QUILTING SUTURE VS CONVENTIONAL CLOSURE IN PREVENTION OF SEROMA FORMATION AFTER MODIFIED RADICAL MASTECTOMY FOR BREAST CANCER: A RANDOMIZED CONTROLLED TRIAL

THESIS

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GENERAL SURGERY

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Dr. SUMIT BISHNOI

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DECLARATION

I hereby declare that this thesis titled **"Quilting Suture vs Conventional Closure in Prevention of Seroma formation after Modified Radical Mastectomy for Breast Cancer: A Randomized Controlled Trial"** is a bonafide and original research work carried out in partial fulfilment of the requirements for the degree of Masters of Surgery in General Surgery under supervision and guidance, in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE BY HEAD OF THE DEPARTMENT

This is to certify that the thesis titled **"Quilting suture vs Conventional Closure for prevention of seroma formation after Modified Radical Mastectomy for Breast cancer: A randomized controlled trial"** is the bonafide work of **Dr Sumit Bishnoi** carried out under our guidance and supervision, in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur. He has fulfilled all the requisites under regulations laid by the All India Institute of Medical Sciences, Jodhpur and no part of the thesis has been submitted to any other university.

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CERTIFICATE BY GUIDE

This is to certify that the thesis titled **"Quilting Suture vs Conventional Closure in Prevention of Seroma formation after Modified Radical Mastectomy for Breast Cancer: A Randomized Controlled Trial"** is the bonafide work of **Dr. Sumit Bishnoi** carried out under my guidance and supervision, in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur. He has fulfilled all the requisites under regulations laid by the All India Institute of Medical Sciences, Jodhpur and no part of the thesis has been submitted to any other university.

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Dedicated To

My Parents & My Teachers

ACKNOWLEDGEMENT

Sanskrit transcript

पावका नः सरस्वती वाजे ि◌वाजजनीवती। यज्ञं वष्टु ि◌यावसुः॥

English translation

“Goddess Sarasvatī, who sanctifies, nourishes, intelligently bestows opulence, may make our sacrifice successful with knowledge and action.”

First and foremost, I would like to express a deep sense of gratitude to my guide and guru, Dr Satya Prakash Meena, Associate Professor, Department of General Surgery, AIIMS Jodhpur, for instructing me and guiding me along the journey of carrying out and finally completing my study. His guidance and valuable criticisms have helped me refine my work and myself.

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LIST OF ABBREVIATIONS

SSI	**Surgical site infection**
MRM	**Modified Radical Mastectomy**
ALND	**Axillary lymph node dissection**
CI	**Confidence Interval**
CONSORT	**Consolidated Standards of Reporting Trials**
IQR	**InterQuartile Range**
IV	**Intravenous**
RCT	**Randomised Controlled Trial**
SE	**Standard Error**
SPSS	**Statistical Package for Social Sciences**
VAS	**Visual Analogue Scale**
SD	**Standard deviation**
POD	**Post operative day**

SUMMARY

Background: Seroma formation is a common adverse event after Modified radical mastectomy and leads to delayed wound healing, increased postoperative pain and increases overall morbidity of patients. Various techniques have been described in literature to reduce incidence of seroma formation. One such technique is application of quilting sutures between skin flaps and underlying muscle. This technique has been described as a method of reducing surgical dead space and thus decreasing the risk of developing seroma. Our study has aimed to compare Quilting suture technique with Conventional closure method to evaluate the efficacy of quilting technique.

Objectives: The primary objective of the study was to compare frequency of seroma formation between groups. The secondary objectives were to compare drain output on post operative day 1, 2, 3, 7, 10 or at the time of removal and to compare total drainage volume, postoperative complications and the requirement of additional procedures for management of related complications.

Methods: The 72 female participants in this study had modified radical mastectomy after being diagnosed with breast cancer. Two groups of patients were randomly selected, with 36 individuals in each group. The Quilting suture technique was used to close the flaps on the patients in Group A. The conventional method of flap closure was used on the patients in Group B. Seroma development frequency and other problems were reported after monitoring all patients for up to 30 days.

Results: 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 postoperative complications ($p=0.641$) did not substantially differ between the two groups..

Conclusion: 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 between the two techniques.

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INTRODUCTION

Modified radical mastectomy is the preferred method and standard treatment for management of breast cancer. Seroma formation is a common adverse event after modified radical mastectomy. Seroma increases risk of postoperative SSI, wound hematoma, delayed wound healing, wound dehiscence and thus increases costs of treatment and prolongs hospital stay of the patient.(1)

While many factors may contribute to the formation of seroma, including the extent of lymph node clearance, the presence of dead space after surgery, the use of postoperative radiation, and ligation of lymphatic channels, the exact etiology of seroma formation is unknown. Various techniques have been described in literature to prevent or reduce seroma formation, but efficacy of these methods is still debatable. Breast cancer patients undergoing mastectomy routinely have negative suction drain inserted in axilla and pectoral regions, which are kept for prolonged periods for the prevention of seroma and delay the initiation of adjuvant treatment.(2)

A number of techniques have been described for minimizing the leakage from dissected blood vessels and lymphatics during breast surgery as well as removing dead space, which may lower the risk of seroma.(3,4) The use of continuous closed suction drains prevents the buildup of seroma underneath skin flaps The use of continuous closed suction drains prevents the buildup of seroma underneath skin flaps.(5)

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.(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) But the efficacy of quilting suture in seroma prevention is 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.

REVIEW OF LITERATURE

Breast, also known as mammary gland lies over anterior chest wall as two prominences and extends from level of second rib to sixth rib. As part of the axillary tail of Spence, breast tissue extends into the axilla as well. Breast functions as milk secreting organ in females.

