Brief Report

Access this article online
Quick Response Code:

Website:
www.jehp.net

DOI:
10.4103/jehp.jehp_47_24

A quilting sutures technique for flap closure in patients undergoing modified radical mastectomy for the prevention of seroma: A single-center, randomized controlled trial

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Abstract:

Seroma formation is a common adverse event following modified radical mastectomy, and it leads to delayed wound healing and increased post-operative pain and increases overall morbidity of patients. The quilting sutures as a newer technique for the skin flap closure is done to reduce incidence of seroma formation. Although it has controversy in the literature for the satisfactory outcome, the study has aimed to compare the Quilting suture technique with the conventional closure method to evaluate the efficacy of the quilting technique. The primary objective of the study was to access and compare the frequency of seroma formation following the quilting suture technique with standard flap closure in MRM. The secondary objectives were to compare drain output, post-operative complications, and the requirement of additional procedures for management of related complications. The 72 female participants in this randomized control trial had modified radical mastectomy after being diagnosed with breast cancer. The quilting suture technique was applied in the 36 patients and conventional technique applied in 36 patients for skin flap closure. The frequency of seroma formation and other complications were reported. Between the two groups, there was no statistically significant difference in the frequency of seroma production (P = 0.233). Total drainage volume (P = 0.213), drainage duration (P = 0.652), and post-operative complications (P = 0.641) did not substantially differ between the two groups. The study concludes that the quilting sutures technique does not decrease the incidence of seroma formation, total drain output, and total duration of drainage. There is no significant difference in complications and requirement of additional procedures compared to the standard technique.

Keywords:

Carcinoma breast, MRM, quilting sutures, seroma

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Received: 09-01-2024
Accepted: 04-03-2024
Published: 11-07-2024

Introduction

Seroma formation is a common adverse event after modified radical mastectomy.[1] Seroma increases risk of post-operative SSI, wound hematoma, delayed wound healing, and wound dehiscence and thus increases costs of treatment and prolongs hospital stay of the patient.[2-4] A newer quilting suture technique involves suturing the skin flaps to the underlying musculature using absorbable sutures to minimize dead space and to restore tissue integrity after surgical dissection.[5,6] There have been a number of recent studies comparing quilting sutures with conventional closures with respect to the prevention of seroma formation after mastectomy.[7] However, the efficacy of quilting suture in seroma prevention is

How to cite this article: Meena SP, Bishnoi S, Badkur M, Lodha M, Vishnoi JR, Sharma N. A quilting sutures technique for flap closure in patients undergoing modified radical mastectomy for the prevention of seroma: A single-center, randomized controlled trial. J Edu Health Promot 2024;13:240.

still under question.[8] The study has aimed to compare the effectiveness of quilting suture as compared with conventional flap closure to prevent seroma formation and related complications.

Material and Methods

Study design, setting, and objectives

The randomized controlled trial study was conducted in 72 female patients undergoing modified radical mastectomy (MRM) in the Department of General Surgery and Department of Surgical Oncology at All India Institute of Medical Sciences, Jodhpur. The study has been done during January 2021 to December 2022 for 2 years.

The primary objective was to compare frequency of post-operative seroma formation in quilting suture with conventional closure following modified radical mastectomy. The secondary objectives were to compare the drain output, the incidence of post-operative complications like SSI, flap necrosis, wound dehiscence, and the number of additional procedures done like aspirations or revise drain insertion and revision surgeries.

Study participants and sampling

The study included all female patients with the diagnosis of breast cancer planned for modified radical mastectomy (MRM). However, the study excluded all the patients planned for breast reconstructive surgery, the patients on chemotherapy for non-breast malignancy, and also all patients who refused to give consent for the study.

Sample size is calculated according to the results obtained by Seenivasagam *et al*.[9] in his study in which the incidence of seroma formation was 35.4% in the conventional suture group and incidence of seroma in the group with flap fixation with quilting suture was 8.2%. With the help of Epi-info sample size estimation software, after using the values of incidence, we estimated a sample size of 36 patients per group according to Kelsey method at 95% confidence interval and 80% power, with α of 0.05 and $P < 0.001$.

