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Original Research Article

Comparison of Seroma Formation in First 72 Hours with and Without Placement of Gel Foam in the Axilla Following Axillary Dissection

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Abstract: *Seroma formation is a common early postoperative complication following modified radical mastectomy with axillary dissection. Although not life-threatening, it can cause wound morbidity, delay adjuvant therapy, and increase healthcare visits. Various techniques have been proposed to reduce seroma, including quilting sutures, arm immobilization, and pharmacologic agents. Gel foam, a homeostatic and space-occupying material, may reduce dead space and fluid accumulation, but evidence regarding its effectiveness remains limited.* ***Objective:*** *To compare the frequency of seroma formation within the first 72 hours following axillary dissection in patients with and without gel foam placement.* ***Methods:*** *A randomized controlled trial was conducted at the Department of General Surgery, Sir Ganga Ram Hospital, Lahore from 16 November 2024 to 16 May 2025. A total of 124 female patients aged 18–60 years undergoing modified radical mastectomy were enrolled and randomized into two groups: Group A (gel foam, n=62) and Group B (no gel foam, n=62). Baseline characteristics including age, BMI, tumor stage, and number of axillary nodes were recorded. Postoperative outcomes assessed were seroma formation within 72 hours and drain output. Data were analysed using SPSS v25; continuous variables were compared with independent t-tests, and categorical variables were analysed with chi-square tests. A p-value ≤0.05 was considered significant.* ***Results:*** *The frequency of seroma formation was significantly lower in the gel foam group compared to controls (6.5% vs. 17.7%, p=0.04). Both flap and axillary drain outputs in the first 72 hours were significantly reduced in patients receiving gel foam (p<0.001). No significant difference was observed in other postoperative complications, including wound infection, hematoma, or flap necrosis. Baseline characteristics were comparable between groups.* ***Conclusion:*** *Gel foam placement in the axilla following axillary dissection significantly reduces early postoperative seroma formation and drain output without increasing other complications. This simple, safe, and effective intervention may improve postoperative recovery and reduce morbidity in patients undergoing modified radical mastectomy.*

Keywords: Breast Cancer, Modified Radical Mastectomy, Seroma, Gel Foam, Axillary Dissection

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Introduction

Breast cancer is the most common malignancy among women worldwide, representing a significant public health concern. According to the GLOBOCAN report by WHO 2050, approximately 1.4 million women are diagnosed with breast cancer annually, with a rising trend in low- and middle-income countries (1). In Pakistan, one in every nine women is affected by breast cancer, the highest prevalence in Asia, often presenting at an advanced stage due to limited healthcare resources, low awareness of self-examination, high illiteracy rates, and inadequate access to early screening programs (2, 3). Advanced-stage disease in younger women poses additional challenges, often leading to poorer prognosis and increased treatment-related morbidity (4).

Surgery remains the cornerstone of breast cancer management, with Modified Radical Mastectomy (MRM) being the most frequently performed procedure in patients with operable disease (5). Despite advances in surgical techniques, early postoperative complications remain common, including wound infection, flap necrosis, hematoma, lymphedema, chronic pain, and seroma formation (6). Among these, seroma defined as a sterile collection of fluid under the surgical flap or axilla is the most frequently observed complication, with reported incidences ranging from 10% to 85%. Although not life-threatening, seroma can cause significant morbidity, including wound dehiscence, flap necrosis, prolonged recovery, multiple hospital visits, and delayed initiation of adjuvant therapy (7, 8).

Multiple strategies have been explored to reduce seroma formation, such as flap fixation with quilting sutures, arm immobilization, negative-pressure wound therapy, and pharmacological interventions like tranexamic acid. However, these approaches have shown variable effectiveness and may be associated with additional costs or patient discomfort (9). Gel foam, a biodegradable hemostatic agent, has been studied in limited settings as a potential intervention to reduce postoperative seroma (10). A study in previous study reported a reduction in seroma formation from 17.5% to 2.5% with gel foam placement in the axilla following MRM. Despite these promising results, there is a paucity of evidence from randomized controlled trials comparing seroma formation with and without gel foam, particularly in the Pakistani population (11, 12).

Currently, no comprehensive study has systematically evaluated the efficacy of gel foam placement in the axilla to reduce early seroma formation in patients undergoing MRM in Pakistan. Understanding its effectiveness could provide a simple, cost-effective strategy to reduce postoperative morbidity and improve patient outcomes. This study aims to address this gap by comparing the frequency of seroma formation within the first 72 hours postoperatively in patients undergoing axillary dissection with and without gel foam placement.