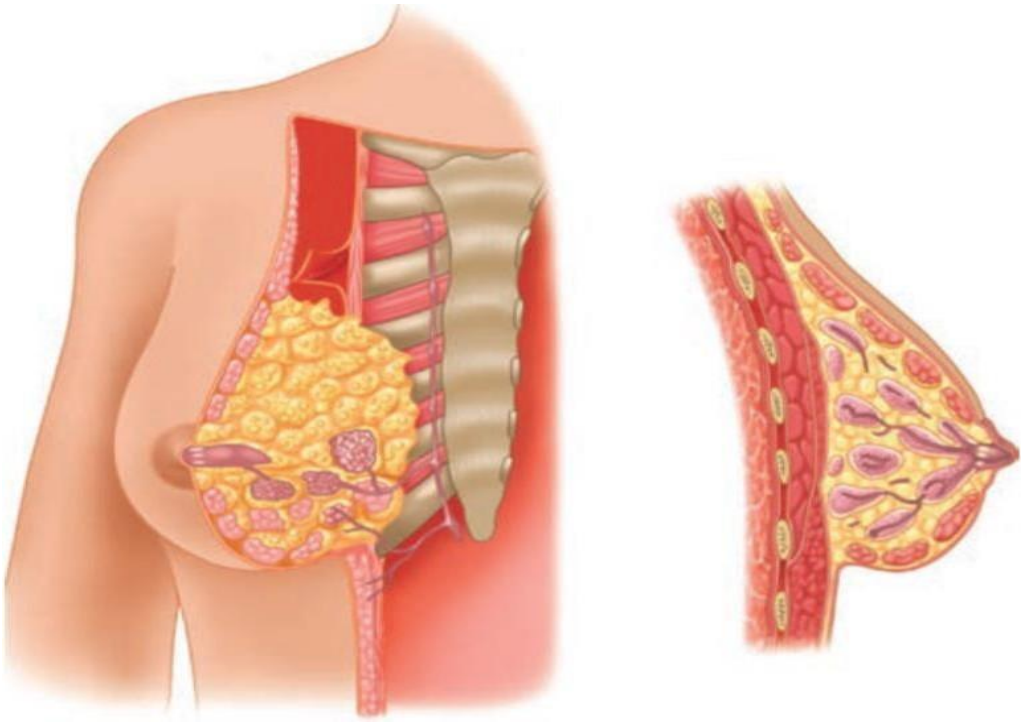

Figure 1: Anatomy of the breast. Tangential and cross sectional (sagittal) views of the breast and associated chest wall (Reproduced from Schwartz's Principles of Surgery, 11th ed., Chapter 17, p. 544)(9)

Breast consists of skin, subcutaneous tissue and breast tissue. Breast tissue is covered between superficial and deep fascia. Superficial fascia lies deep to the dermis and deep fascia lies anterior to the pectoralis major muscle. Suspensory ligaments of Cooper are fibrous bands that run through breast tissue and attach breast tissue to dermis.

Breast receives its blood supply from three major routes: Medial aspect of breast is supplied from branches of internal mammary artery. Lateral thoracic artery and Pectoral branches of Thoraco-acromial artery supply the upper and outer aspect of breast. Rest of breast tissue is supplied by branches of posterior intercostal arteries. This network provides most of the blood supply to the deeper tissue of the breast. The veins form an anastomotic circle around the nipple, then follow a similar path to that of the arteries.

Breast lymphatic drainage is mainly directed to lymph nodes in the axilla. Axillary lymph nodes are classified according to their position from pectoralis minor muscle.

Level I: Lateral to pectoralis minor

Level II: Anterior and posterior to pectoralis minor

Level III: Medial to pectoralis minor

The interlobular connective tissue and the lactiferous duct walls give rise to the breast lymphatic plexus, which connects to the subareolar lymphatic plexus. Afferent lymphatics leave the breast near the lateral edge of the pectoralis major muscle and enter the anterior, or "pectoral," group of lymph nodes, which is called the external mammary group. On their route there, they also pierce through the clavipectoral fascia.

The subscapular (posterior, scapular) group of lymph nodes is reached by a few lymphatic vessels. The subclavicular (apical) lymph nodes are directly accessible from the upper portion of the breast by a number of lymphatic vessels.

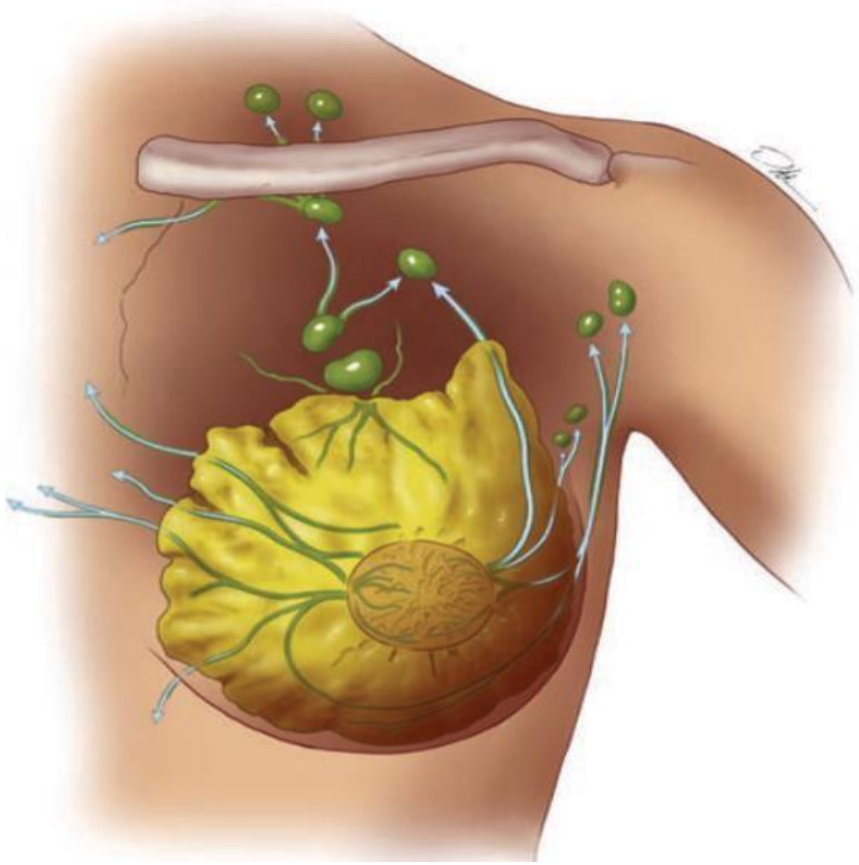

Figure 2 shows the lymphatic pathways in the breast. Arrows indicate the direction of lymph flow. (Reproduced from Schwartz's Principles of Surgery, 11th ed., Chapter 17, p. 546)(9)

