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Original Research Article

A randomized controlled trial evaluating the efficacy of mastectomy flap quilting sutures in reducing post modified radical mastectomy seroma formation

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ABSTRACT

Background: One of the most common complication post modified radical mastectomy is the formation of seroma. Seroma formation in-turn delays wound healing, increases susceptibility to infection, skin flap necrosis, persistent pain and thus prolongs convalescence. For this, several techniques have been tried and trialed to improve primary healing and decrease the formation of seroma.
Methods: Between Aug 2014 and July 2016, 60 patients with carcinoma of the breast, posted for modified radical mastectomy at KR Hospital, Mysuru, Karnataka, India were randomly divided into 2 groups, the study group (30) and the control group (30). In the study group; the mastectomy flap quilting sutures were put between the flap and the pectoral fascia and muscle at different parts of the flap and at the flap edge with absorbable sutures (polyglactin 3-0). In the control group; the flaps were approximated by the conventional method at the edges. Closed suction drains were placed in both the groups. Patients, tumour characteristics and operative related factors were documented. The volume and colour of the fluid drained was recorded everyday. The drains were removed when the amount became less than 30 cc in a 24 hour period. The total volume and duration (number of days) of fluid drained and the complications were recorded and compared.
Results: In the study group, the drain was removed much earlier when compared to the control group ($p < 0.001$). The total amount of fluid drained was much lower in the study group ($p < 0.001$). The study group showed a much lower frequency of seroma formation when compared to the control group.
Conclusions: The mastectomy quilting suture technique is an effective procedure that considerably reduces the incidence of seroma formation in patients undergoing modified radical mastectomy.

Keywords: Flap, Mastectomy, Quilting, Seroma

INTRODUCTION

Seroma formation is one of the most common complication post modified radical mastectomy. The incidence documented ranges from 15-81%.[1-4] Seroma formation increases chances of infection, delays wound healing, flap necrosis, persistent pain, dehiscence of the wound and thus increases the convalescence period.[5] Ideal closure of the Modified radical mastectomy flaps aims at decreasing the lymphatic spillage and serum oozing, should obliterate the dead space and also allow enhanced removal of the fluid which is formed.

Considering this, several techniques of flap fixation have been tried and trialed to minimize the local wound complications.[6-7] The aim of the present study was to study the efficacy of mastectomy flap quilting sutures to the underlying chest wall, on the volume and duration of the fluid drained and also seroma formation post modified radical mastectomy.

METHODS

Our prospective comparative study was conducted between Aug 2014 and July 2016 at KR hospital, Mysuru, Karnataka, India. 60 patients who were posted for modified radical mastectomy were included in the study. Female patients with carcinoma breast planned for modified radical mastectomy were enrolled for the study, patients on anticoagulant treatment, with altered blood clotting or immune systems; having uncompensated diabetes mellitus, advanced liver disease, severe obesity, and any previous surgery on the axillary lymphatic system or immediate reconstructive procedure were excluded from the study. Informed consent was obtained from all the patients included in the study. The enrolled patients were randomly divided into 2 groups, the study group and control group of 30 each.

In the study group, after finishing the modified radical mastectomy procedure, the mastectomy flaps were approximated with the help of quilting sutures (using polyglactin 3-0) to the underlying chest wall (pectoral fascia and muscle).Multiple alternating quilting sutures were placed 2-3 cm apart between subcutaneous layer of the flaps and the underlying pectoral fascia/muscle at various parts of the flap, at the wound edges and axilla was also obliterated accordingly.

In the control group, after the modified radical mastectomy, the flaps were approximated by conventional method at the edges. Closed suction drain was placed in both the group of patients. Patients and their tumor characteristics and operative related factors were documented.The volume and colour of the drained fluid were documented daily. The drains were removed when the volume of the collected fluid became less than 30cc in 24 hours. Local examination was done over the flaps and axilla 2weeks after removal of the drain and was supported in doubtful cases by local chest wall ultrasound to exclude or confirm the presence of collections/seroma. The total volume of the drained fluid and seroma formation were documented. The final results were then compared between the two groups with the help of Mann Whitney test. The effect of mastectomy quilting sutures on the volume and duration of the fluid drained and seroma formation were thus concluded.

