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To Study the Outcome of Dead Space Closure Utilizing Quilting Suture Versus Conventional Closure with Drainage for The Prevention of Seroma After Mastectomy for Breast Cancer

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ABSTRACT

Background: Postoperative seroma is a common complication after mastectomy with a highly variable cited incidence of 3% to more than 90%. Complications of seroma vary from delayed wound healing, repeated seroma aspirations with the risk of infection, prolonged hospital stay, skin flap necrosis, patient discomfort, repeated visits to the out-patient clinic, delay in commencing adjuvant therapies and higher surgical expenditures. Closing the dead space after mastectomy can be achieved by closed suction drainage, quilting of the skin flaps or application of adhesive tissue glues to the skin flaps before wound closure. There is however no consensus on which technique is most superior and their sequelae. Quilting suture consists in suturing the skin flaps to the underlying musculature to reduce 'dead space'. The primary objective of this RCT is to assess the effect of flap fixation using sutures on the number of seroma aspirations after mastectomy for breast cancer in the first year following surgery. Secondary objectives include assessment of the number of out-patient clinic visits, infection rate, cosmesis and shoulder movement. Methods: This study was conducted in the department of General surgery, IGIMS, Patna, from to, on patients diagnosed with carcinoma breast undergoing mastectomy. They were randomised into 'Quilting' and 'Conventional' group by systematic random method. Subsequently the patients underwent mastectomy (simple/ modified radical) with or without axillary dissection. Quilting of the subcutaneous tissue to the pectoralis muscle was done with the help of several parallel rows of continuous running sutures with 2-0 vicryl sutures in the 'Quilting' cohort. A close suction drain was placed in the cavity. If axillary dissection was done, a separate drain was placed. In the 'Conventional' group, the patients underwent mastectomy (simple/ modified radical) with or without axillary dissection with drain placement in axilla and beneath the flaps separately but without quilting. The wound was closed in 2 layers with vicryl 2-0 and skin staplers. 24-hour drain volume was recorded daily and drains was removed once drain volume was less than 40 mL over 24 h for 3 consecutive days, regardless of time elapsed after surgery or at 5 days following surgery. Result: The study enrolled a total of 229 patients after excluding 35 patients that did not meet the exclusion criteria and 15 patients were lost to follow up. 111 patients belonged to 'Quilting' cohort and 118 to the 'Conventional' group. The mean operative duration observed in the 'Quilting' was significantly higher than the Conventional group (p value-0.0274). The mean total drain content noted during the post-operative hospital stay in the 'Quilting' group was significantly lower (p value= 0.019). A significant higher mean frequency of aspirations was performed in the 'Conventional' group ($p<0.001$). The total number of visits were higher in the 'Conventional' group (p value=0.037). The infection rates consistent with the wound erythema and the need for surgical drainage evaluated in the two cohorts were not significant (p value: 0.190). The rates of wound dehiscence were significantly lower in the 'Quilting' cohort (p= 0.035). The range of arm abduction was non-significant with a p value of 0.106. The 'Quilting' cohort had a significantly better wound cosmesis than the 'Conventional' cohort (p value- 0.029). Conclusion: We conclude that 'Quilting' integrated in the wound closure helps in seroma reduction in the patients undergoing mastectomy in breast cancer patients. The incidence of seroma was significantly lower in the 'Quilting' group thus reducing the patients' discomfort and the cost of the treatment. The mean total drain output, the frequency of hospital visits and aspirations were also lower. 'Quilting' was also associated with lower rates of wound dehiscence thus giving better cosmesis than the 'Conventional' patients. However, the mean total postoperative stay and infection rates were similar in both the groups.

