



Evaluation of Quilting Technique for Reduction of Post Mastectomy Seroma Formation - A Randomized Control Study

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Aim

To evaluate the quilting technique for reduction of the incidence of post mastectomy seroma formation.

Objectives

- To determine the incidence of post mastectomy seroma
- To measure the volume and duration of the drainage fluid
- To identify factors influencing seroma formation
- To evaluate the effectiveness of quilting of the mastectomy flap with obliteration of the axillary space in reducing post mastectomy seroma by comparing the amount of volume of discharge in both the quilting and conventional groups.

Introduction

Seroma is an accumulation of serous fluid that develops following the formation of skin flaps during mastectomy or in the axillary dead space in the immediate or acute postoperative period. Seroma is the most common complication after mastectomy and axillary lymph node dissection [1].

Many studies have been done in the past regarding pathophysiology and various treatment modalities of seroma. Pathogenesis of seroma is that it is due to acute inflammatory exudates in response to surgery and acute phase of healing. It is believed that the fibrinolytic activity contributes to seroma formation [2]. The most significant influencing factors in the causation of seroma were the number and extent of axillary lymph node involvement. However, the most significant factor influencing the incidence of seroma formation was the type of surgery. Extensive dissection in mastectomy and axillary lymphadenectomy damages several blood vessels and lymphatics and the subsequent oozing of blood and lymphatic fluid from a large surface area when compared with breast conserving surgery leads to seroma formation [3].

A number of techniques have been employed in an attempt to reduce or prevent seroma formation among mastectomy patients using both mechanical and chemical approach. Quilting is a simple surgical procedure that eliminates the anatomical dead space remaining after mastectomy. It involves placing interrupted absorbable sutures between the mastectomy flap and pectoral muscle prior to wound closure. It has been discussed in several studies assessing the technique at donor sites of autologous breast reconstruction [4]. Our study aims to evaluate the effect of surgical quilting after mastectomy in the prevention of postoperative seroma formation.

Review of Literature

Seroma formation being one of the most common and traumatizing complication for the patients, the need for the evidence-based intervention is essential. The reported incidence of seroma varies widely from 5% to 85% [5]. Increase in incidence of the disease and the wide spread availability of surgical intervention for the same, substantiates the need for preventing this post-operative complication. Seroma is an acute inflammatory exudate in response to a surgical trauma, via the activities of proteinases, cytokines and growth factors. To reduce this inflammatory response various surgical techniques have been employed. Moreover, it is cost effective than any other method [6].

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RCT study done in 2014 showed that quilting technique has significantly reduced the incidence in seroma formation in post mastectomy patients. The study concluded the need for further research to see the efficacy of quilting method in post mastectomy patients [4]. The efficacy of quilting technique in reduction of seroma in postoperative mastectomy was studied which stated that the mean volume of seroma, duration of complete cessation of seroma is significantly reduced with use of quilting technique. The use of quilting technique intraoperatively owed that there is reduction in volume of seroma than the control group and also reduces the risk of infection [7].

The seroma formation was assessed and its sequela in patients undergoing mastectomy and concluded that mastectomy followed by flap necrosis with either sutures or adhesive tissue glue reduces the number of seroma aspirations when compared to simple wound closure [8]. There was a significant reduction in seroma formation and fewer complications in patients treated with flap fixation compared to conventional wound closure [9].

A prospective randomized clinical trial was done to evaluate a new surgical technique of suturing flaps without wound drainage combined with early discharge in women undergoing surgery for breast cancer [10]. The various factors influencing seroma formation post MRM was studied which concluded the incidence of seroma is 22.5% that is 18 out of 80 developed seroma post-surgery. It also stated that increasing age and obese individuals had higher incidence of seroma. Early mobilization and physiotherapy help in seroma reduction [11].

Research Question

Is the use of mastectomy with quilting of flap and obliteration of the axillary space an efficient method to significantly reduce the postoperative seroma in addition to significantly reducing the duration and volume of wound drainage?

Subjects and Methods

This is a randomized controlled trial that will be conducted in Mahatma Gandhi Medical College and Hospital between January 2020 to October 2021. After obtaining ethical committee approval, patients who are posted for total mastectomy with axillary dissection during this period will form the study population.

Available literature shows that the incidence of seroma postoperatively in carcinoma breast patients can be as high as 85%. To find out a 30% reduction in proportion of carcinoma breast patients developing seroma postoperatively at a confidence level of 95% and power of 80%, we got a sample size of 19 in each group.

The formula used is as follows:

$$N = \frac{2(z_{\alpha/2} + z_{\beta})^2}{\ddot{a}^2}$$

where $z_{\alpha/2}=1.96$ at 95% confidence level and $z_{\beta}=0.84$ for a power of 80%

$$\ddot{a} = \text{effect size} = \frac{p_1 - p_2}{\sqrt{p(1-p)}}$$

where $p_1=0.85$, $p_2=0.55$ and $p=(p_1 + p_2)/2$

Substituting the values in the formula we get a sample size of 19 in each group. Considering an attrition rate of 10% our final sample size will be 21 in each group.

Inclusion criteria

- All patients more than 18 years of age who undergo total mastectomy with axillary dissection for carcinoma breast and willing to give written consent to participate during the period of January 2020 to June 2021.

Exclusion criteria

- Patients who have in operable breast cancer,
- Prior history of breast surgery,
- Collagen vascular diseases,
- Bleeding disorders and
- Inflammatory carcinoma of breast.

After approval by the Institute Ethics Committee, patients fulfilling inclusion criteria will be enrolled in the study by convenient/ sequential method.

