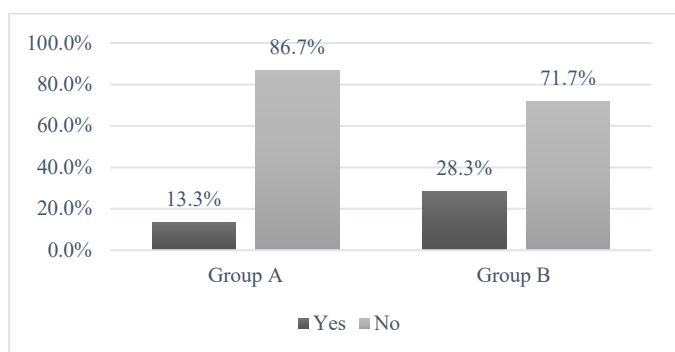
| Age Group (years) | Group A — Quilting (n=60) | Group B — Conventional (n=60) | Total (n=120) | p-value |
|-------------------|---------------------------|-------------------------------|---------------|---------|
| Mean Age          | $49.85 \pm 6.91$          | $51.5 \pm 5.6$                | —             | 0.249   |
| 31–40             | 2 (3.3%)                  | 1 (1.7%)                      | 3 (2.5%)      | 0.397   |
| 41–50             | 31 (51.7%)                | 25 (41.7%)                    | 56 (46.7%)    |         |
| 51–60             | 21 (35.0%)                | 30 (50.0%)                    | 51 (42.5%)    |         |
| 61–70             | 6 (10.0%)                 | 4 (6.7%)                      | 10 (8.3%)     |         |

**Table 2: Comparison of tumor size**

| Tumor Size (cm) | Group A (n=60)  | Group B (n=60)  | Total (n=120) | p-value |
|-----------------|-----------------|-----------------|---------------|---------|
| Mean (cm)       | $4.20 \pm 0.91$ | $4.40 \pm 0.85$ | —             | 0.209   |
| 2.6–3.4         | 14 (23.3%)      | 8 (13.3%)       | 22 (18.3%)    | 0.298   |
| 3.5–4.4         | 20 (33.3%)      | 26 (43.3%)      | 46 (38.3%)    |         |
| 4.5–5.8         | 26 (43.3%)      | 26 (43.3%)      | 52 (43.3%)    |         |

### Primary Outcome: Seroma Formation

The number of patients with seroma in Group A was 8 (13.3%), and in Group B was 17 (28.3%). This difference was statistically significant ( $p = 0.043$ ) indicating that the quilting suture group had a significantly lower incidence.

**Figure 1: Postoperative seroma****Stratified Analysis**

When stratified by four effect modifiers, the seroma rate was consistently lower among Group A (Table 3). Statistical significance was achieved in two subgroups: intermediate-sized tumors 3.5–4.4 cm (5.0% vs. 38.5%;  $p = 0.008$ ) and Stage II disease (10.9% vs. 27.1%;  $p = 0.046$ ). A numerical trend was observed but did not reach statistical significance for the stratum 61–70 (0% vs. 50.0%;  $p = 0.053$ ). The largest tumor stratum ( $p = 1.000$ ), Stage III disease ( $p = 0.495$ ), and the two neoadjuvant chemotherapy groups ( $p = 0.094$  and  $p = 0.223$ ) were not significantly different. Sub-group analyses were exploratory and should be interpreted with caution given the small sample sizes and multiple comparisons.

**Table 3: Stratified analysis of postoperative seroma formation across all effect modifiers**

| Stratification Variable                   | Sub-group    | Seroma   | Group A-Quilting | Group B - Conventional | p-value       |
|-------------------------------------------|--------------|----------|------------------|------------------------|---------------|
| <b>A. Age Group (years)</b>               |              |          |                  |                        |               |
| Age Group                                 | 31–40        | Yes / No | 0 / 2            | 0 / 1                  | —             |
|                                           | 41–50        | Yes / No | 5 (16.1%) / 26   | 6 (24.0%) / 19         | 0.461         |
|                                           | 51–60        | Yes / No | 3 (14.3%) / 18   | 9 (30.0%) / 21         | 0.193         |
|                                           | 61–70        | Yes / No | 0 (0.0%) / 6     | 2 (50.0%) / 2          | <b>0.053*</b> |
| <b>B. Tumor Size (cm)</b>                 |              |          |                  |                        |               |
| Tumor Size                                | 2.6–3.4      | Yes / No | 1 (7.1%) / 13    | 1 (12.5%) / 7          | 0.674         |
|                                           | 3.5–4.4      | Yes / No | 1 (5.0%) / 19    | 10 (38.5%) / 16        | <b>0.008*</b> |
|                                           | 4.5–5.8      | Yes / No | 6 (23.1%) / 20   | 6 (23.1%) / 20         | 1.000         |
| <b>C. Disease Stage</b>                   |              |          |                  |                        |               |
| Disease Stage                             | Stage II     | Yes / No | 5 (10.9%) / 41   | 13 (27.1%) / 35        | <b>0.046*</b> |
|                                           | Stage III    | Yes / No | 3 (21.4%) / 11   | 4 (33.3%) / 8          | 0.495         |
| <b>D. Neoadjuvant Chemotherapy (NACT)</b> |              |          |                  |                        |               |
| NACT                                      | Received     | Yes / No | 4 (14.8%) / 23   | 9 (34.6%) / 17         | 0.094         |
|                                           | Not Received | Yes / No | 4 (12.1%) / 29   | 8 (23.5%) / 26         | 0.223         |

\*  $p < 0.05$  (statistically significant). Bold p-values indicate significance. Yes/No cells report the number of patients with and without seroma within that subgroup.

