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Original Article

Optimizing Post-Mastectomy Recovery: Reducing Seroma Formation with the GELFOAM Technique

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ABSTRACT

Background: Breast cancer has consistently been the second leading cause of cancer-related deaths among women globally for the past three decades, significantly contributing to the surgical load associated with cancer treatment. Surgical options for breast cancer include breast conservation therapy and mastectomy, with or without axillary dissection, depending on the stage of the disease. The most common surgical procedure for this cancer is modified radical mastectomy (MRM), which often leads to complications such as skin flap necrosis, hematoma, seroma, and surgical site infection. These postoperative complications can demoralize patients and potentially delay adjuvant treatments, leading to adverse outcomes.

Methods: This prospective analytical study aimed to investigate the efficacy of using GELFOAM to reduce seroma formation post-MRM. Conducted at Pt. J.N.M. Medical College & Dr. B.R.A.M. Hospital, Raipur, Chhattisgarh, from December 2022 to January 2023, the study included 38 patients undergoing MRM. All patients received GELFOAM during surgery, and postoperative follow-ups were conducted on days 2, 7, 14, and 30 to monitor seroma formation and other complications.

Results: The study revealed that 29 patients experienced a reduction in seroma volume, while 9 patients had an increase despite the use of GELFOAM. Significant associations with seroma formation were observed for smoking, hypertension, BMI, and neoadjuvant chemotherapy/radiation (P=0.0001 each), as well as for diabetes mellitus and dense breast tissue (P=0.044 and P=0.040, respectively). The extent of lymph node dissection also played a crucial role, with a highly significant association (P=0.00001). Flap necrosis and surgical site infections were strongly associated with seroma formation (P=0.0001). Early removal of drains and shorter hospital stays were linked to less seroma formation (P=0.00001).

Conclusion: Utilizing GELFOAM during MRM significantly reduces the occurrence and volume of seroma formation, facilitating early removal of suction drains and improving postoperative outcomes. Therefore, incorporating GELFOAM as a standard step in MRM is highly recommended.

Keywords: *Breast cancer; Modified radical mastectomy; Seroma formation; GELFOAM; Postoperative complications.*

INTRODUCTION

Breast cancer has consistently been the second leading cause of cancer-related deaths among women globally for the past three decades,[1] significantly contributing to the surgical load associated with cancer treatment. Surgical options for breast cancer include breast conservation therapy and mastectomy, with or without axillary dissection, depending on the stage of the disease.[2] The most common surgical procedure for this cancer is modified radical mastectomy.[3] However, this procedure often leads to complications such as skin flap necrosis, hematoma, seroma, and surgical site infection.[4] These postoperative complications can demoralize patients and potentially delay adjuvant treatments, leading to adverse outcomes.

Seroma formation, occurring in 15 to 18% of cases post-breast cancer surgery, is a particularly prevalent issue.[5] It is now considered a side effect of surgery rather than a complication, with associated morbidity including prolonged drainage which can delay adjuvant therapy and increase infection risks. In some cases, persistent seroma may necessitate reoperation. Acute inflammatory exudates form seromas in response to surgical trauma and during the acute phase of wound healing.[6]

Various techniques have been reported to prevent or reduce seroma formation, such as surgical techniques, the use of sealants and sclerotherapy, compression dressing, the use of drains, shoulder exercises (delayed vs. early), and the application of Octreotide.[7] GELFOAM, a widely used intraoperative gelatin compressed sponge for hemostasis, is made of purified swine gelatin and aids in clot formation.[8] This absorbable gelatin holds blood and provides a matrix for clot and granulation tissue formation. It is commonly used to achieve hemostasis in neurosurgical and spinal procedures.

According to a study by Elshahidy et al., using GELFOAM during modified radical mastectomy effectively decreases the occurrence of seroma.[9] However, limited literature is available on the use of the GELFOAM technique to reduce the incidence of seroma formation following modified radical mastectomy. Therefore, this study aims to explore the efficacy of the GELFOAM technique in reducing seroma formation after a modified radical mastectomy.