Patients will be divided into two groups: Group A (Quilting method), Group B (Conventional method) by computer generated block randomization with concealment of allocation. The primary investigator will generate the random allocation sequence, enroll the participants and assign them to interventions. Patient's demographic data will be recorded. A detailed history and clinical examination will be done and necessary investigations (mammography, ultrasonography and true cut biopsy) will be done followed by staging and risk stratification and all the data will be entered in the pro forma.

The term seroma will be used when the drain volume obtained is more than 30 ml. In the study group, after the breast tissue along with the tumor has been excised, the mastectomy flap will be approximated with the help of quilting sutures using polyglactin 2-0 to the underlying pectoral fascia and muscle. Multiple alternating quilting sutures will be placed 2 cm to 3 cm apart between the subcutaneous layer of the flap and the underlying pectoral fascia/muscle at various parts of the flap, at the wound edges and the axilla. The axilla will be obliterated by suturing its lateral wall to the fascia of the serratus anterior and medial axillary wall. In the control group, after the breast tissue along with the tumour will be excised out, the flaps will be approximated by conventional method at the edges. Closed suction drains will be placed under the lower flap and axilla in both the groups. Patient's tumour characteristics and the operative related factors will be documented. Postoperative management will be done as per department protocol including early mobilization and physiotherapy.

The volume and color of the drained fluid will be documented. The drain will be removed when the volume of the collected fluid becomes <30 ml in 24 h in both groups.

Local examination will be done over the flap and axilla 2 weeks after drain removal will be supported in doubtful cases by local chest wall USG to exclude or confirm the presence of seroma/collection. The total volume of drained fluid and seroma formation will be documented. Mann Whitney test will be used to compare both the study groups.

Consort chart for sequence of events

See Figure 1.

Study termination

The study will be terminated in the month of October 2021 once

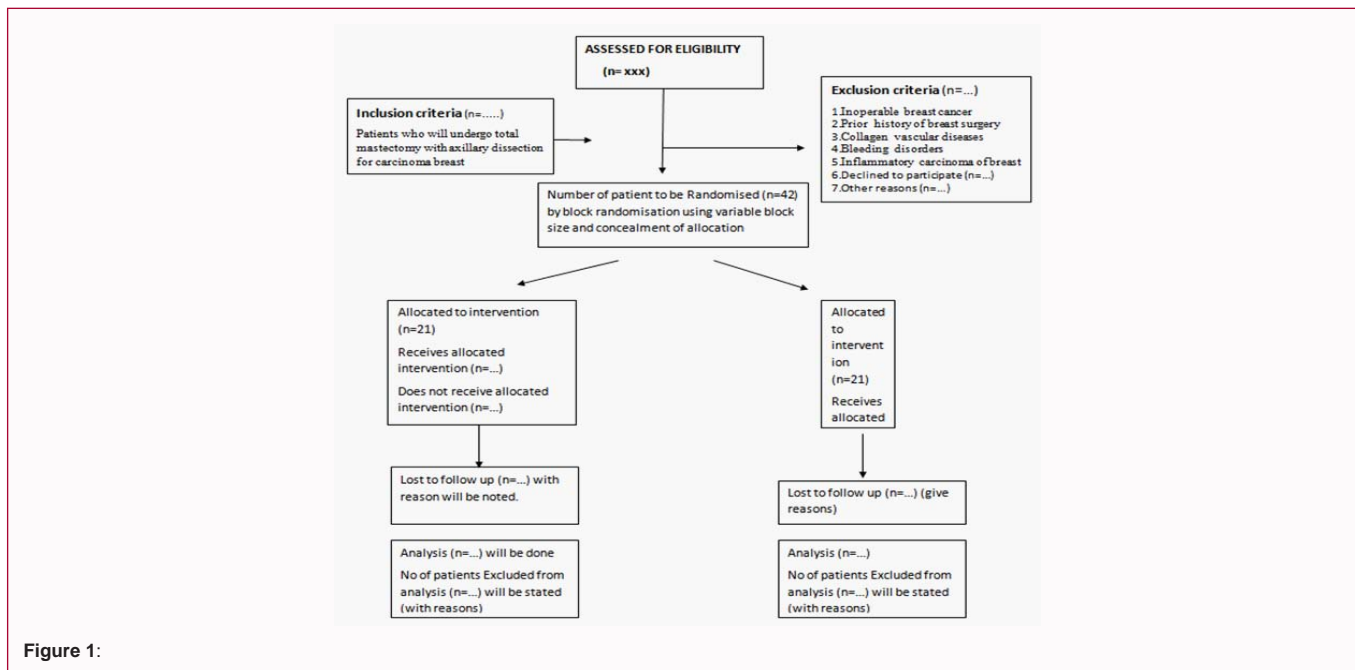


Figure 1:

Table 1:

S. No	Variable	Type of Variable	Statistics Used	Day 3	Day 5	Day 7
1	Proportion of Patients Developing Seroma	Qualitative	Chi Square Test			
2	Volume of Drain Output	Quantitative	ANOVA			
3	Time of Drain Removal	Quantitative	Unpaired T Test			
4	Wound Infection Rate	Qualitative	Chi Square Test			

the sample size is achieved.

Study variables

Variables measured during study:

- I. Seroma incidence
- II. Volume of drain output
- III. Nature of the drainage fluid
- IV. Time of removal of drain
- V. Wound infection.

Mention the demographic and other independent variables likely to influence seroma formation.

Co varieties (Table 1)

- Age
- BMI
- Tumour location
- Tumour size
- Tumour grade
- Type of surgery
- Axillary LN status
- HPE
- Mobilization
- Physiotherapy

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