Breast cancer is the most commonly diagnosed cancer in the female population around the world and is the most leading cause of cancer related deaths in females. A total of 13.5% of cancer cases and 10.6% of deaths are caused by breast cancer in India.(10)

Surgery remains the mainstay treatment of Breast cancer along with Chemoradiotherapy. Modified radical Mastectomy has been the gold standard treatment for Breast cancer. In this procedure, the breast is en bloc resected, including the nipple-areola complex, the axillary lymphatics, and the overlying skin.(11,12)

Seroma formation is a common complication after mastectomy and the reported incidence of Seroma formation can range from 3% to 85%.(13)

Seroma is defined as clinically significant collection of serous fluid in Axillary dead space or under skin flaps following mastectomy or axillary dissection.(14)

Pathophysiology of seroma formation:

Seroma formation after breast surgery has been attributed to various factors. These factors can be broadly categorised as:(15)

1. Anatomical factors: Extensive dissection during breast cancer surgery creates a potential dead space which allows tissue fluid to accumulate by beneath skin flaps. This fluid prevents skin flaps to adhere from underlying surface and prevents restoration of integrity of tissue planes.
2. Nature of Seroma fluid: Various causes of seroma formation have been proposed based on the nature of fluid collection. Leakage from transected axillary lymphatic trunks is believed to be the cause of collection of lymph like fluid. Acute inflammatory reactions can also lead to collection of reactionary fluid under the skin flap.

Seroma can be graded as:(16)

Grade 1: Asymptomatic, no intervention indicated

Grade 2: Symptomatic, requires simple aspiration

Grade 3: Symptomatic, requires interventional radiology or operative intervention

Seroma formation also leads to other postoperative complications: delayed wound healing, increased postoperative pain, surgical site infection etc. All these can lead to increased postoperative stay and delay in start of adjuvant treatment.(17)

Various techniques have been described for prevention of seroma formation after mastectomy. Most of these techniques aim for obliteration of residual dead space.(18,19,20)

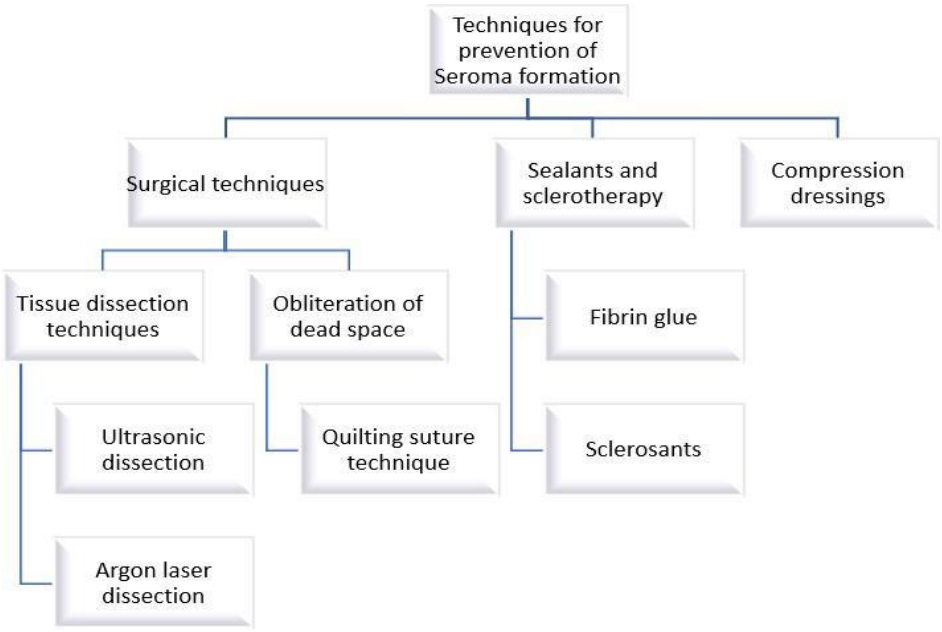

Figure 3: Various described techniques to reduce postoperative seroma

Prolonged duration of negative suction drainage has been used to reduce postoperative seroma.(21). However, presence of surgical drainage and for prolonged time duration increases risk for SSI and related complications.(22) Quilting has been described as fixation of skin flap to pectoralis muscles and thus achieving closure of dead space to reduce seroma.