Study procedure

All patients were admitted in the Department of General Surgery and Surgical Oncology. Basic pre-operative evaluation including demography, clinical evaluation, routine blood investigations, imaging, and histopathology was done. They were explained in detail about the format of the study with the help of a patient information sheet after which an informed consent was obtained. The randomization sequence was generated using the website www.randomization.com. The sequence thus generated was sealed in serially numbered opaque envelopes. An envelope was opened at the time of surgery. In quilting group, patients underwent MRM and skin flap closure done by the quilting suture technique. In the conventional group, patients underwent MRM and skin flap closure with conventional technique. Electro-cautery was used for initial dissection of skin flap, followed by axillary dissection done by harmonic scalpel. Post-operatively patients were assessed for seroma formation by clinical assessment. Drain volumes from both groups were noted on post-operative days (POD) 1, 2, 3, 7, and 10 or at the time of drain removal. Total drain output from the day of surgery till the day of removal was also noted. Pectoral drain was taken out on day 3 before discharge in both groups. Patient follow-up was done on day 7, 10, 14, 21, and 30 or earlier if required, either telephonically or physically in out-patient department (OPD). Axillary drain was removed on POD 7th or later, when drain output was <30 ml (over 24 hrs.). Patients underwent clinical assessment to look for seroma formation. Seroma was diagnosed clinically as fluctuant, non-tender swelling or collection under mastectomy flaps or axilla. Needle aspiration was done for seroma if clinically significant seroma was present after drain removal. Other complications arising post-operatively were graded according to Clavien-Dindo score and were managed accordingly.

Techniques

Conventional closure technique

A transverse or oblique elliptical incision made over the breast. Incision extended laterally up to axilla for axillary dissection. Skin flaps raised in the plane deep to the subcutaneous tissue and superficial to breast parenchyma using scissors, scalpels, or electrocautery. Superior and inferior flaps were raised. Breast tissue dissected off from the pectoral muscle using electrocautery. When the lateral border of the breast reached, the pectoral muscle was gently retracted medically and clavi-pectoral fascia incised to expose the axillary contents, followed by axillary dissection done. Closed suction drains were placed in the axillary and pectoral region and both drains connected to a single suction device. Closure of flaps was done in two layers. The subcutaneous layer was closed with interrupted vicryl sutures. Skin was closed with interrupted nylon sutures.

Quilting suture technique

All dissection made as a conventional closure technique. However, before closure of skin flaps, quilting was done as skin flaps were sutured to underlying muscle with multiple parallel rows of interrupted vicryl sutures size 3-0 placed at periodic intervals (1–2 cm) in both axillary and pectoral regions. The subcutaneous layer was closed with interrupted vicryl sutures. Skin was closed with interrupted nylon sutures [Figure 1].

Statistical analysis

The Statistical Package for Social Sciences (SPSS) version (25.0) was used to enter and analyze the data. For each variable, descriptive data are presented. Calculated descriptive statistics include the mean, standard deviation, and frequency for continuous variables, along with percentages for categorical variables. Tables and graphs are used to present compiled data. The Mann Whitney U test is used to compare numerical data that do not follow a normal distribution. For categorical data, we can use the Chi-square test or Fisher exact test. A *P* value of 0.05 or lower has been deemed significant. According to the intention to treat principle, all the data were analyzed.

Results

A total of 72 patients were included in the study and underwent Modified Radical Mastectomy during the study period of 2 years from January 2021 to December 2022. These patients were then randomized to the quilting group and conventional group in the ratio of 1:1 as described in the consort flow diagram [Figure 2].

Demography, comorbidities, and operative duration of study patients have been compared and found no significant difference between groups [Table 1].

Primary outcome

The incidence of seroma formation between Quilting and Conventional did not differ significantly. Two patients in Quilting and five patients in Conventional group developed seroma post-operatively. The data were analyzed using Chi square test, and the result is found to be non-significant (*P* value = 0.233, CI = 95%). [Tables 2 and 3].