METHODOLOGY:

Study Design and Setting: This prospective analytical study was designed to investigate the efficacy of the GELFOAM technique in reducing the incidence of seroma formation following modified radical mastectomy. The study was conducted in the Department of General Surgery at Pt. J.N.M. Medical College & Dr. B.R.A.M. Hospital, Raipur, Chhattisgarh, from December 2022 to January 2023.

Study Population: The study population comprised all patients with carcinoma of the breast undergoing modified radical mastectomy in the Department of General Surgery at Dr. B.R.A.M. Hospital, Raipur.
Inclusion Criteria: The study included all patients with carcinoma of the breast undergoing modified radical mastectomy in the Department of General Surgery at Dr. B.R.A.M. Hospital, Raipur.
Exclusion Criteria: Patients with advanced stage IV carcinoma of the breast, those with recurrent disease following modified radical mastectomy, and patients unwilling to provide consent for the study were excluded.
Sample Size Calculation: The sample size was calculated to be 38 based on the formula:

$$\boldsymbol{n = \frac{Z^2.p.(1-p)}{ME^2}}$$

Where:
n = Sample size; p = Prevalence of seroma formation using GELFOAM technique = 2.5%;[9] ME = Marginal error (4%)

Data Collection: Eligible patients were recruited after providing informed written consent. All patients underwent a triple assessment, which included a complete medical history, clinical breast examination, radiological imaging, and non-excisional biopsy. Patients were staged according to the American Joint Committee on Cancer (AJCC) breast cancer staging system 8th edition and categorized into early breast cancer (EBC) stages (IA, IB, IIA, IIB) and locally advanced breast cancer (LABC) stages (IIIA, IIIB). Patients were then scheduled for modified radical mastectomy.

Intraoperative Procedure: During the surgery, breast tissue was dissected and removed from medial to lateral, including the axillary tail and contents. The axillary vessels were identified by retracting the pectoralis minor muscle. The axilla was dissected, preserving the thoracodorsal bundle (nerve and vessels) and the nerve to the serratus anterior. Hemostasis was secured using electrocautery, and the operative area was irrigated with warm saline. Two sheets of GELFOAM were placed under the mastectomy flaps, and one sheet was placed under the axillary flap. The GELFOAM sheets were fixed using two interrupted sutures (Vicryl 2/0) from the pectoralis major muscle through the GELFOAM sheets to the subcutaneous tissue of the mastectomy flap. A suction drain with two limbs was inserted, with one limb placed under the upper flap and the other under the lower flap, with tips toward the axilla. Skin edges were closed using staples or interrupted sutures.