RESULTS

Tumor characteristics of patients of both the groups were compared and summarized in the Table 1.There was no significant differences detected between the two groups with respect to age, histological type, grade of the tumor and the neoadjuvant chemotherapy received.

Table 1: Tumor characteristics of the two groups.

	Study group (n = 30)	Control group (n = 30)	P-value
Patient age			
Mean (range), Y	51 (37-62)	54 (38-72)	
Histological types			
Intraductal carcinoma (IDC)	27	27	
Intralobular carcinoma (ILC)	2	2	1.00
Mixed	1	1	
Grade			
II	24	23	
III	6	7	1.00
T stage			
T1	2	2	
T2	23	15	0.242
T3	5	9	
T4	0	4	
N Stage			
N0	18	9	
N1	9	15	0.178
N2	3	6	
Neoadjuvant chemotherapy			
Yes	4	9	
No	26	21	0.451

Table 2: Operative features of the two studied groups.

	Study Group (n = 30)	Control group (n = 30)	P value
Volume of the tumor mass removed			
Mean (range) (ml)	332.8 (14.1-3592.8)	465.5 (10.3-2145.5)	0.125
Area of the skin removed			
Mean (Range) (cm^2)	827.7 (471.4-1885.7)	821.9 (251.4-1386.0)	0.829
Total Number of lymph nodes removed			
Mean (Range)	18.9 (12.0-30.0)	20.8 (7.0-56.0)	0.273
Number of Positive lymph nodes removed			
Mean (Range)	2.8 (0.0-18.0)	5.9 (0.0-55.0)	0.775

Table 3: Post-operative outcome measures.

	Study group (n = 30)	Control group (n = 30)	p value
Day of drain removal			
Mean (range)	5.0 (2.0-12.0)	13.4 (5.0-22.0)	<0.001
Total amount of drained fluid (ml)			
Mean (range)	524.8 (170.0-1525.0)	2017.8 (445.0-5615.0)	< 0.001
Amount of drained fluid in the last 3 days (ml)			
Mean (range)	207.8 (130.0-300.0)	213.0 (125.0-600.0)	0.175
Amount of drained fluid in the last day (ml)			
Mean (range)	35.0 (20.0-50.0)	51.5 (25.0-200.0)	0.002

Table 4: Frequency of seroma and complications in the two studied groups.

	Study group (n = 30)	Control group (n = 30)	P value
Seroma (clinical)			
No seroma	27 (90.0%)	12 (60.0%)	
G2 seroma	3 (10%)	11 (35.0%)	0.028
G3 seroma	0	7 (5.0%)	
Seroma (ultrasonographic)			
No seroma	24 (80.0%)	15 (50.0%)	
G1 seroma	3 (10%)	3 (10.0%)	
G2 seroma	3 (10%)	9 (30.0%)	0.047
G3 seroma	0	3 (10.0%)	
Complications			
Cellulitis	2	2	
Partial flap necrosis	0	2	

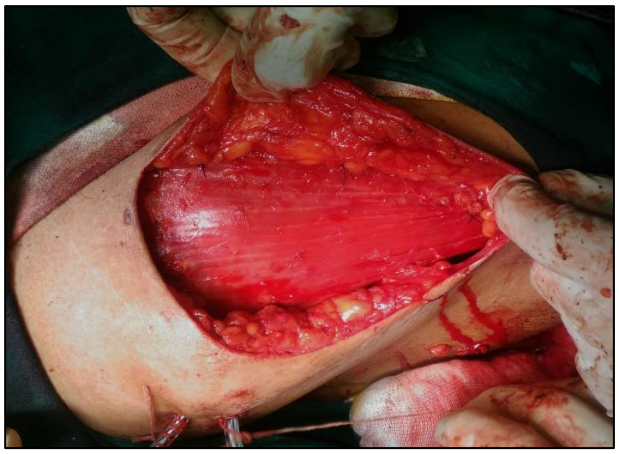

Figure 1: Per-operative picture depicting mastectomy flap quilting sutures.