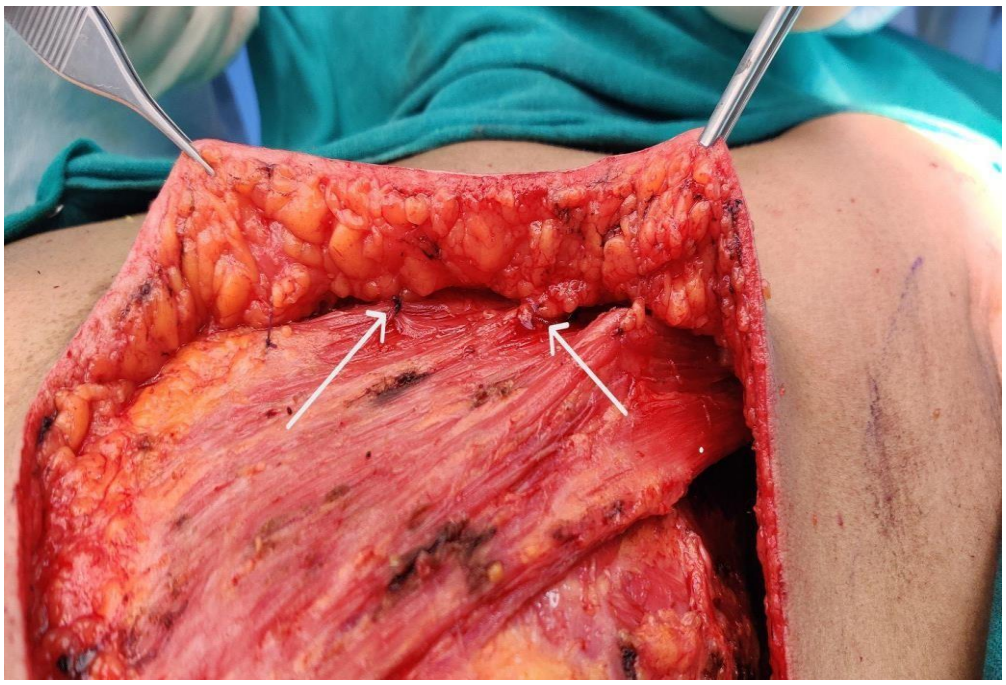

Figure 4: Quilting suture technique for fixation of skin flap with pectoralis muscle. (Arrows indicate quilting sutures)

Y. Gong et al (2010) performed a randomised controlled trial on a total 201 patients in two groups. A total of 101 underwent axillary lymphatic vessel ligation and skin flap fixation with underlying muscle and 100 patients underwent mastectomy using conventional technique. They concluded that incidence of seroma formation in quilting group was significantly less than conventional flap closure group($P<0.01$) and the drainage volume in initial 3 days and duration of drainage in Quilting group was significantly lower as compared to Conventional group.(23)

In a retrospective analysis, B. ten Wolde et al. (2013) compared quilting (fixation of the skin flap to the underlying muscles) with the conventional group (n=87) on a total of 176 patients. They came to the conclusion that seroma incidence reduced from 80.5% to 22.5% (p 0.01). The mean number of aspirations reduced from 4.86 to 2.40, and the volume reduced from 1660 ml to 611 ml (p=0.05).).(24)

In a prospective feasibility research, Chafika Mazouni et al. (2015) compared seroma development between patients undergoing mastectomy with or without axillary lymphadenopathy (n=41) and patients receiving mastectomy with or without quilting. The quilting group's mean drainage volume on days 1 and 2 was found to be considerably lower than that of the control group. The quilting group's mean drainage period was shorter. The two groups' median aspirations did not differ considerably from one another.(25)

Sakkary et al (2012) did a randomised controlled study on 40 patients with breast carcinoma who underwent MRM. They made two groups of 20 patients each comparing flap fixation with sutures and conventional closure methods. They concluded that flap fixation resulted in significantly decreased frequency of seroma formation, decreased total drainage volume and resulted in early drain removal.(16)

Najeeb et al (2019) did a randomised study to compare 2 groups where 35 patients underwent flap fixation to obliterate dead space and 35 patients in other group underwent closure without flap fixation. Total of 5 patients out of 70 developed seroma and incidence of seroma formation between two groups was not statistically significant (p=0.643).(26)

A retrospective observational study by L. Ouldamer et al. (2015) compared two groups—the quilted suture group (n=59) and the standard closure group (n=60). They came to the conclusion that the quilting group had a significantly lower overall incidence of seroma formation and a significantly lower VAS pain level at days 15 to 21.(27)

In a comparative randomised controlled trial on a total of 161 patients, Kottayasamy Seenivasagam et al. (2013) compared the effectiveness of compression dressing (n = 53), flap fixation (n = 49), and traditional method of closure (n = 48) in preventing seroma formation. Additionally, patients were randomly divided into two subgroups with 75 patients each: standard drain removal and early drain removal. Suture flap fixation considerably decreased seroma formation, drainage duration, and total drain output, while compression dressing decreased drainage length but did not significantly decrease seroma formation, the researchers found. Early drain removal (on POD 7) had no statistically significant influence on seroma development..(28)

Van Zeelst et al. (2021) performed a combined prospective and retrospective study over 254 patients who underwent mastectomy with or without ALND comparing quilting and conventional closure methods. They concluded that quilting significantly reduced seroma formation as compared to conventional group(12.9% vs 62.3%).(29)

In a randomised controlled study, Yilmaz et al. (2021) compared quilting suture (n = 52) and conventional technique (n = 53) for closure following mastectomy on a total of 105 patients. They concluded that there was no significant disparity in seroma formation rates between the two groups.. The amount of time needed to remove the drain, the length of the hospital stay, and the number of aspirations were not significantly different.(8)

A systematic review of studies that examined methods for preventing seroma formation was conducted by Jeffrey E. Janis et al. in 2016. They included 75 papers, including 7173 people in prospective non-randomized comparative studies and prospective randomised controlled trials. 11 studies examined the use of progressive tension or quilting sutures on a total of 793 patients. They came to the conclusion that the application of quilting sutures and progressive tension sutures significantly reduced seroma formation.(30)

Huang et al (2021) did a retrospective comparative study on 388 patients comparing the role of quilting sutures and conventional closure with prolonged drainage time with conventional closure in reduction of seroma formation . They concluded that overall difference in incidence of seroma formation was not statistically significant.(31)

In order to find out whether quilting sutures are effective at preventing seroma formation and reducing the volume and length of drainage, T. Eliav et al. (2021) performed a meta-analysis involving 11 randomised controlled studies with 2009 patients. They evaluated relative risk

across 11 studies and came to the conclusion that quilting had a statistically significant impact on the number of seroma. Although the overall amount of drainage did not considerably decrease, quilting did lessen the duration of drainage.(32)

A meta-analysis of 12 trials comprising 1887 patients was conducted by Velotti et al. in 2021 to examine the function of flap fixation in the prevention of seroma and SSI. Six of the papers that were included were retrospective, two were prospective, and four were RCTs. They came to the conclusion that while there was no difference in the incidence of SSI, there was a statistically significant difference in seroma formation between groups. (33)

AIMS AND OBJECTIVES

AIM:

To compare incidence of seroma and other postoperative complications in modified radical mastectomy for breast cancer with quilting sutures vs conventional closure

OBJECTIVES:

Primary objective:

- To compare frequency of postoperative seroma formation in quilting suture vs Conventional closure for modified radical mastectomy

Secondary objective:

- To compare the drain output between two groups
- To compare the incidence of postoperative complications like SSI, flap necrosis, wound dehiscence and other complications
- To compare the number of additional procedures like aspirations or revise drain insertion and revision surgeries required postoperatively

MATERIALS AND METHODS

STUDY SETTING:

This study was conducted in patients undergoing modified radical mastectomy (MRM) in All India Institute of Medical Sciences, Jodhpur.