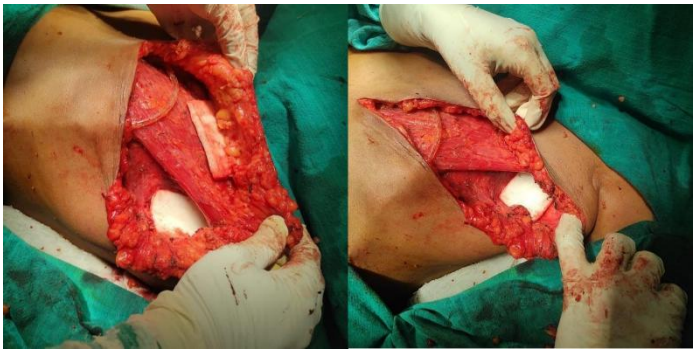

Figure 1. Placement of Gelfoam under the upper and lower mastectomy flap

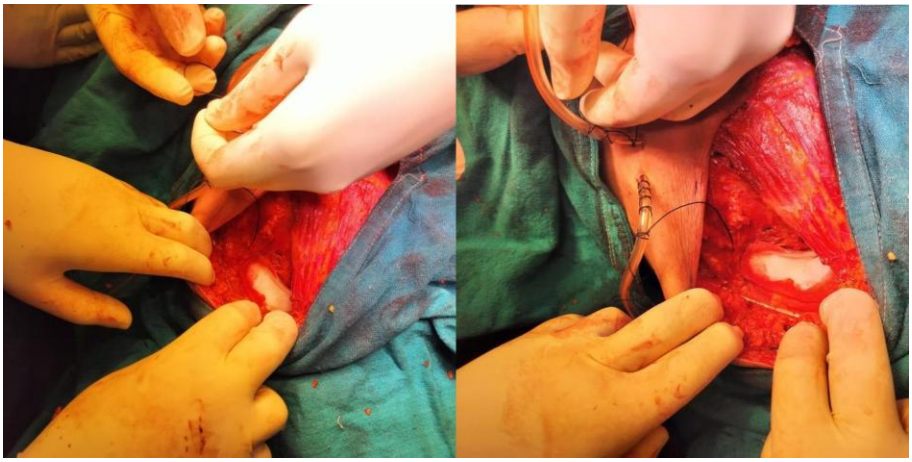

Figure 1. Insertion of Suction drain

Postoperative Follow-up: Postoperative follow-up included weekly assessments for one month to detect seroma formation on postoperative days 2, 7, 14, and 30, using clinical examination and superficial probe ultrasound after drain removal. Drains were removed when the output was less than 50 cc in 24 hours for two consecutive days. Any complications were recorded, and sutures were removed 15 days postoperatively.

Statistical Analysis: Data were verified, coded, and analyzed using IBM-SPSS for Windows, version 26.0. Descriptive statistics were calculated to interpret the data, including means, standard deviations, and percentages.

Ethical Consideration: The Ethical Committee of the Pt. J.N.M. Medical College approved the study.

RESULTS

The study, which included 38 patients, examined the effects of GELFOAM in modified radical mastectomy. Among the participants, 29 experienced a reduction in the volume of seroma formation due to the use of GELFOAM. However, 9 patients faced an increase in seroma volume despite its application.

The mean age of the study population was 47.86±9.23 years. Most patients (36.8%) were in the age group 41-50, followed by 28.9% in the 51-60 age group, and only 7.9% were above 60. Most patients (68.4%) were vegetarians, while 31.6% had a mixed diet. The age of menarche was 11 years for 65.8% of patients, 12 years for 18.4%, and 10 years for 15.8%. Regular menstrual cycles were reported in 84.2% of cases, while 15.8% had irregular cycles. Menopause was attained by 26.3% of patients, with the age of menopause being 51-56 years. The age at first childbirth was 16-20 years for 63.2% of patients and 21-25 years for 36.8%. Among the patients, 47.4% had three children, 44.7% had two children, and 7.9% had four children. Breastfeeding was practiced by 97.4% of patients, with only 2.6% not breastfeeding. (See Table 1)

Table 1. Distribution and Association of patients according to Demographic Profile (n=38)

Demography		Less Seroma (n=29)	More Seroma (n=9)	P-Value
Age Group	31 to 40	9	1	0.180
	41 to 50	11	3	
	51 to 60	6	5	
	Above 60	3	0	
Diet	Mixed	8	4	0.572
	Veg	21	5	
Number ofChildren	2	15	2	0.102
	3	13	5	
	4	1	2	
Age of Menarche	10	6	0	0.193
	11	19	6	
	12	4	3	
Menstrual Cycle	Irregular	5	1	0.660
	Regular	4	8	
Menopause Attained	No	22	6	0.584
	Yes	7	3	
Hysterectomy	No	27	8	0.682
	Yes	2	1	
Breast Feeding	No	1	0	0.572
	Yes	28	9	

The study showed significant associations between several risk factors and seroma formation among the 38 patients. Specifically, smoking, hypertension, BMI, and neoadjuvant chemotherapy/radiation were highly significant, with P-values of 0.0001 each, indicating that patients with these conditions were more likely to develop seroma. Diabetes mellitus and dense breast tissue were also significant, with P-values of 0.044 and 0.040 respectively, suggesting an increased risk of seroma formation. In contrast, oral contraceptive pills/hormone replacement therapy (OCPs/HRT) and radiation exposure did not show significant associations with seroma formation, with P-values of 0.314 and 0.572 respectively. Overall, the results highlight that certain risk factors, particularly those related to lifestyle and pre-existing health conditions, play a crucial role in the likelihood of seroma development. (See Table 2)

Table 2. Association between Risk Factors and Seroma Formation (n=38)