Operative related findings were compared between the two groups (Table 2). There was no significant differences detected between the two groups with respect to volume of tumor mass removed (p = 0.125) and total number of positive lymph nodes removed. Post-operative outcome measures were recorded and depicted in Table 3. In the study group, drain was removed much earlier when compared to the control group (p<0.001) and the total volume of drained fluid was also much less in the study group.

Finally, study group patients showed a significantly much lower frequency of seroma formation compared to the control group both clinically(p=0.028) and sonographically(p=0.047). Complication rate was less in study group and none developed flap necrosis in study group, while complications of cellulitis and flap necrosis

were seen in control group and the same has been depicted in Table 4.

DISCUSSION

Axillary lymphadenectomy being a part of modified radical mastectomy, in particular has higher incidence of seroma formation (15-81%). It delays the wound healing, prolongs the hospital stay, delays adjuvant radiotherapy and chemotherapy.[1,3,5,8,9]

Severity of seroma is graded according to the common terminology criteria for adverse events 6 v 3.0.

Grade 1: Asymptomatic (only diagnosed by ultrasound)

Grade 2: Symptomatic (medical intervention or simple aspiration indicated)

Grade 3: Symptomatic (interventional radiology or operative intervention indicated)

Seroma is thought to be formed by acute inflammatory exudates in response to surgical injury and acute phase of wound healing. The dissection in mastectomy and axillary lymphadenectomy injures and damages several small blood vessels and lymphatics with subsequent oozing of blood and lymphatic fluid from the raw surface area. The accumulated fluid lifts the flaps from chest wall and axilla thereby hindering their approximation to the chest wall bed and thus delays wound healing.[10]

Petrek et al. showed that number and extent of axillary lymph node involvement is the most significant factor in causation of seroma.[11]

Halsted et al was the first to advocate fixation of the skin flaps to the deep structures at the edge to cover the contents of the axilla, and to obliterate dead space under the clavicle. The remaining wound defect was covered with a skin graft, and a drain was not inserted.[12]

Subsequently, Larsen et al. recommended subcutaneous suture fixation to the deep muscles and fascia with 35 to 50 fine cotton sutures after radical mastectomy with a large pressure dressing. Drains were not inserted unless the chest wall was unusually wet or unless a dead space persisted.[13]

Aitken et al. assessed the usefulness of subcutaneous tacking sutures using absorbable material to secure the flaps.[14] O'Hea et al. reported that an external compression dressing failed to decrease postoperative drainage and seroma formation compared with dressing using a loosely fitted front-fastening Surgibra.[15]

Similarly, Chen et al. failed to find any significant advantage of the use of a pressure garment.[16]

Purushotham et al. reported that breast surgery without drainage did not increase surgical or psychological morbidity including seroma formation if flaps were fixed with sutures.[17]

Several investigators have also found that flap fixation technique is useful in decreasing seroma formation.[17] It has been reported by few that total drainage volume may range from 2-5 litres if flap fixation technique was not used.[18]

It has also been reported that most surgeons tend to remove drain when volume is <30-50 ml in preceding 24 hours which takes up to 10days post operatively.[18,19]

At present, axillary flap fixation with sutures has not gained widespread acceptance, possibly because of the longer operation time required (10 to 20 minutes).[20,21] However, if this additional time is well invested, it results in fewer seromas and other complications, less nursing care, and fewer office visits for the patients.

CONCLUSION

Based on the findings of the literature review and based on the results of our study, closure of the dead space by mastectomy quilting sutures will reduce the total volume of drained fluid, seroma formation and the number of aspirations, thus simplifying postoperative management and facilitating early discharge.

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Ethical approval: The study was approved by the institutional ethics committee

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