1. INTRODUCTION

Breast cancer is the most common cancer worldwide and mastectomy is a commonly performed surgery. Postoperative seroma is a common complication after mastectomy with a highly variable cited incidence of 3% to more than 90%. Complications of seroma vary from delayed wound healing, repeated seroma aspirations with the risk of infection, prolonged hospital stay, skin flap necrosis, patient discomfort, repeated visits to the out-patient clinic, delay in commencing adjuvant therapies and higher surgical expenditures. The pathophysiology of seroma formation still remains a mystery with no defined answer. Several factors have been suggested and investigated for seroma formation, such as the use of electrocautery, extensive dissection in breast surgery and the extent of axillary lymph node involvement. Many publications have focused on the surgical prevention of seroma formation following mastectomy and/or axillary clearance. The success of all these interventions seems to have common ground, which is, reduction of the dead space. Closing the dead space after mastectomy can be achieved by closed suction drainage, quilting of the skin flaps or application of adhesive tissue glues to the skin flaps before wound closure (1). There is however no consensus on which technique is most superior and their sequelae. Several retrospective studies have shown that diminishing the dead space by means of flap anchoring can be very beneficial (2–4). A review published by Van Bastelaar et al. concluded that mechanical flap fixation seems to reduce seroma formation and seroma aspiration after mastectomy with or without axillary clearance. Some recent evidence suggests that quilting suture reduces the incidence of seroma [5] Quilting suture consists in suturing the skin flaps to the underlying musculature to reduce 'dead space'. The primary objective of this RCT is to assess the effect of flap fixation using sutures on the number of seroma aspirations after mastectomy for breast cancer in the first year following surgery. Secondary objectives include assessment of the number of out-patient clinic visits, infection rate, cosmesis and shoulder movement.

2. MATERIALS AND METHODS:

Patient consenting and meeting the inclusion criteria were recruited for the study.

Inclusion criteria-1. patients suffering from invasive breast cancer or DCIS with indication for mastectomy with or without sentinel lymph node biopsy or modified radical mastectomy, 2. female sex,3. age 18 years to <70 years.

Exclusion criteria:1. patients undergoing breast conserving therapy, 2. patients undergoing direct breast reconstruction, 3. non-consenting patients.

Patients diagnosed with Carcinoma breast, unilateral or bilateral, histopathologically or radiologically were admitted to the department of general surgery, IGIMS, Patna. They were randomised into 'Quilting' and 'Conventional' group by systematic random method. Subsequently the patients underwent mastectomy (simple/ modified radical) with or without axillary dissection. Quilting of the subcutaneous tissue to the pectoralis muscle was done with the help of several parallel rows of continuous running sutures with 2-0 vicryl sutures in the 'Quilting' cohort. The sutures were roughly placed at 2-3 cm apart, starting from the upper and innermost corner of the flap to lowermost and outermost corner of the flap. A close suction drain was placed in the cavity. If axillary dissection was done, a separate drain was placed. In the 'Conventional' group, the patients underwent mastectomy (simple/ modified radical) with or without axillary dissection with drain placement in axilla and beneath the flaps separately but without quilting. The wound was closed in 2 layers with vicryl 2-0 and skin staplers. 24-hour drain volume was recorded daily and drains was removed once drain volume was less than 40 mL over 24 h for 3 consecutive days, regardless of time elapsed after surgery or at 5 days following surgery. Early limb physiotherapy was initiated.

Following discharge, the patients were periodically evaluated on the outpatient basis at 2 weeks, 6 weeks, 3 months, 6 months and 12 months postoperatively.

The primary outcome of the study was assessed by the number of seroma aspirations, as measured by the number of needle aspirations performed during the first post-operative year. There were strict criteria for seroma aspiration; the mere presence of seroma did not warrant aspiration. Seroma aspirations were performed if there was a risk of wound dehiscence or impaired healing or discomfort or pain. The seroma at the risk of infection or already infected seroma were aspirated or managed accordingly with surgical drainage. All the patients that underwent seroma aspirations were treated with antibiotics based on the local bacteriological sensitivity.