STUDY DESIGN:

Randomised controlled trial.

STUDY PARTICIPANTS:

1. Inclusion criteria-

- All female patients with the diagnosis of breast cancer planned for Modified Radical Mastectomy (MRM) in the Department of General Surgery and Department of Surgical Oncology at All India Institute of Medical Sciences, Jodhpur.

2. Exclusion criteria-

- Patients planned for breast reconstructive surgery
- Patients on chemotherapy for non-breast malignancy
- Patient who refused to give consent for the study

SAMPLE SIZE:

Sample size is calculated according to the results obtained by Seenivasagam et al in his study in which incidence of seroma formation was 35.4% in the conventional suture group and incidence of seroma in group with flap fixation with quilting suture was 8.2%.(28) With the help of Epi-info sample size estimation software, after using the values of incidence, we estimate a sample size of 36 patients per group according to Kelsey method at 95% confidence interval, 80% power., with α of 0.05 and $P<0.001$.

STUDY DURATION:

Two years from Jan 2021 to Dec 2022.

STUDY PROCEDURE:

All Patients were admitted in the Department of General Surgery and Surgical Oncology. Basic preoperative 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. 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. Group A patients underwent mastectomy with quilting suture technique and Group B underwent mastectomy with conventional technique. Post-operatively patients were assessed for seroma formation by clinical assessment. Drain volume from both groups were noted on POD 1, 2, 3, 7, 10 or at the time of drain removal. Total drain output from day of surgery till 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, 30 or earlier if required, either telephonically or physically in OPD. Axillary drain was removed on post operative day 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 postoperatively 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 upto 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 raised. Breast tissue dissected off from the pectoral muscle using electrocautery. When lateral border of breast reached, pectoral muscle was gently retracted medically and clavipectoral 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. Subcutaneous layer was closed with interrupted vicryl sutures. Skin was closed with interrupted nylon sutures.

QUILTING SUTURE TECHNIQUE:

A transverse or oblique elliptical incision made over the breast. Incision extended laterally upto 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 raised. Breast tissue dissected off the muscle using electrocautery. When lateral border of breast reached, pectoral muscle was gently retracted medically and clavipectoral 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. Before closure of flaps, quilting was done where skin flaps were sutured to underlying muscle with multiple parallel rows of interrupted vicryl sutures size 3-0 placed at periodic intervals (1-2cm) in both axillary and pectoral regions. Subcutaneous layer was closed with interrupted vicryl sutures. Skin was closed with interrupted nylon sutures.

STATISTICAL ANALYSIS:

The Statistical Package for Social Sciences (SPSS) version(25.0) was used to enter and analyse 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 The U test is used to compare numerical data that does not follow a normal distribution. For categorical data, you 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 analysed.

RESULTS

A total of 72 patients were included in the study and underwent Modified Radical Mastectomy during the study period of 2 yrs from January 2021 to December 2022. These patients were then randomised to Group A and Group B in the ratio of 1:1 as described in the consort flow diagram (Fig. 5).

