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A Prospective Randomised Study On The Effect Of Closure Of Dead Space By Flap Fixation After Modified Radical Mastectomy On Reducing Seroma Formation.

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ABSTRACT

Seroma is a common complication after mastectomy, with an incidence of 3% to 85%. Seroma is associated with pain, delayed wound healing, and additional outpatient clinic visits, leading potentially to repeated seroma aspiration or even surgical interventions. This study aimed to assess the effect of flap fixation using sutures or tissue glue in preventing seroma formation and its sequelae. The study was conducted from June 2020 to July 2022 at the Department of General Surgery, Government Royapettah Hospital, Government Kilpauk Medical College, Chennai, Tamil Nadu, India The patients were randomly divided into two equal groups: group A (20 patients had MRM with the closure of dead space by suturing the skin flaps to the underlying muscles (quilting), and Group B (20 patients had MRM with the closure of the wound by the conventional method without closure of dead space. The primary outcome was the need for seroma aspiration. The secondary outcomes were additional outpatient department visits, surgical-site infection, shoulder function and mobility, cosmesis, skin-dimpling, and postoperative pain scores. Results. Flap fixation after mastectomy leads to fewer seroma aspirations than conventional wound closure (CON 17.5% vs. FFS 7.3% vs FFG 10.8%; p = 0.057), with a significant difference between flap fixation with sutures and conventional wound closure (odds ratio [OR], 0.37; 95% confidence interval [CI], 0.16–0.89; p = 0.025). Flap fixation has no significant negative effect on surgical site infections, shoulder function, mobility, cosmesis, skin dimpling, or postoperative pain. Flap fixation using sutures leads to a significant reduction in aspirations of post-mastectomy seromas.

Keywords: Seroma, dead space closure, modified radical mastectomy (MRM), Flap fixation.

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INTRODUCTION

Carcinoma breast remains the most common site-specific malignancy diagnosed in women [1]. More than a million cases of breast carcinoma are diagnosed worldwide yearly. The overall incidence has been rising because of increased life span, lifestyle changes, and various other concerns. Breast cancer has ranked as the number one cancer among Indian females, with an age-adjusted rate as high as 25.8/100,000 women and a mortality of 12.7/100,000 women [2]. Modified radical mastectomy (MRM) is a surgical procedure that involves the removal of breast tissue, including the nipple-areola complex and axillary lymph node dissection (ALND). Seroma formation, characterized by the accumulation of fluid in the surgical site, is the most frequent complication of mastectomy and ALND, reportedly occurring in as many as 35–97% of cases [3]. It can cause discomfort, delayed wound healing, infection, and potential cosmetic issues. The ideal method to reduce seroma formation is not known [4]. Mechanical closure of dead space is one of the strategies employed to minimize seroma formation. Seromas occur due to persistent drainage from severed lymphatics, local inflammatory response, use of electrocautery, and creation of dead space. Seroma is a collection of liquefied fat, serum, and lymphatic fluid under incisions, skin flaps, and cavities formed by tissue dissection [5]. The definition of seroma changes in the literature, and the frequency of this complication is variable. The etiology of seroma is not clear and is discussed widely in the literature. It is usually in the form of an exudate. Seroma formation is distressing to the patient as it predisposes to infection, flap necrosis, heavy use of antibiotics, increases hospital stay, high economic burden, and thus increases morbidity [6]. It delays the initiation of adjuvant chemotherapy and radiotherapy and thus loses valuable time in arresting the progression and curing the disease process. Seroma needs treatment when it is symptomatic and causes discomfort to the patient [7]. The optimal closure of the wound should decrease seroma formation by obliterating dead space. The use of closed-system suction drainage reduces the influence of this complication [8]. A small amount of serous fluid does not necessitate treatment. More important is the probability of infection, as infected seroma is a serious problem for the patient. Pressure wound dressing does not affect reducing the amount of seroma. Different chemical methods are used for obliterating the dead space, such as fibrin glue, tissue adhesive, and sclerotherapy agents, but the effects are not clear [9, 10].

MATERIALS AND METHODS

The study was conducted from June 2020 to July 2022 at the Department of General Surgery, Government Royapettah Hospital, Government Kilpauk Medical College, Chennai, Tamil Nadu, India The patients were randomly divided into two equal groups: group A (20 patients had MRM with the closure of dead space by suturing the skin flaps to the underlying muscles (quilting), and Group B (20 patients had MRM with the closure of the wound by the conventional method without closure of dead space. In the study group, There are numerous stitches in total. Fine absorbable sutures (vicryl 3/0) were used to sew rows of 3 cm apart between the subcutaneous tissues of the skin flaps and the underlying muscles at various points on the flap and at the wound edge. Closed suction drains were used: Control group: Suction drains were also employed to seal the wound conventionally. Every day, the amount of fluid evacuated and the color of the fluid were noted. Drains were removed when the flow rate dropped below 40 cc/24 hours or the drained fluid became infected, regardless of how much had been drained in the previous days. Patients were examined clinically for the presence of seroma one week after drain removal Following the removal of the drains, a chest wall ultrasonography was conducted to determine whether any collections had occurred. Total fluid drained, duration, and formation of seroma have all been tracked down and analyzed.