Additionally, the rates of seroma infection, the restriction of range of arm movement and cosmesis were also noted. Infection rates were measured by 1) the need for antibiotics, 2) erythema along and around the wound or 3) surgical drainage during the first post-operative year. Wound dehiscence perceived as major or minor. Minor wound dehiscence was labelled when $\leq$ 25 % was affected and conversely, major wound dehiscence labelled when > 25% of the wound was affected. The range of arm movement was graded from 1 to 4 according to estimated angles of arm abduction as Grade 1 (less than 90°), Grade 2 (90–134°), and Grade 3 (135–179°). It was measured by the surgeon before surgery and at the recommended follow up visits. Cosmesis was assessed by both patient and surgeon at all follow up visits, with possible response categories as follows: poor, acceptable, and excellent

Statistical analysis

The characteristics of patients were compared between quilting and conventional suture group. Categorical variables were analysed by $\chi 2$ test or Fisher exact test, and continuous variables were analysed by t test or Wilcoxon rank-sum test. Statistical significance was defined at p value <0.05. SPSS version 19.0 was used for statistical analysis.

3. RESULTS

The study enrolled a total of 229 patients after excluding 35 patients that did not meet the exclusion criteria and 15 patients were lost to follow up. 111 patients belonged to 'Quilting' cohort and 118 to the 'Conventional' group. The patient characteristics were similar between the two groups, except for the familial history of cancer (Table 1).

TABLE 1: the table compares various patient risk factors among the 'conventional' & 'quilting' group.

		Conventional N=118	Quilting N= 111	P Value
Age	Mean (SD)	55.6 (13.7)	56.8 (14.3)	0.302
BMI (kg/m2)	Mean (SD)	20.8 (2.1)	19.9 (2.32)	0.450
Hypertension	n (%)	13 (11)	19	0.154
Diabetes	n (%)	16 (13.6)	10 (9)	0.071
Smoking	n (%)	0 (0)	0 (0)	0
Menopause	n (%)	96 (81.3)	98 (88.3)	0.486
Familial history of cancer	n (%)	6 (5.4)	15 (13.5)	0.120
Neoadjuvant chemotherapy	n (%)	25 (21.2)	23 (20.7)	0.94
TNM				0.164
I	n (%)	29 (22.3)	27 (24.4)	
II	n (%)	46 (39)	52 (46.8)	
III	n (%)	43 (38.7)	32 (28.8)	

The mean operative duration observed in the Quilting (136.57± 76.348 minutes) was significantly higher than the Conventional group (115.65± 32.873 minutes), p value-0.0274. The mean total drain content noted during the post-operative hospital stay in the 'Quilting' group was significantly lower (p value= 0.019) than the 'Conventional' group. Furthermore, a significant higher mean frequency of aspirations was performed in the 'Conventional' group than the 'Quilting' group. (Table 2)

Table 2:

	Conventional	Quilting	P value
Mean total number of seroma aspirations (SD)	4.95± 3.798	1.76 ± 1.367	0.001
Mean operative duration in minutes (SD)	115.65± 32.873	136.57± 76.348	0.0274

Mean Total Drain content (in ml) (SD)	237.97 ±32.83	133.45 ±35.12	0.019
Mean total postoperative hospital stay	8.01± 1.02	7.9 ± 1.34	0.392

Seroma arose in 39 (33%) patients in the 'Conventional' groups and 20 (18%) in the 'Quilting' group at 2 weeks. Although, the frequency of visits decreased with time in either of the groups, the initial number of visits were still higher in the 'Conventional' group. Comparing the total number of visits, the results were still significant with p value of 0.037. (Table 4).

Table 4: comparison of number of OPD visits with complaints of seroma in the 'Conventional' and 'Quilting' group.

			Conventional	Quilting	p- value
Number of patients with seroma visiting OPD at					0.037
	2 weeks	N (%)	39 (33)	20 (18)	
	6 weeks	N (%)	23 (19.5)	12 (11)	
	3 months	N (%)	6 (5)	4 (3.6)	
	6 months	N (%)	2 (1.7)	0	
	12 months	N (%)	0	0	