Secondary outcomes

Drain output

The total drainage volume (mean) for the quilting group and conventional group is 687.5 (IQR = 532.5-930.0) and 782.5 (IQR = 611.2-1045.0), respectively, and the data were analyzed using an independent sample *t*-test and showed no significant difference between two groups (*P* value = 0.213). The mean of total duration of drainage for the quilting group and conventional group was 11.8 (SD = 3.2) and 12.2 (SD = 3.5), respectively, and the difference between two groups is non-significant (*P* value = 0.652, CI = 95%). [Table 2].

Post-operative complications

Two patients in the quilting group developed

Table 1: Comparison of baseline characteristics between the groups

Variable	Quilting group (*n*=36)	Conventional group (*n*=36)	*P
Age (yrs), Median (IQR)	51 (43-56)	51 (42-62)	0.738
TNM stage, *n* (%)			
Stage 1	0	0	-
Stage 2	18 (50)	22 (61)	0.343
Stage 3	18 (50)	14 (59)	0.343
Hormonal receptors (Positive, %)			
ER	19 (52.7)	23 (63.1)	0.339
PR	18 (50)	20 (55.5)	0.637
HER-2	14 (59.1)	13 (36.1)	0.309
Triple Negative, *n* (%)	5 (13.8)	5	1.00
Comorbidities, *n* (%)			
Hypertension	7 (19.4)	8 (22.2)	0.772
Diabetes	1 (2.7)	4 (11.1)	0.164
CAD	1 (2.7)	0	0.314
Thyroid disorder	1 (2.7)	1 (2.7)	1.00
Neoadjuvant chemotherapy, (*n*%)	21 (0.58)	18 (0.50)	0.478
Operative duration Mean (SD), (mins)	159.6 (18.8)	141.9 (15.9)	0.308

*P>0.05 for all the above variables

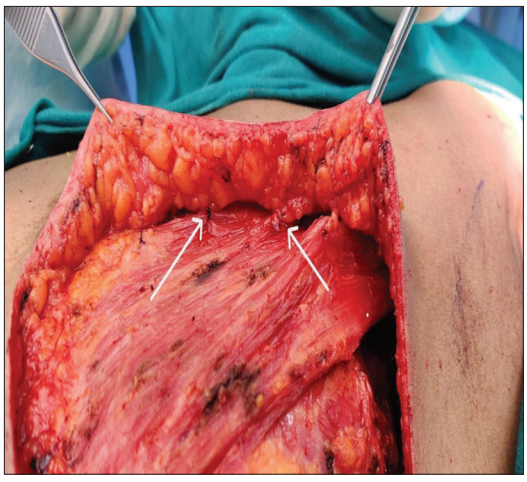

Figure 1: Quilting suture technique (Arrow showing quilting sutures)

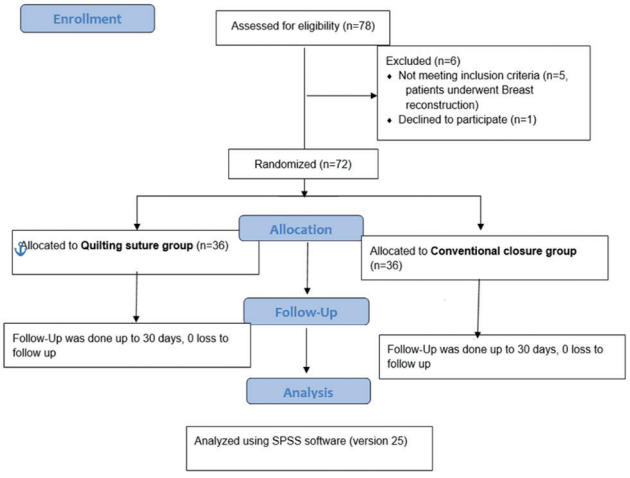

Figure 2: Consort flow diagram

post-operative SSI, and one of these patients developed wound dehiscence. In the conventional group, two patients developed SSI, which was managed with antibiotics and resulted in prolonged post-operative hospital stay. In the conventional group, one patient developed skin flap necrosis for which the patient underwent debridement and skin grafting.