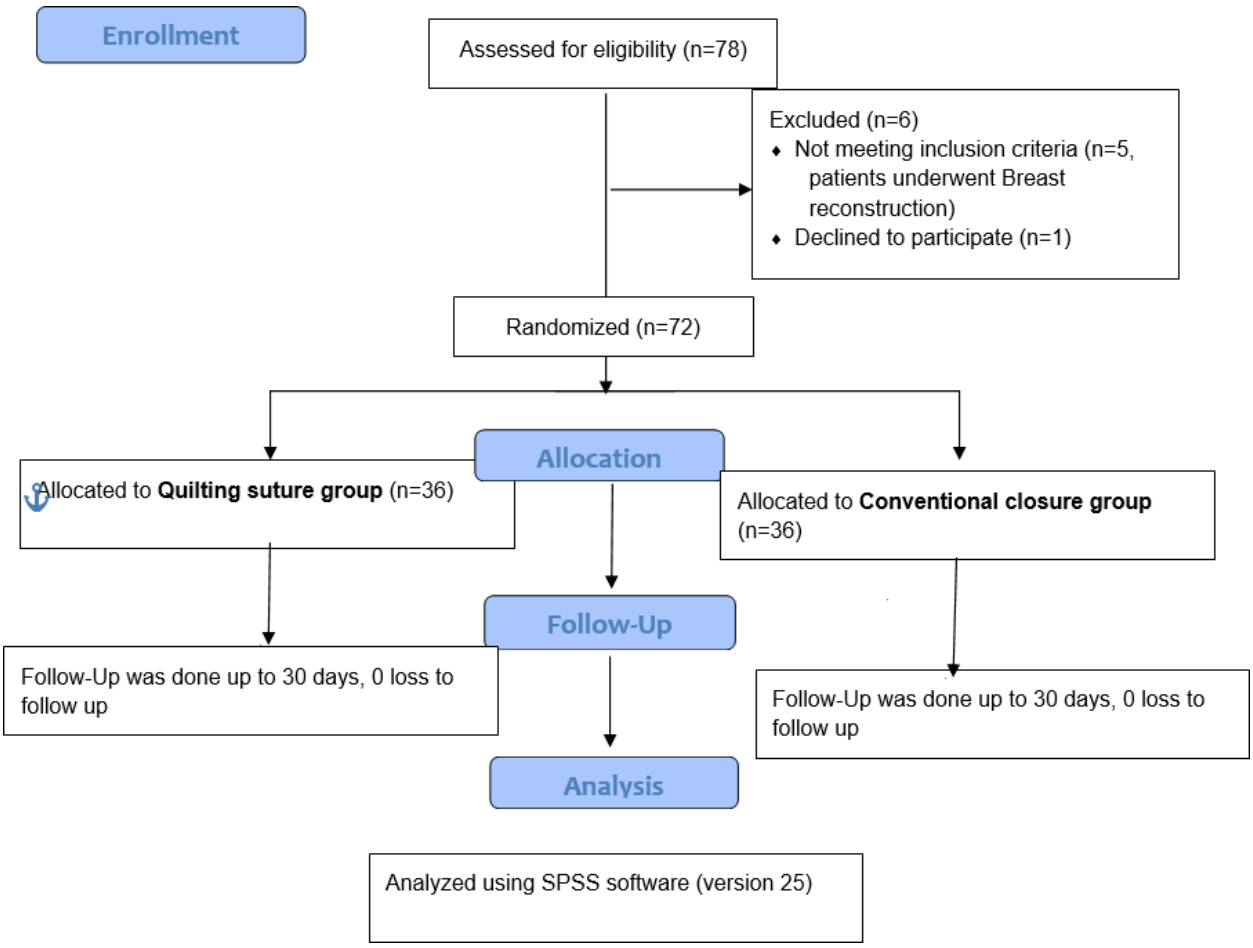

Figure 5: CONSORT diagram

Patients and Group characteristics:

The two groups were similar with respect to the baseline characteristics. Baseline characteristics are compared in Table 1.

Table 1: Comparison of baseline characteristics between the groups.

Baseline characteristics of the group			
Variable	**Group A (n=36)**	**Group B (n=36)**	**P-value**
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,%)	19(52.7)	23(63.1)	0.339
ER	18(50)	20(55.5)	0.637
PR	14(59.1)	13(36.1)	0.309
HER-2	5(13.8)	5	1.00
Triple Negative, n(%)			
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-value >0.05 for all the above variables

The outcomes are summarised in table 2 and 3 given below.

Table 2: Comparison of outcome and a test of significance.

Comparison of postoperative outcome variables				
Variable		**Group A (n=36)**	**Group B (n=36)**	***P-value**
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

Table 3: Comparison of complications and a test of significance.

Comparison of other postoperative complications variables			
Variables	**Group A (n=36)**	**Group B (n=36)**	***P-value**
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

Comparison of other postoperative complications variables			
Variables	**Group A (n=36)**	**Group B (n=36)**	***P-value**
****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** **Grade 2** **Grade 3a** **Grade 3b**	 10(27.7) 0 3(8.3) 0	 6916.6) 0 3(8.3) 1(2.7)	 0.257 - 1.0 0.314

*p-value is calculated using chi square test

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

Primary outcome:

The incidence of seroma formation between Group A (Quilting) and Group B (Conventional) did not differ significantly. Two patients in Group A and 5 patients in Group B developed seroma postoperatively. The data was analysed using Chi square test and the result is found to be non significant (p value=0.233, CI=95%).

Secondary outcomes:

1) Drain Output:

Total drainage volume (Mean) for Group A and Group B is 687.5(IQR=532.5-930.0) and 782.5(IQR=611.2-1045.0) respectively and the data was analyzed using an independent sample t-test and showed no significant difference between two groups (p value=0.213).

Similarly, mean daily drain output for Group A and Group B at POD 1: 119.0(SD=36.6) and 129.5(SD=34.2){p=0.211, CI=95%}, at POD 2: 96.6(SD=29.4) and 110.8(SD=31.4) {p=0.051,CI=95%},at POD3: 79.4(SD=24.4) and 89.5(SD=30.6){p=0.127,CI=95%}, at POD 7: 51.9(SD=19.3) and 54.7(SD=15.9){p=0.511,CI=95%}, at POD 10: 38.3(SD=11.0) and 39.6(SD=12.9){p=0.682, CI=95%), at POD 14: 34.0(SD=8.5) and 36.4(SD=9.1){p=0.526, CI=95%), respectively.

Mean of total duration of drainage for Group A and Group B 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%).

2) Postoperative complications:

Two patients in Group A developed postoperative SSI and one of these patients developed wound dehiscence. In Group B, 2 patients developed SSI which was managed with antibiotics and resulted in prolonged postoperative hospital stay. In group B, 1 patient developed skin flap necrosis for which the patient underwent debridement and Skin grafting. Postoperative complications were graded using Clavien Dindo score. In group A, 9 patients had Clavien Dindo grade 1 and 3 patients had grade 3a complication. In group B, 6 patients had Clavien Dindo grade 1 complication and 3 patients had grade 3a complications. In group B, 1 patient developed flap necrosis for which she underwent skin grafting over raw area under general anaesthesia and the patient was classified as Grade 3b complication. The data was compared using Chi square test and there is no significant increase in complications with use of quilting suture technique(p value=0.641).

3) Additional procedures or surgery:

Mean number of aspirations for postoperative seroma in Group A is 2(SD=1.4) and in Group B is 1.67(SD=0.5){p value=0.724}. Mean volume of seroma aspiration in Group A is 142.5(SD=152.0) and Group B is 51.7(SD=28.4). One patient in Group B required reinsertion of drain for drainage of seroma.

In Group A, 1 patient developed wound dehiscence due to SSI for which she underwent Debridement under local anaesthesia. In Group B, 1 patient developed flap necrosis for which she underwent debridement followed by skin grafting under general anaesthesia.