Upon measuring the infection rates consistent with the wound erythema and the need for surgical drainage evaluated in the two cohorts were not significant, p value: 0.190 (Table 5). Moreover, the rates of wound dehiscence were significantly lower in the 'Quilting' cohort with majority of the patients experiencing a minor wound dehiscence (n=8;7.2%). Analogous to the 'Quilting' group, the 'Conventional' group, too, saw minor wound dehiscence in most patients (n=15; 12.7%), although with higher p value-0.035 (Table 6). Most of the patients had Grade 3 range of arm abduction in both groups. However, higher the decreased range of movement (Grade 1) of the ipsilateral or operated side arm were observed in the 'Conventional' cohort (n= 13;11%.). The comparison of the two cohort yielded a non-significant p value of 0.106 (Table 7). The 'Quilting' cohort had a significantly better wound cosmesis than the 'Conventional' cohort (p value- 0.029). Most of the patients that had undergone 'Quilting' had excellent wound cosmesis with wound healing minimal complications (n=78; 70.3%). Contrariwise, the most patients that had undergone conventional closure had either acceptable wound cosmesis or excellent wound cosmesis (n= 56; 47.4%) (Table: 8).

Table 5: Infection rates in either group measured by wound erythema and the rates of surgical drainage.

			Conventional	Quilting	P value
Infection rates					0.990
	Wound erythema	N (%)	26 (22)	23 (20.7)	

	Surgical drainage	N (%)	14 (11.9)	15 (13.5)	
		Total n (%)	40 (33.9)	38 (34.2)	

Table 6: Rates of wound dehiscence (major/minor) analysed in either of the groups.

			Conventional	Quilting	P value
Wound dehiscence/ flap necrosis					0.035
	Minor	N (%)	15 (12.7)	8 (7.2)	
	Major	N (%)	8 (6.8)	2 (1.8)	
	Total	N (%)	23 (19.5)	10 (9)	

Table 7: Grades restriction of ipsilateral arm abduction perceived between the two cohorts.

		Conventional	Quilting	P value
Range of Arm abduction				0.946
Grade 1 (less than 90°)	N (%)	13 (11)	6 (5.4)	
Grade 2 (90–135°)	N (%)	22 (18.6)	10 (9)	
Grade 3 (135–180°)	N (%)	83 (70.3)	95 (85.6)	

Table 8: Wound cosmesis observed in either groups.

			Conventional	Quilting	P value
Cosmesis					0.029
	Poor	N (%)	6 (5.1)	2 (1.8)	
	Acceptable	N (%)	56 (47.4)	31(27.3)	
	Excellent	N (%)	56 (47.4)	78 (70.3)	

4. DISCUSSION-

Seroma represents a frequently encountered complication subsequent to mastectomy performed for either malignant or benign pathologies. Seroma extends the duration of hospital admission and adversely affects wound healing, consequently

postponing adjuvant therapeutic interventions and contributing to increased healthcare expenditures [6].

In 1953, Keyes et al. [7] employed through and through sutures for the purpose of securing the skin flaps to the chest wall. In addition to these methodologies, techniques such as suturing of flaps with subcutaneous tissue [8], the avoidance of axillary drains subsequent to breast conservation therapy [9], and the obliteration of axillary dead space through muscle approximation [10,11] have all been explored as strategies to mitigate seroma formation.

Various studies have been conducted to devise techniques to reduce seroma formation. Seroma develops as a result of substantial tissue dissection coupled with the constant motion of the chest wall during respiration and shoulder movement, producing a shearing force that compromises flap adhesion. Quilting facilitates the apposition of the flap to the chest wall. Furthermore, it mitigates the impact of the shearing forces between the chest wall and the flap.[12]

In our study, age, tumour characteristics, BMI, smoking, hypertension, age of menopause did not affect the rate of seroma formation similar to studies of Myint et.al.[12]. However, Burak et. al. found a positive correlation with BMI and the seroma formation [13] and Zielinski et.al. showed increased age ($\geq$60 years) was associated with increased mean total seroma volume and increased duration for seroma treatment. Additionally, it was hypothesized that a positive correlation exists between tumour size and tumour-host interaction, which, in turn, elevates the risk of seroma formation.[14]