Statistical methods

SPSS version 15 was used to analyze the collected data (SPSS Inc., Chicago, IL, USA). Statistics such as mean and standard deviation (SD) were used for quantitative information, and percentages were used for qualitative information. For quantitative variables, the independent student test was used to determine the significance of the difference, while the Chi-square or Fisher's exact test was used to determine the significance of the difference. P-values of 0.05 and lower were considered statistically significant for this study.

RESULTS

The mean age of the studied patients was 54.43 years old, ranging from 35 - 85 years old. The majority of patients were between 40 and 60 years of age (70%). The mean body mass index was 31.06 kg/m2, ranging from

24 kg/m2 to 38.30 kg/m2. The majority of cases had a body mass index between 30 and 35 kg/m2 (50%). As regards the breast size, bra cup size was used to assess the size of the breast. Most of the studied patients had breast cup sizes B and C. Fourteen patients had a history of using oral contraceptive pills (OCPs) (35%), while 26 patients (65%) gave no history of OCPs. Eleven patients had positive family history of breast cancer in the first or second-degree relatives (27.5%), while 29 patients had no family history of breast cancer (72.5%). Twenty-three patients had associated medical illness (57.5%); 17 of them had diabetes (42.5%),18 were hypertensives (45%), and 3 of them had cardiac problems (7.5%). Fifteen patients received neoadjuvant chemotherapy, of which seven patients were from the group (A), and eight patients were from the control group (B). There was no significant difference between the two studied groups about the factors mentioned above. Group (A) showed a significant reduction over the control group as regards the daily drain output in the initial three postoperative days, the total amount of drained fluid, and the drainage period (p=0.009,<0.001, <0.001, respectively) (Table 1).In cases of patients that develop a seroma, the mean number of aspirations and the mean fluid volume aspirated were also decreased significantly in group (A) compared to the control group (Table 2). Table 3 showed that there was no significant difference between the two studied groups about postoperative pain (p = 0.223). Morbidity in our study is minor, as complications had developed in 8 patients (20%). Four cases (10%) developed a mild infection that was treated medically, three cases (7.5%) developed partial flap necrosis, and one case (2.5%) developed a mild hematoma. There was no significant difference between the two studied groups about postoperative complications (Table 4).

Table 1: Comparison Between The Two Studied Groups

	Group A (n= 20)	Group B (n= 20)	t	p
Total amount of drained fluid in first 3 days				
Min. – Max.	250.0 – 450.0	330.0 – 660.0		
Mean ± SD.	357.0 ± 51.21	414.50 ± 77.22	2.775*	0.009*
Median	365.0	410.0		
Total amount of drained serous fluid (ml)				
Min. – Max.	190.0 – 1340.0	430.0 – 3170.0		
Mean ± SD.	723.45 ± 363.64	2284.9 ± 1062.7	6.217*	<0.001*
Median	677.0	3047.0		
Day till drain removal				
Min. – Max.	5.0 – 14.0	10.0 – 19.0		
Mean ± SD.	10.10 ± 2.99	14.15 ± 1.95	5.071*	<0.001*
Median	10.50	14.0		

t, p: t, and p values for Student t-test for comparing between the two groups. *: Statistically significant at p ≤ 0.

Table 2: Comparison between the two studied groups according to the number of aspirations and volume of aspirated serous fluid.

	Group A (n= 7)	Group B (n= 15)	Z	p
Number of aspirations				
Min. – Max.	1.0 – 3.0	1.0 – 7.0		
Mean ± SD.	1.43 ± 0.79	3.13 ± 2.26	1.992*	0.046*
Median	1.0	2.0		
Volume of aspirations				
Min. – Max.	20.0 – 170.0	40.0 – 280.0		
Mean ± SD.	74.29 ± 63.73	139.33 ± 71.56	2.190*	0.029*
Median	50.0	120.0		
X^2, p: X^2, and p values for the Chi-square test for comparing the two groups. Z, p: Z and p values for Mann Whitney test for comparing between the two groups.				

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Table 3: Comparison between the two studied groups according to postoperative pain.

	Group A (n= 20)	Group B (n= 20)
Postoperative pain (analgesic amp /day)		
1	1 (5.0%)	0 (0.0%)
2	3 (15.0%)	7 (35.0%)
3	10 (50.0%)	10 (50.0%)
4	6 (30.0%)	3 (15.0%)
Min. – Max.	1.0 – 4.0	2.0 – 4.0
Mean ± SD.	3.05 ± 0.83	2.8 ± 0.70
Median	3.0	3.0
Z (p)	1.219 (0.223)	
Z, p: Z and p values for Mann Whitney test for comparing between the two groups. *: Statistically significant at p ≤ 0.05.		