DISCUSSION

Seroma formation is associated with increased hospital visit, comorbidity and increased burden on health care. Our study aimed to measure the role of quilting sutures for the prevention of seroma formation and 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 our randomised controlled trial, the result did not reach statistical significance. In a randomised controlled trial, Sakkary et al. (2012) found that the quilting technique significantly reduced overall seroma formation after MRM and reduced total drainage volume. (16) In a related study, B. ten Wolde et al (2013) found that the use of quilting sutures significantly reduced the formation of seromas. (24) However, quilting did not significantly reduce seroma formation in the study done by Najeeb et al. (2019). (26) Yilmaz et al. (2021) also found that quilting had no discernible effect on seroma formation.(8)

There was no significant decrease in total drain output and daily drain output between quilting and conventional groups. Chafika Mazouni et al (2015) compared the role of quilting suture and concluded that quilting resulted in a significant decrease in mean daily drain output on Post operative day 1 and 2.(20) However, Myint et al (2020) performed a randomised comparative study and concluded that quilting resulted in significant decrease in incidence of seroma but total amount of drain output and duration of drainage was not different.(29)

Mean number of seroma aspirations was also not statistically different between two groups for our study which was comparable with the result Chafika Mazouni et al (2015) had concluded in their study.(25) B. ten Wolde et al (2013) 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.(24)

Our study showed that quilting did not result in significant increase in incidence of postoperative SSI between two groups, and the overall incidence of SSI was also less in our study. Myint et al (2020) et al in their study had comparable results for incidence of SSI. Velotti et al (2021)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.(34) L Ouldamer et al (2015) concluded in their study that quilting was beneficial with reduction in Surgical site infections.(27)

Overall postoperative complications in our 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 our study showed a decrease in seroma formation and a decrease in postoperative drain volume, the results are not statistically significant. In our study weight of breast tissue was not measured which could act as a confounding factor.

Quilting technique increases the overall operative duration as Myint et al (2020) had concluded in their study.(34) In our study also duration of surgery had prolonged, however the difference was not statistically significant. As such this technique could not be recommended yet, hence further studies on larger sample sizes with or without adjuncts will be required to define the role of this technique.

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 total drainage volume. Longer duration of drain is still a preferred method for decreasing risk of seroma formation. Although the incidence of SSI may increase with external drain. There is no standard cut-off value of drain volume before removal of drain, however most of the surgeons preferred drain removal between 20-50 ml of drainage volume. Further comparative studies should be done on larger sample sizes and with or without adjuncts to define the exact role of this technique.

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ANNEXURES

ANNEXURE I

Institutional Ethical Clearance Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/3561 **Date: 12/03/2021**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3396**

Project title: **"Quilting suture vs conventional closure in prevention of seroma formation after modified radical mastectomy for breast cancer: A randomised controlled trial"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.S. Dissertation**
Student Name:	**Dr.Sumit Bishnoi**
Guide:	**Dr. Satya Prakash Meena**
Co-Guide:	**Dr. Jeewan Ram Vishnoi, Dr. Ashok Puranik & Dr. Naveen Sharma**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE II

INFORMED CONSENT FORM

Title of Thesis/Dissertation :

QUILTING SUTURE VS CONVENTIONAL CLOSURE IN PREVENTION OF SEROMA FORMATION AFTER MODIFIED RADICAL MASTECTOMY FOR BREAST CANCER: A RANDOMIZED CONTROLLED TRIAL

Name of PG Student **: DR SUMIT BISHNOI (Mobile No.:8890070029)**

Patient/Volunteer Identification No. :_____

I_____S/o or D/o _____

R/o_____give my full, free, voluntary consent to be a part of the study ―QUILTING SUTURE VS CONVENTIONAL CLOSURE IN PREVENTION OF SEROMA FORMATION AFTER MODIFIED RADICAL MASTECTOMY FOR BREAST CANCER: A RANDOMISED CONTROLLED TRIAL‖ procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and I am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records can be seen by the person responsible for the regulatory authorities.

Place:_____ Signature/Left thumb impression

This to prove that the above consent has been received in my presence.

Date: _____

Place: _____

Signature of PG Student

1. Witness 1

Signature_____

Name:_____

Address: _____

2. Witness 2

Signature_____

Name:_____

Address: _____

ANNEXURE III

ऑर इं डमा इंस्टीट्मूट ऑप भे डकर

साइंसेज जोधनुय, याजस्थान

थी सस / ननफंध का शीर्क : **"क्रिरटटग ननमंत्रित नयीं ण"**

सचय औय नायंनरयक एभ. अय. एभ. सजयी भें सीयोभा नय एक

नीजी छाि का नाभ: SUMIT BISHNOI

योगी / स्िमंसेिी नहचान संख्मा: _____

भ,ैं _____नुि/नुिी_____

ननिासी _____इस अध्ममन का टहस्सा फनने के रए नयू े सहभनत देता/देती हूं

"क्जसकी प्र िमा औय प्रकृ नत भुझे भेयी बार्ा भें भेयी संतुक्टट तक सभझा दी गई है।। भैं नुक्टट कयता हूं

क भुझे प्रश्न नछू ने का न ा अिसय भरा है, क्जनके जिाफ से भैं संतुटट बी हंू ।

भैं सभझता हूं क भेयी बागीदायी स्िैक्छछक है औय भुझे कसी बी कायण के त्रफना, कसी बी सभम अध्ममन से फाहय ननकरने का अ धकाय है।

भैं जानता हूं क भेये औय भेये कसी बी भे डकर रयकॉडष के फाये भें एकि की गई जानकायी को गुप्त् यखा जामेगा I

टदनांक : _____

स्थान: _____ हस्तां य / फाएं अंगठ े की छान

मह प्रभा णत कयने के रए क उन्नमुवत सहभनत भयी उन्नक्स्थनत भें प्राप्त की गई है।

नीजी छाि के हस्तां य: _____

टदनांक:_____

स्थान:_____

ANNEXURE IV

Patient Information Sheet- English

Title of Thesis/Dissertation: QUILTING SUTURE VS CONVENTIONAL CLOSURE IN PREVENTION OF SEROMA FORMATION AFTER MODIFIED RADICAL MASTECTOMY FOR BREAST CANCER: A RANDOMIZED CONTROLLED TRIAL

Name: Age/Gender:

Phone No:

Address:

AUTHORIZATION:

I feel free to accept or refuse to participate in this study. I have been informed that this study will be done by applying suture below skin flap during surgery. For which, I will be put into one of the two groups on random basis for the purpose of surgery, which will defer in respect to the suture applied or not. The consequences of being assigned in any of the two groups has been well informed to me some of which are infection, pain etc. These complications are common to both the groups and are due to procedure and not due to study. The purpose of the study is to compare seroma formation and other variables amongst the two groups. The duration of the study will be of 30 days during which I will be followed up in OPD or telephonically for 4 times to obtain information regarding the above-mentioned variables.