**DISCUSSION**

In the present RCT, the quilting suture group had a statistically significant reduction in seroma formation compared with the conventional dual-drain closure group. This aligns with the growing international literature supporting quilting sutures as the preferred method for dead-space management after MRM.<sup>8,9,10</sup> Quilting sutures appear to be a simple and effective technique; however, multicenter trials with larger samples are needed before universal adoption is recommended.

The pathophysiological basis is very well known. MRM creates a potential cavity spanning 200–400 cm<sup>2</sup> of surface area, with potential fluid volumes of 50–300 mL.<sup>4</sup> Conventional suction drains, however, act by passively removing fluid as it collects, without modifying the anatomical substrate, and seroma will often re-collect after their removal.<sup>6</sup> Quilting sutures eliminate this cavity mechanically, fixing the flap to the chest wall and subdividing the space into micro-compartments that obliterate rapidly as the apposed surfaces permit fibroblast ingrowth and fibrous adhesion formation.<sup>7</sup>

The 13.3% seroma incidence rate of the quilting group is consistent with published trial data. The pooled relative risk of quilting versus no quilting from the meta-analysis by Drivas *et al.*<sup>8</sup> was 0.367 ( $p < 0.001$ ) with no increase in hematoma, surgical site infection, or flap necrosis. Similarly, Eliav *et al.*<sup>9</sup> reported that quilting also significantly decreased the amount of seroma. A large-scale randomized controlled intervention (laced QUILT) stepped-wedge cluster RCT by van Zeelst. *et al.*<sup>12</sup> in 9 teaching hospitals in the Netherlands showed better healthcare use outcomes and lower healthcare costs with the implementation of quilting sutures. These data are extrapolated in the current study to a Pakistani tertiary care setting where MRM rates are still higher than expected for late presentation.

There was no age distribution of seroma in the quilting group, but a numerical trend towards higher seroma incidence with age was observed in the conventional group ( $p = 0.053$ ), most strikingly at age 61–70 years (50.0% vs. 0.0%). Although these comparisons were not age-stratified and were not statistically significant, this directionality is consistent with published data suggesting that older age is an independent seroma risk factor, related to decreased tissue tensile strength, altered inflammatory kinetics, and diminished capacity for lymph regeneration.<sup>5</sup>

In the intermediate-sized tumor group (3.5–4.4 cm), the most obvious subgroup finding was that the proportion of patients with seroma decreased from 38.5% to 5.0% ( $p = 0.008$ ) after quilting. Tumors of this size require moderately wide dissection, which results in a definite dead space that is easily filled mechanically. In the largest tumor stratum (4.5–5.8 cm; seroma 23.1% each group), no significant benefit was observed, which may be due to the limits of quilting, particularly with extensive dissection of the tumor and thinner flaps, with more disruption of the lymphatics, and may require additional methods of external compression or additional longer retention of the drains in this subset.<sup>8</sup> These subgroup findings are hypothesis-generating and require validation in larger, adequately powered studies.

Staging analysis showed a significant quilting benefit in Stage II disease (10.9% vs. 27.1%;  $p = 0.046$ ) but not Stage III (21.4% vs. 33.3%;  $p = 0.495$ ). As observed, seroma risk is higher in advanced-stage patients, and Stage III patients have a greater lymphatic disruption and larger axillary dead space, which only partially responds to fixation of the flaps.<sup>5,11</sup>

Neoadjuvant chemotherapy-stratified comparisons failed to show significance, consistent with previous literature,<sup>9,13</sup> because it affects leucocyte function, inhibits angiogenesis, and reduces fibroblast proliferation, thereby delaying obliteration of dead space after quilting has been performed. Among NACT-treated patients, the differences in numbers were consistently in favor of quilting (14.8% vs. 34.6%), as were those among NACT-untreated patients (12.1% vs. 23.5%), although the numbers were not large enough for significance. More studies are required to determine if the NACT has a separate effect on the quilting benefit.

## CONCLUSION

This RCT demonstrates that the use of mastectomy flap quilting sutures with one axillary drain is associated with significantly less seroma following MRM than is conventional dual-drain closure, with the strongest benefit in Stage II disease and intermediate-sized tumors (3.5–4.4 cm). In conclusion, quilting is an easy, versatile, inexpensive, and repeatable procedure that can be used as a preferred method to close MRM.

## LIMITATIONS

The present study did not systematically quantify several secondary endpoints, including hospital length of stay, number of aspiration procedures, operative time, suture-related complications, and drain duration. These results, together with validated quality-of-life instruments and longer follow-up, should be included in future trials.

## SUGGESTIONS / RECOMMENDATIONS

Multi-centre randomized controlled trials, increase sample size, long term follow up, standardization of surgical technique.

## CONFLICT OF INTEREST / DISCLOSURE

The authors declare no conflict of interest.

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