Methodology

This randomized controlled trial was conducted in the Department of General Surgery at Sir Ganga Ram Hospital, Lahore, over a period of six months following approval from the Institutional Review Board (IRB) from 16 November 2024 to 16 May 2025. The study included a total of 124 female patients diagnosed with breast carcinoma who were scheduled for Modified Radical Mastectomy (MRM). Patients were randomly allocated into two equal groups (n=62 each) using a lottery method. The

sample size was calculated based on a 95% confidence level, 80% power, and an expected seroma incidence of 2.5% with gel foam placement compared to 17.5% without gel foam, as reported in previous studies.

Eligible participants were female patients aged 18 to 60 years, with a confirmed diagnosis of breast carcinoma via fine-needle aspiration and scheduled for MRM. Patients with a history of neoadjuvant therapy, recurrent or metastatic breast cancer, tumors adherent to the pectoralis major muscle, ASA physical status grade ≥3, hemoglobin levels below 8 mg/dl, or pregnancy were excluded from the study. All patients underwent standard MRM performed by the same surgical team to minimize procedural variability. In Group A, gel foam was placed in the axilla following axillary dissection, while in Group B, no gel foam was used. Two drains, one in the flap and one in the axilla, were placed in all patients, and wounds were closed in layers with aseptic pressure dressings applied. Drains were removed once the output fell below 25 mL per 24 hours. Baseline patient data including age, body mass index (BMI), tumor stage, tumor type, and number of axillary lymph nodes were documented. Patients were followed up at 72 hours postoperatively, and seroma formation was assessed using ultrasonography, defined as a sterile fluid collection beneath the flap or in the axilla. Any postoperative complications, including seroma, wound infection, hematoma, or flap necrosis, were recorded and managed appropriately.

Data were analysed using SPSS version 25. Continuous variables, including age, BMI, and number of axillary lymph nodes, were expressed as mean ± standard deviation, while categorical variables such as tumor stage, tumor type, and seroma formation were presented as frequencies and percentages. Stratification was performed for age, BMI, number of axillary nodes, and tumor characteristics, followed by post-stratification chi-square tests to determine the association between gel foam placement and seroma formation. A p-value of ≤0.05 was considered statistically significant.

Results

A total of 124 patients were included in the study, with 62 patients in the Gel Foam group (Group A) and 62 patients in the control group without Gel Foam (Group B). The baseline demographic and tumor-related characteristics were well balanced between the Gel Foam group and the control group. There were no statistically significant differences in age, body mass index, tumor stage, tumor histology, or number of axillary lymph nodes dissected (all $p > 0.05$). This comparability indicates successful randomization and minimizes the likelihood that baseline differences influenced postoperative outcomes. Consequently, any observed differences in postoperative results can be reasonably attributed to the intervention rather than confounding patient or disease-related factors in Table 1.

Early postoperative seroma formation was significantly less frequent in patients who received Gel Foam placement following axillary dissection compared to those who did not. The incidence of seroma was 6.5% in the Gel Foam group versus 17.7% in the control group ($p = 0.04$). This finding suggests that Gel Foam is effective in reducing early postoperative seroma formation, likely by promoting hemostasis and reducing dead space within the axilla during the immediate postoperative period in Table 2.

Patients in the Gel Foam group demonstrated significantly lower postoperative drain outputs during the first 72 hours after surgery. Both flaps drain output and axillary drain output were reduced compared to the control group ($p = 0.001$ and $p < 0.001$, respectively). These results indicate decreased postoperative fluid accumulation in patients treated with Gel Foam, supporting its role in limiting lymphatic leakage and serous fluid collection following axillary dissection in Table 3.

The rates of postoperative complications other than seroma—including wound infection, hematoma, and flap necrosis—were low and did not differ significantly between the two groups (all $p > 0.05$). This finding indicates that the use of Gel Foam does not increase the risk of postoperative morbidity and appears to be a safe adjunct in axillary dissection procedures in fig 1.

The findings of this study demonstrate that Gel Foam placement following axillary dissection significantly reduces early postoperative seroma formation and postoperative drain output without increasing the risk of surgical complications. These results support the use of Gel Foam as a safe and effective measure to improve early postoperative outcomes after axillary surgery.