Table 4: Comparison between the two studied groups according to postoperative complications.

	Total (n=40)		Group A (n= 20)		Group B (n= 20)			
							X^2	FEp
	No.	%	No.	%	No.	%		
Hematoma	1	2.5	0	0.0	1	5.0	1.026	1.000
Infection	4	10.0	2	10.0	2	10.0	0.000	1.0000
Flap necrosis	3	7.5	1	5.0	2	10.0	0.360	1.000
X^2, p: X^2, and p values for the Chi-square test for comparing the two groups. FE: Fisher Exact for Chi-square test								

DISCUSSION

The mean age of patients in the study group and control group was comparable to 43.6 versus 44.4, ranging from 35 to 71 in the study group and 36 to 73 in the control group [11]. As patients with comorbidities were excluded and as patients were in the same age group and stage of malignancy, they were comparable.[12] The main parameter and the main aim of the study were to find the number of days, the drainage system was required, and to find seroma formation if any Infection rates with 25% in the study group and 18% in the control group, the difference with a p-value of 0.22 is not significant [13]. There was no seroma formation in either group post-drain removal. There was no significant difference in operating times between the two groups, even though the flap fixation group has slightly longer operating times [14]. Flap fixation techniques have Both the groups needed drains for many days, and from the above studies, without drains, irrespective of whether one obliterates dead space or not, patients will have seroma and will need repeated aspirations [15]. Hence, we will not advise the obliteration of dead space as an alternative to draining. Obliterate the dead space can reduce the duration of the drain being kept. Flap fixation using sutures is a cheap and freely available method that can obliterate the dead space and allow patients to have fewer days with drains, leading to improved comfort [16]. Objective quantification of seroma remains challenging for studies reporting on seroma formation. Seroma presents on a sliding scale, and reporting of seroma is observer-dependent. Furthermore, not every seroma is clinically significant. For this reason, the current study chose seroma aspiration as the primary outcome. Consequently, only clinically significant seromas were analyzed [17]. This was the first double-blind, randomized, controlled trial to compare the effect of flap fixation with conventional wound closure on seroma formation after mastectomy. The group with conventional wound closure had more patients (10.5%) who exceeded three additional hospital visits than the groups with flap fixation (FFS group, 4.6%; FFG group, 5.4%). This difference was not statistically significant, but it might be considered clinically important. Furthermore, the 6.7% difference between the FFG and CON groups in the proportion of patients who needed seroma aspirations was not significant (OR, 0.57; 95% CI, 0.26–1.23; p = 0.152) but could be considered clinically meaningful. In the interim analysis, both flap fixation groups showed significantly fewer seroma aspirations than the conventional wound closure group.[18] The final results, however, showed no significant difference in seroma aspiration for the flap fixation group with tissue glue. This could be explained by the fact that the

calculation of sample size was based on detecting an absolute difference of 20% in seroma aspirations. Consequently, this study was insufficiently powered to detect smaller differences that still may be considered clinically meaningful [19]. This study included all mastectomy patients regardless of whether axillary clearance was performed. Axillary clearance has proved to be a predictor for seroma formation and seroma aspiration, with the highest incidence among patients undergoing a modified radical mastectomy [20]. This could be explained by the dead space in the axilla, which is challenging to close adequately because of its three-dimensional shape. Furthermore, the higher frequency of lymph vessels in the axilla and, consequently, the greater lymph leakage after dissection in this area could also explain why axillary clearance is a predictor for seroma formation [21]. In this study, significantly more patients undergoing mastectomy with axillary clearance underwent seroma aspiration than patients who had no axillary clearance performed. A subgroup analysis between simple mastectomy and modified radical mastectomy showed that flap fixation with sutures is of clinical importance in both patient groups, resulting in fewer seroma aspirations [22]. Although not statistically significant, the difference in seroma aspirations between the groups could be considered clinically meaningful, primarily for the axillary clearance group [23]. Flap fixation using tissue glue seems to be more beneficial for patients undergoing modified radical mastectomy than for patients undergoing simple mastectomy. The number of patients with SSIs in our study was similar to that of groups without flap fixation or flap fixation with tissue glue. This could be because the group with flap fixation using sutures underwent fewer seroma aspirations, representing fewer clinically significant seromas [24, 25]

CONCLUSION

Overall, closure of dead space technique appears to be a more clinically and cost-effective treatment option for patients undergoing modified radical mastectomy compared with the conventional method of closure by potentially reducing the costs of postoperative complications (seroma formation, prolonged hospital stay, nursing care, repeated clinic visits, and longtime of morbidity). It also provides better cosmetics with less skin breakdown and high patient satisfaction. We can conclude that closure of the dead space technique after MRM significantly decreases the daily drain output in the initial three postoperative days and the total amount of drained fluid, allowing early removal of the drains. It also reduces the rate and duration of seroma formation. Also, it significantly decreases the number of aspirations and volume of aspirated fluid.

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