The data were compared using Chi square test, and there is no significant increase in complications with use of quilting suture technique (*P* value = 0.641) [Table 3].

Additional procedures or surgery

The mean number of aspirations for post-operative seroma in the quilting group is 2 (SD = 1.4), and that in the conventional group is 1.67 (SD = 0.5) {*P* value = 0.724}. The mean volume of seroma aspiration in the quilting group is 142.5 (SD = 152.0), and that of the conventional group is 51.7 (SD = 28.4). One patient in the conventional group required reinsertion of drain for drainage of seroma.

In the quilting group, one patient developed wound dehiscence due to SSI, for which she underwent debridement under local anesthesia. In the conventional group, one patient developed flap necrosis for which she underwent debridement, followed by skin grafting under general anesthesia.

Table 2: Comparison of postoperative outcomes of patients between the groups

Variable		Quilting group (*n*=36)	Conventional group (*n*=36)	*P
Drain output (ml) mean (SD)	Day 1st	119.0 (36.6)	129.5 (34.2)	0.211
	Day 2nd	96.6 (29.4)	110.8 (31.4)	0.051
	Day 3rd	79.4 (24.4)	89.5 (30.6)	0.127
	Day 7th	51.9 (19.3)	54.7 (15.9)	0.511
Total drainage volume (ml), Median (IQR)		687.5 (532.5-930.0)	782.5 (611.2-1045.0)	0.213
Duration of drainage (days), mean (SD)		11.8 (3.2)	12.2 (3.5)	0.652

**P*-value is calculated using independent sample *t*-test

Discussion

Seroma formation is associated with increased hospital visit, comorbidity, and increased burden on health care. The study aimed to measure the role of quilting sutures for the prevention of seroma formation and a decrease in morbidity related to dead space formation after Modified Radical Mastectomy.

Although the use of quilting sutures was found to reduce the incidence of seroma formation in this randomized controlled trial, the result did not reach statistical significance. In a randomized controlled trial, Sakkary *et al*. (2012)[10] found that the quilting technique significantly reduced overall seroma formation after MRM and reduced total drainage volume. In a related study, B. ten Wolde *et al.* (2013)[11] found that the use of quilting sutures significantly reduced the formation of seromas. However, quilting did not significantly reduce seroma formation in the study done by Yilmaz *et al*. (2021) and Najeeb *et al*. (2019)[8,12] also found that quilting had no discernible effect on seroma formation.

There was no significant decrease in total drain output and daily drain output between quilting and conventional groups. Chafika Mazouni *et al*. (2015)[13] compared the role of tetracycline sclerotherapy during mastectomy and no significant difference found in total amount of drain output. Myint *et al.* (2020)[14] compared the role of quilting suture and concluded that quilting resulted in a significant decrease in mean daily drain output on POD 1 and 2. However, Myint *et al.* (2020)[14] performed a randomized comparative study and concluded that quilting resulted in a significant decrease in incidence of seroma, but the total amount of drain output and duration of drainage was not different.

Table 3: Comparison of postoperative complications and intervention variables

Variable	Quilting group (*n*=36)	Conventional group (*n*=36)	*P
Seroma, *n* (%)	2 (5.4)	5 (13.8)	0.233
SSI, *n* (%)	2 (5.4)	2 (5.4)	1.00
Flap necrosis, *n* (%)	0	1 (2.7)	0.314
Wound dehiscence, *n* (%)	1 (2.7)	0	0.314
**Number of aspirations, Mean (SD)	2 (1.4)	1.67 (0.5)	0.724
**Total aspiration volume, Mean (SD)	142.5 (152.0)	51.7 (28.4)	0.353
Drain re-insertion, *n* (%)	0	1 (2.7)	0.314
Debridement, *n* (%)	1 (2.7)	1 (2.7)	1.00
Skin grafting, *n* (%)	0	1 (2.7)	0.314
Postoperative complications graded as per Clavien-Dindo grades			
Grade 1	10 (27.7)	6916.6)	0.257
Grade 2	0	0	-
Grade 3a	3 (8.3)	3 (8.3)	1.0
Grade 3b	0	1 (2.7)	0.314