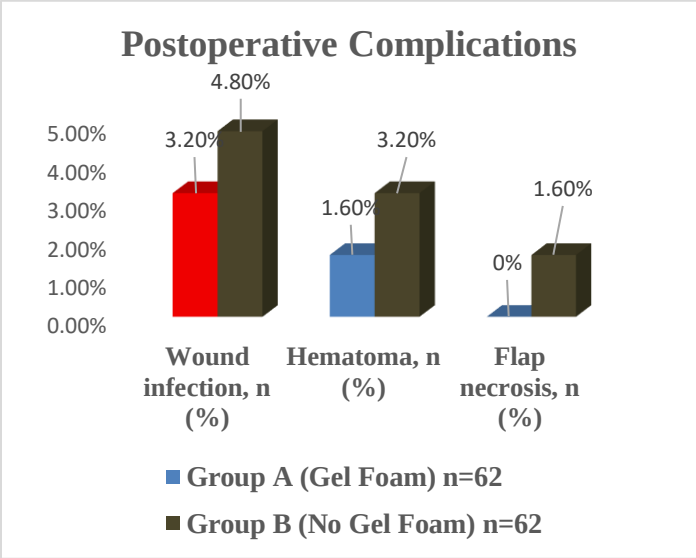

Figure 1. Postoperative Complications (Other than Seroma)

Table 1: Baseline Characteristics

Variable	Group A (Gel Foam) n=62	Group B (No Gel Foam) n=62	p-value
Age (years), mean ± SD	47.2 ± 8.5	46.8 ± 9.0	0.74
BMI (kg/m²), mean ± SD	27.5 ± 3.2	27.8 ± 3.0	0.62
Number of axillary nodes, mean ± SD	8.2 ± 2.5	8.5 ± 2.8	0.55
Tumor stage (I/II/III)	15 / 30 / 17	14 / 32 / 16	0.91
Tumor type (Invasive Ductal/Invasive Lobular)	55 / 7	53 / 9	0.61

Table 2: Postoperative Seroma Formation within 72 Hours

Outcome	Group A (Gel Foam) n=62	Group B (No Gel Foam) n=62	p-value
Seroma formation, n (%)	4 (6.5%)	11 (17.7%)	0.04*

Table 3: Drain Output in First 72 Hours

Outcome	Group A (Gel Foam)	Group B (No Gel Foam)	p-value
Flap drain output	75 ± 20	95 ± 25	0.001*
Axillary drain output	60 ± 15	82 ± 18	<0.001*

Discussion

In the present study, the frequency of seroma formation within the first 72 hours after axillary dissection was significantly lower in patients who received gel foam placement compared to those without gel foam (6.5% vs. 17.7%, p = 0.04). Similarly, the mean drain output in the first 72 hours, both from the flap and axillary sites, was significantly reduced in the gel foam group. These findings suggest that gel foam is effective in minimizing early postoperative fluid accumulation and may reduce the morbidity associated with seroma formation (13, 14).

Seroma is a common early postoperative complication following modified radical mastectomy and axillary dissection, reported in up to 15–40% of cases in various studies (14). Although seroma is rarely life-threatening, it can lead to wound dehiscence, flap necrosis, prolonged hospital stays, repeated aspirations, and delay in adjuvant therapy. Therefore, preventive measures to reduce seroma formation are clinically important (15, 16).

The use of gel foam, a hemostatic and space-occupying material, appears to reduce dead space and stabilize lymphatic channels, thereby decreasing fluid accumulation. Our results are consistent with the previous study, who reported a reduction in seroma formation from 17.5% in the control group to 2.5% in the gel foam group following mastectomy (17). Similarly, reduced drain output in the gel foam group aligns with findings by previous report, indicating that interventions targeting dead space can effectively reduce early postoperative drainage (18).

Interestingly, there was no significant difference between the groups in terms of other postoperative complications, such as wound infection, hematoma, or flap necrosis. This demonstrates that gel foam placement is safe and does not increase the risk of adverse outcomes. This finding corroborates previous reports that the use of absorbable hemostatic agents does not compromise wound healing or increase infection risk (19).

The current study adds to the limited body of literature regarding the use of gel foam in axillary dissection. Most previous studies have focused on quilting sutures, immobilization, or pharmacologic agents such as tranexamic acid for seroma prevention (20). By demonstrating a clear reduction in seroma formation and drain output, our study highlights gel foam as a simple, safe, and effective adjunct to standard surgical technique (21).

Limitations of this study include the relatively short follow-up period (72 hours) and the single-centre design, which may limit generalizability. Future multicentre studies with longer follow-up are recommended to assess delayed seroma formation and impact on overall recovery and quality of life..

Conclusion

In conclusion, gel foam placement in the axilla following axillary dissection significantly reduces early postoperative seroma formation and drain output without increasing complications. This intervention can be considered a practical and effective strategy in patients undergoing modified radical mastectomy.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-SGRH/2323-24)

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

AA (PGR), KMG (VC)
Designed the study, collected the data, analyzed the results, and wrote the major part of the manuscript.
Contributed to the study design and supervised the research work.
SA (PGR), AA (PGR), NF (PGR)
Contributed to data collection and literature review.
Assisted in data collection.
Also contributed to data collection.

All authors reviewed the manuscript, approved the final version, and agreed to be accountable for all aspects of the work.

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