The quilting suture technique was associated with a statistically significant (115.65$\pm$ 32.873 vs 136.57$\pm$ 76.348; p value-0.0274) increase in mean postoperative duration, directly related to the time required for suture placement. We had measured the total operative duration from the skin incision to final closure of the wound. Assorted studies by Wu et.al. and Conveney et. al. on the same subject found similar outcomes [15,16]. Conversely, this method led to a significant reduction in mean total drain output in the 'Quilting' group (237.97 $\pm$32.83 vs 183.45 $\pm$35.12; p value- 0.019). In our study, the drains

were removed on the day 5 in cases of minimal output or when the output was less than 40 ml/day for 3 consecutive days. While, in our study, the drain contents in both cohorts were comparable during the first postoperative week, Mazouni et al. observed mean drain content was significantly lower in the Quilting group on the postoperative day 1 itself [17]. In a study involving 176 patients, ten Wolde et.al., observed a significant decrease in seroma formation after implementing a quilting technique. The average number of aspirations dropped from 4.86 (non-quilting) to 2.40 (quilting) (P = 0.015), and the average aspirated fluid volume decreased from 1660.90 mL to 611.25 mL (P = 0.05).[18]

We did observe a slightly increased mean postoperative hospital stay in the conventional group, but this was not significant (p value-0.392) probably due to similar wound infection rates prolonging the hospital stay and no seroma formation in the first week.

The 'Conventional' suturing group demonstrated a higher frequency of outpatient department (OPD) visits for discomfort, cystic swelling or seroma in the second week. Although both groups showed a temporal decline in these complaints, the quilting group exhibited a markedly lower absolute number of such occurrences. There were increased frequency of seroma aspiration in the 'Conventional' group with an average of 3 than the 'Quilting' group where a single aspiration had sufficed the resolution of seroma. A case resistant seroma was observed in 2 patients at 6 months in the 'Conventional' cohort where surgical drainage was required. whereas no patients had visited us with seroma in the 'quilting' group at 6 months. Consistent with ten Wolde et al.'s research, this study demonstrated that quilting significantly reduced the mean aspiration frequency relative to the conventional approach.[18]

The rates of wound infection suggested by surrounding erythema or associated discharge and need for surgical drainage due to wound infection per se in both the groups were not significant (p value-0.990) disclosing the fact that various patient co morbidities and environmental factors were in play for wound healing. This observation was similar to the study conducted by Murugiah et. al [19].

The range of arm movement was restricted by the pain and the patient's apprehension of impaired wound healing. Most patient in either group exhibited grade 3 of arm motion that prevented restriction of their daily activities. The restriction of arm movements was insignificant amongst the groups (p value:0.946).

The minor cases of skin dimpling in the 'Quilting' group was attributed to the inadvertent sutures that penetrated the superficial dermis in the thinner skin flaps. In these instances, the quilting sutures impacted the cosmesis. Transient dimpling of the epidermis may ensue following the quilting procedure, typically resolving without intervention. Nonetheless, there exists a risk that this phenomenon could precipitate flap necrosis.in their study, Gong et. Al., minimal dimpling was deemed acceptable. This was anticipated to resolve with time giving them good scar. Conversely, should moderate to severe dimpling be identified, the stitch would be removed and substituted.[20]. Minority patients exhibited poor cosmesis across the groups (6 (5.1) vs 2 (1.8%) due to major wound dehiscence. The 'Quilting' cohort saw the preponderance of the excellent cosmesis owing to the fact that most patients had minor wound dehiscence, although the absolute numbers of wound dehiscence was significantly comparable to the 'Conventional' group (p value: 0.035). Morarasu et. al., in their systemic review observed the skin dimpling, flap necrosis and cosmesis were comparable in the groups.[21]

5. CONCLUSION-

We conclude that 'Quilting' integrated in the wound closure helps in reduction of seroma in the patients undergoing mastectomy in breast cancer patients. The incidence of seroma was significantly lower in the 'Quilting' group thus reducing the patients' discomfort and the cost of the treatment. The mean total drain output, the frequency of hospital visits and aspirations were also lower. 'Quilting' was also associated with lower rates of wound dehiscence thus giving better cosmesis than the

'Conventional' patients. However, the mean total postoperative stay and infection rates were similar in both the groups.

The smaller sample size and single centered limits the study to project its data on the general population. Furthermore, the tumour characteristics and its interaction with host was accounted in the study. The bulk of the breast tissue removed and its rate of seroma formation were not included in the study.

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