**P*-value is calculated using Chi square test. ***P*-value is calculated using independent sample *t*-test

The mean number of seroma aspirations was also not statistically different between two groups for this study, which was comparable with the result Chafika Mazouni *et al.* (2015)[15] had concluded in their study. Vettuparambil A *et al.* (2021)[16] in their study, however, showed a significant decrease in the required number of seroma aspirations and a decrease in the mean volume of aspirations with use of quilting sutures.

As the literature has shown increased incidence of seroma formation following electrocautery dissection compared with harmonic scalpel, axillary dissection and deep flap dissection performed by harmonic only to prevent incomplete coagulation of lymphatics or inadequate hemostasis.[17]

Previous studies have shown seroma formation or frequent aspiration of seroma after early removal of drain (immediate after 24 hours of surgery) or after no drain techniques. Usually, axillary drain is removed after 48 hours of surgery if the daily drain volume is less than 50 ml for continuous 2 days. In this study, pectoral drain was removed on day 2 and axillary after 5 days if the drain volume is less than 30 ml for 2 consecutive days; hence, the drain removal protocol is comparable to most of the studies in the literature. Also, no significant difference was found for complications including seroma formation with the use of a single drainage tube compared to the standard two drain technique, although the standard two drain technique is followed in this study.[18]

This study showed that quilting did not result in a significant increase in incidence of post-operative SSI between two groups, and the overall incidence of SSI was also less in the study. Seroma is a risk factor of SSI; however, the vice versa was not concluded in this study. Myint *et al.* (2020) *et al.* in their study had comparable results for incidence of SSI. *van Zeelst LJ et al.* (2022)[19] study had comparable results for incidence of SSI. Velotti *et al.* (2021)[20] performed a meta-analysis on role of quilting sutures and concluded no significant difference in incidence of SSI and no statistically significant heterogeneity between studies. L Ouldamer *et al.* (2015)[21] concluded in their study that quilting was beneficial with reduction in surgical site infections.

Overall post-operative complications in the study, as measured with Clavien Dindo score, were slightly higher in the quilting group than the conventional group; however, this conclusion did not reach statistical significance. Quilting could be used as a method of reducing seroma with no major risk of surgical site infections.

Although this study showed a decrease in seroma formation and a decrease in post-operative drain volume, the results are not statistically significant. Also, in this study, the weight of breast tissue was not measured, which could act as a confounding factor.

The quilting technique increases the overall operative duration as Myint *et al.* (2020) had concluded in their study.[14] In this study also, the duration of surgery had prolonged; however, the difference was not statistically significant.

There is a possibility that a multi-center study with the objective of increasing textbook outcomes may lead to a better answer for the standardization of the flap closure technique. By quilting sutures following MRM, we might reduce health care consumption and morbidity and improve the overall outcome of patients.[22]

Conclusion

Quilting suture is a new and safe technique that has been described to reduce incidence of seroma formation after modified radical mastectomy. The present study concludes that quilting does not significantly reduce seroma formation. Also, this technique does not help in early drain removal and decrease the total drainage volume. Longer duration of drain is still a preferred method to decrease the risk of seroma formation. Although the incidence of SSI may increase with external drain. There is no standard cut-off value of drain volume for the removal of drain; however, most of the surgeons preferred drain removal between 20 and 50 ml of drainage volume.

Acknowledgement
We are very thankful to Prof Ashok Puranik, to encaurage in research, help us in data collection of patients and proof reading of manuscript.

Ethical consideration
Consent was obtained or waived by all participants in this study. Institutional Ethics Committee, All India Institute of Medical Sciences Jodhpur issued research approval. (AIIMS/IEC/2021/3396)

CTRI registration no: REF/2021/06/044617

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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