I have had a choice to ask questions and all of my questions were answered to my Satisfaction

I have been assured that the information obtained from me will solely be used for the purpose of the study and shall remain confidential.

By signing this form, I give my free and informed consent to take part in this study as outlined in the information sheet and this consent form. I understand that I am free to withdraw from the study at any given time. By signing up this form I have not given up my legal rights.

Hence, I hereby give my wilful consent for my inclusion in this study which is being conducted by the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur by Dr Sumit Bishnoi

In any case of queries, you may contact:

Dr Sumit Bishnoi

Academic Junior Resident, General Surgery

All India Institute of Medical Sciences, Jodhpur

Phone no. 8890070029

शीर्कष नाभ: : क्रिरटटग

ANNEXUREV Patient Information Sheet-Hindi

सचय औय ऩायंऩरयक एभ. आय. एभ. सजयी भें सीयोभा ऩय एक ननमंत्रित ऩयी ण

आमु / रगं

: फोन

नंफय:

ऩता:

भैं इस अध्ममन भें बाग अऩनी भजी भुतात्रफक रे यहा हूं।

भुझे सभझामा गमा है की इस अध्ममन भें सजयी के दौयान चभड़ी के नीचे सच

य का उन्नमोग होगा।

अध्ममन के रए दो सभह फनाए गए हैं क्जसभें सजयी के रए भुझे कसी दो भें से एक सभह भें यखा

जाएगा। दोनों सभुह भें सच य रगने औय नहीं रगने का पकष होगा। दोनों सभह के न्नरयणाभों के फाये भें

भुझे अछछे से सभझा टदमा गमा है। अध्ममन का उद्देश्म दोनों सभहों भें हुए ऑन्नयशने के फाद के फाद

सेयोभा फनने की तुरना कयना है। अध्ममन भें भुझे 30 टदन तक यखा जाएगा, क्जसभें 4 फाय भुझ ऑन्नयेशन संफं धत भुझसे जुड़ी जानकायी देने के रए ओ. न्नी. डी. फुरामा जाएगा।

भुझे अध्ममन औय सजयी से संफं धत प्रश्न न्न भुझे न्नयू ी संतुक्टट है। ने का न्न ा भौका टदमा गमा क्जनसे भरे जिाफ से

भुझे न्नूया आश्ि ासन टदरामा गमा है की भुझसे भरी जानकायी को के ि र औय के ि र अध्ममन के रए इस्तेभार कमा जाएगा, औय भुझसे भरी जानकायी को न्नूये तयीके से गोन्ननीम यखा जाएगा।

भुझे मह सभझामा गमा है औय भैं जानता हूं की भैं इस अध्ममन को अन्ननी इछछा भुतात्रफक कबी बी छोड़ सकता हूं।

इस रए, भैं इस अध्ममन के रए अन्ननी इछछा-सहभनत प्रदान कयता हूं, जो क जनयर सजयी ि बाग, आर इं डमा इंक्स्टट्मूट ऑफ भे डकर साइंसेज, जोधन्नुय द्ि ाया डॉ. सु भत त्रफश्नोई द्ि ाया की जा यही है।

जानकायी संफं धत कसी बी सिाय के रए

संन्नकष कयें: डॉ. सु भत त्रफश्नोई

अकाद भक जनू नमय येक्जडेंट, जनयर सजयी

आर इं डमा इंक्स्टट्मूट ऑफ भे डकर साइंसेज, जोधन्नुय

ANNEXURE VI

Patient Proforma

Title of Thesis/Dissertation:

QUILTING SUTURE VS CONVENTIONAL CLOSURE IN PREVENTION OF SEROMA FORMATION AFTER MODIFIED RADICAL MASTECTOMY FOR BREAST CANCER: A RANDOMIZED CONTROLLED TRIAL

Group - A/B

Demographic details-

Name-

Age/Sex-

Residence -

Patient ID-

DOA- _ _/_ _/_ _ DOS_ _/_ _/_ _ DOD-_ _/_ _/_

Preoperative diagnosis:

Comorbidities (Diabetes/ HTN/ TB/ Connective tissue disorders)

Pre operative investigations:

Hb: TLC: Plt:

Creatinine:

Albumin:

Neo adjuvant therapy given

(Yes/No) Drain Output:

POD 1	POD 2	POD 3	POD 7	POD 10	POD 14	POD 21	POD 30	Total drain output

Date of pectoral drain removal:

Date of axillary drain removal:

Postoperative hospital stay:

	POD 1	POD2	POD3
Drain output			
Flap necrosis/ Dehiscence			
SSI			
Hematoma			

Follow up visits:

	First visit(day)	Second visit(day)	Third visit(day)	Fourth visit(day)	Last visit (day)
Drain output					
Flap necrosis					
SSI					
Seroma					
Hematoma					
Abscess					
Aspiration					
Insertion of drain					
Debridement f/b sec. closure					
Skin graft					
Drain removal day					

Clavien Dindo grade:

ANNEXURE VII

Key To Master Chart

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Complications	**1**	**DM**
	2	**HTN**
	3	**CAD**
	4	**Thyroid disorder (Hypo/Hyper)**
T stage	**1**	**T1**
	2	**T2**
	3	**T3**
	4	**T4a**
	5	**T4b**
	6	**T4c**
	7	**T4d**
N stage	**1**	**N1**
	2	**N2a**
	3	**N2b**
	4	**N3a**
	5	**N3b**

	6	**N3c**
	0	**N0**
STAGE	**1**	**Stage 1**
	2	**Stage 2a**
	3	**Stage 2b**
	4	**Stage 3a**
	5	**Stage 3b**
	6	**Stage 3c**
	7	**Stage 4**
Clavien Dindo Grade	**0**	**No complications**
	1	**Grade 1**
	2	**Grade 2**
	3	**Grade 3a**
	4	**Grade 3b**
	5	**Grade 4a**
	6	**Grade 4b**
	7	**Grade 5**

ANNEXURE VII

MASTER CHART