Risk Factors		Less Seroma	More Seroma	P-Value
Smoking	No	27	3	**0.0001****
	Yes	2	6	
Hypertension	No	26	0	**0.0001****
	Yes	3	9	
BMI	< 25	27	0	**0.0001****
	≥ 25	2	9	
Diabetes Mellitus	No	23	4	**0.044***
	Yes	6	5	
Dense Breast	No	19	9	**0.040***
	Yes	10	0	
OCPs/HRT	No	26	9	0.314
	Yes	3	0	
Radiation Exposure	No	28	9	0.572
	Yes	1	0	
Neoadjuvant Chemo Radio	No	26	0	**0.0001****
	Yes	3	9	

The results indicate that at axillary sampling, all 6 patients experienced less seroma formation, with none experiencing more. At Level 2 dissection, 22 patients had less seroma formation, again with no patients experiencing more. However, at Level 3 dissection, only 1 patient had less seroma formation, while 9 patients experienced more seroma formation. (See Figure 1) The Chi-square test revealed a highly significant difference with a P-value of 0.00001, demonstrating that the extent of lymph node dissection plays a crucial role in the likelihood of seroma formation. This strong association underscores the impact of surgical extent on postoperative outcomes.

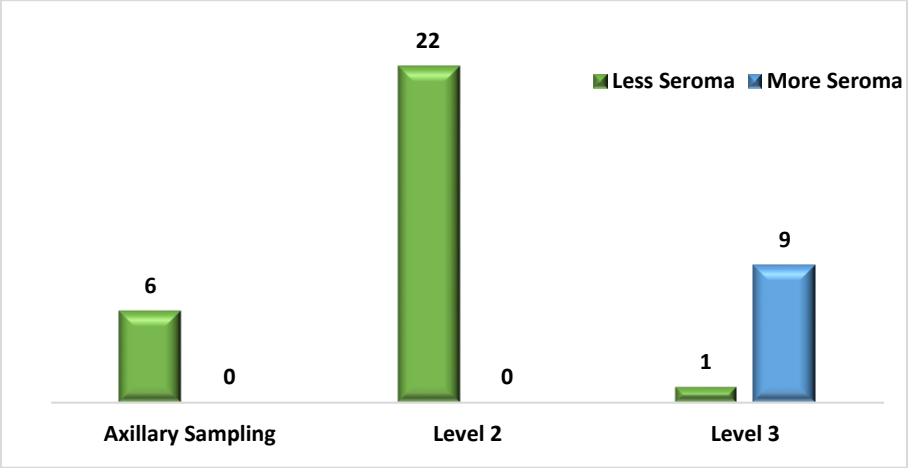

Figure 2. Association between MRM level of dissection and Seroma Formation (n=38)

Flap necrosis and surgical site infections were strongly associated with seroma formation, as all patients without these complications had less seroma, while those with the complications had more, with P-values of 0.0001 for both. The duration until drain removal and the number of hospital admission days also showed highly significant associations, with P-values of 0.00001 each. Patients who had drains removed within 6-10 days and were hospitalized for the same period had less seroma formation, whereas those requiring 11-15 days had more seroma. Drain output on postoperative days (POD) 2 and 7 were significantly associated with seroma formation, with P-values of 0.0001 for both, indicating that patients with lower drain output (≤50 ml) had less seroma. On POD 14, however, the association could not be calculated due to the absence of data for seroma formation among patients with more than 50 ml output. Overall, these results underscore the critical impact of postoperative complications and management on seroma formation, highlighting the need for careful monitoring and timely intervention.

Table 3. Association between Complications and Seroma Formation (n=38)

Complications		Less Seroma	More Seroma	P-Value
Flap Necrosis	No	29	5	**0.0001****
	Yes	0	4	
Surgical Site Infection	No	29	5	**0.0001****
	Yes	0	4	
Number of till drain removal	0-5	0	0	**0.00001****
	6-10	29	0	
	11-15	0	9	
	16-20	0	0	
Number of Hospital admission days	0-5	0	0	**0.00001****
	6-10	29	0	
	11-15	0	9	
	16-20	0	0	
Drain output (POD 2)	≤50 ml	29	0	**0.0001****
	>50ml	0	9	
Drain output (POD 7)	≤50 ml	14	0	**0.0001****
	>50ml	0	3	
Drain output (POD 14)	≤50 ml	0	3	Not calculated
	>50ml	0	0	

DISCUSSION

Breast cancer is one of the leading causes of death among women. Modified radical mastectomy (MRM) involves the removal of the entire breast, overlying skin, areola, nipple, and most axillary lymph nodes, and often leads to seroma formation, a common postoperative complication. Careful surgical techniques are essential to minimize blood vessel and lymphatic leakage, thereby reducing seroma formation. This prospective analytical study, involving 38 patients, aimed to assess the effectiveness of using GELFOAM in reducing seroma formation post-MRM.

The mean age of patients was 47.86 ± 9.23 years. The majority were aged 41-50 (36.8%), followed by 51-60 (28.9%), and above 60 (7.9%). The study found no significant difference in seroma formation across demographic variables such as diet, number of children, age of menarche, age at first childbirth, menstrual cycle regularity, menopause status, and breastfeeding practices. These findings align with studies by Elshahidy et al.[9] and Hashemi et al.,[10] where the mean patient ages were 45.5 and 46.3 years, respectively. A significant association with seroma formation was observed for smoking, diabetes, dense breast tissue, neoadjuvant chemo-radiotherapy, hypertension, and BMI. These findings are supported by studies from Liu et al.,[11] Fan et al.,[12] and Kumar et al.,[13] which highlight the impact of BMI and hypertension on seroma formation.

The extent of lymph node dissection played a major role in seroma formation. Most patients (57.9%) underwent Level 2 dissection, followed by Level 3 (26.3%) and axillary sampling (15.8%). The extent of dissection, lymphatics cut, and free space created were critical factors in seroma formation. Hashemi et al.'s study further supports this, indicating a 2.5 times higher risk of seroma formation with MRM compared to breast preservation.[10]

In this study, 23.7% of cases had more seroma formation, 10.5% had flap necrosis, and 13.2% had surgical site infections (SSI). Drain output was less than 50 ml in most cases on POD 2 (76.3%) and POD 7 (92.1%). Hospital stays and the duration until drain removal was also associated with seroma formation, with shorter durations linked to a reduced seroma. These findings are consistent with studies by Faisal et al.[14] and Elshahidy et al.,[9] which reported shorter drain duration and lower complication rates with alternative techniques like harmonic dissection.

The use of GELFOAM in MRM resulted in a decrease in seroma volume for 76.3% of patients, while 23.7% experienced increased volume despite GELFOAM use. This aligns with Elshahidy et al.'s findings, which showed a reduction in seroma cases with GELFOAM application.[9] Similar results were reported by Porter et al.[15] and Akinci et al.,[16] demonstrating the effectiveness of various techniques in reducing seroma formation.

Various approaches have been used to prevent seroma formation, including closing the dead space under the mastectomy skin flap by suturing, delaying shoulder exercises during the recovery phase, using external compression dressings, ultrasound cutting devices, or suction drainage systems, applying bovine thrombin during surgery, tetracycline sclerotherapy, talc poudrage and using fibrin sealant. Under our study, Elshahidy et al. reported that seroma formation was detected in 10% of all cases.[9] The use of GELFOAM under mastectomy flaps during modified radical mastectomy led to decreased seroma formation postoperatively, with statistically significant differences between groups. Porter et al. showed that seroma was formed in 38% of wounds in the electrocautery group compared to 13% in the scalpel group. Similarly, Akinci et al. observed that 3 out of 45 patients developed seroma with flap fixation, whereas 15 out of 35 patients

without flap fixation developed seroma.[16] Pabri et al. found that the incidence of seroma formation was 19% in patients who underwent MRM using a harmonic scalpel compared to electrocautery.[17]

However, it is important to note the limitations of this study. It was conducted at a single center, and the sample size was not sufficiently large to validate the findings fully. Further research with larger sample sizes and multiple centers is necessary to confirm these results and improve the generalizability of the findings.

CONCLUSION

Utilizing GELFOAM during modified radical mastectomy has proven to be an effective technique for significantly reducing both the occurrence and volume of seroma formation. This method not only enhances patient recovery by minimizing seroma-related complications but also facilitates the early removal of suction drains. Consequently, incorporating the use of GELFOAM as a standard step at the end of modified radical mastectomy is highly recommended to improve postoperative outcomes and patient comfort.

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