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COMPARISON OF ONE VERSUS TWO DRAINS FOR MANAGEMENT OF SEROMA FORMATION IN PATIENTS UNDERGOING MODIFIED RADICAL MASTECTOMY: A QUASI-EXPERIMENTAL STUDY

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ABSTRACT

Background: Postoperative seroma represents the most frequent early complication following modified radical mastectomy (MRM), posing significant morbidity, and its persistence can prolong wound healing and postpone the initiation of adjuvant therapy.
Objective: To evaluate, in women undergoing modified radical mastectomy for breast carcinoma, whether one axillary drain produces a different incidence of postoperative seroma compared with the placement of two drains.
Methods: This quasi-experimental trial study was undertaken at the Surgical Units of the Department of General Surgery, Jinnah Hospital, Lahore from January 2026 and April 2026. Sixty-four patients with biopsy-confirmed breast carcinoma were enrolled and allocated in alternating sequence to Group A, receiving a single axillary suction drain (n = 32), or Group B, receiving two drains placed in the axilla and beneath the mastectomy flap (n = 32). All cases were followed for 30 postoperative days; seroma was diagnosed clinically and confirmed sonographically. Continuous variables were analysed using the independent-samples t-test, and categorical variables using the chi-square or Fisher's exact test. Significance was set at $p \leq 0.05$.
Results: The two arms were comparable for all baseline and intraoperative parameters ($p > 0.05$). Seroma developed in 8 patients (25.0%) in Group A and 6 patients (18.8%) in Group B, without statistical significance ($p = 0.763$). Cumulative drain output (423 ± 84.7 vs 460 ± 79.6 mL, $p = 0.074$) and drain removal day (5.62 ± 2.20 vs 5.42 ± 2.05, $p = 0.721$) were similar. Postoperative pain on day one was significantly higher in Group B (VAS 4.6 ± 1.4 vs 3.8 ± 1.2, $p = 0.018$).
Conclusion: A single axillary drain after MRM is comparable to dual-drain placement for seroma control while reducing pain and cost.

KEYWORDS: Modified radical mastectomy; Seroma; Drain placement; Breast cancer; Postoperative complication

INTRODUCTION

Breast carcinoma remains the most common cancer in women in the world [1]. Globally, an estimated 685,000 women died, and 2.3 million new cases were reported during 2020 [2, 3]. This epidemiological burden is also unequally shared among the developing countries and Pakistan is particularly burdened. Breast cancer is the most common cancer among women in Pakistan, as revealed by the national cancer registry records from 1994 to 2021, which showed that its incidence rate in women was 24.2% [4]. The incidence of this disease is higher in Pakistan than in any other Asian country, with an estimated 90,000 new cases and nearly 40,000 deaths reported annually [5, 6]. Most women present with locally advanced T3 and T4 disease at tertiary referral centres [7]. This trend of late presentation also puts a significant burden on health services with limited resources and capacity. Although patients also present early with small lumps, yet in resource-limited countries like Pakistan, breast-conserving surgery is not always an option [8], and modified radical mastectomy (MRM) remains the most common surgical approach in such cases as well

. Seroma formation is the most common of the known postoperative complications of MRM. The collection occurs in the dead space created by the axillary clearance of nodal burden and the chest wall after the removal of the breast parenchyma. The reported incidence ranges widely, up to 71.1%, largely due to variations in case definition and detection modality [9]. The sequelae of this clinical picture are not insignificant. The following are reported risks associated with persistent seroma: postoperative pain, wound dehiscence, flap necrosis and delayed adjuvant chemotherapy or radiotherapy [10]. Several preventive measures have been tested, such as flap quilting sutures, compression dressings or closed suction drainage [11, 12]. Although closed-suction drain placement has long been practised to prevent post-surgical collections, the optimal number and location of drains after MRM remain controversial. Shaikh et al. reported a series of 77 patients, in which 21.1% of those with a single drain developed a seroma, compared with 23.8% with two drains, a difference that was not statistically significant [13]. The opposite trend was reported by Khan et al., who found that the one-drain group had a 13.4% seroma rate and the two-drain group a 6.1% seroma rate, which was not significant [14]. The trials were performed in different patient cohorts in the Northwest of Pakistan and internationally, with varying demographic and oncological backgrounds. Evidence generated locally in Pakistan tertiary care hospitals for drainage decisions is limited. This study was thus conducted at Jinnah Hospital, Lahore, to compare the incidence of seroma formation in patients undergoing MRM who were treated with a single axillary drain versus those treated with two drains, one in the axilla and the other under the mastectomy flap.

METHODS

The present quasi-experimental study was conducted at the Surgical Unit-I, Department of Surgery, Jinnah Hospital, Lahore, between January 2026 and April 2026. Institutional Ethical Review Board approval was secured prior to commencement (Ref: ERB148/16/10-08-2023/5, dated 10th August 2023). The required sample size of 64 (32 per group) was derived from formula $n = \{ Z_{1-\alpha} \sqrt{[2\bar{P}(1-\bar{P})]} + Z_{1-\beta} \sqrt{[P_1(1-P_1) + P_2(1-P_2)]} \}^2 \div (P_1 - P_2)^2$, applied at $\alpha = 0.05$ with 80% statistical power, anticipated 21.1% seroma incidence in the single-drain arm [13] and 6.1% in the two-drain arm [14]. Recruitment used non-probability consecutive sampling.

Patients of either sex, between 25 and 65 years of age, presenting to the Outpatient Department with histologically confirmed breast carcinoma and clinically palpable axillary lymphadenopathy were screened for eligibility. Exclusion criteria comprised chest wall involvement (stage T4a), distant metastatic disease, inflammatory breast carcinoma, mastectomy requiring flap reconstruction, active sepsis at any site, coagulopathy or therapeutic anticoagulation, and any condition rendering the patient unfit for general anaesthesia. Patients who failed to complete the 30-day postoperative review were withdrawn and replaced sequentially to preserve the calculated sample size.

Group allocation proceeded in an alternating sequence according to the order of presentation: the first eligible patient was assigned to Group A, the second to Group B, the third to Group A, and so on, until the target enrolment was reached. The drain allocation remained concealed from the operating surgeon until completion of the mastectomy and axillary clearance, thereby ensuring that the operative steps were identical across both arms. Written informed consent was secured from each participant after counselling regarding the procedure and its potential complications. Drains were removed once the 24-hour output fell below 50 mL. All patients were reviewed in the outpatient clinic at scheduled intervals over a 30-day postoperative period for assessment of seroma. Postoperative pain was assessed on the first postoperative day using a 0–10 visual analogue scale (0 corresponding to no pain and 10 to the maximum pain intensity the patient perceived, the worst pain imaginable), recorded by the outcome assessor at the bedside prior to the morning analgesic dose. Seroma was operationally defined as a soft, fluctuant collection within the post-mastectomy dead space on clinical palpation, corroborated by an anechoic or hypoechoic fluid pocket on ultrasonography at any review within the 30 postoperative day period. [9, 12]. Modified radical mastectomy was defined as the en bloc resection of the entire breast together with overlying skin and the nipple-areolar complex, in continuity with the level I and level II axillary lymph nodes [8]. All procedures were performed by a team of three general surgery consultants, each with at least 5 years' operative experience in the index procedure. The skin incision was fashioned with a No. 15 surgical blade. Mastectomy flaps were elevated using monopolar diathermy, and the pectoral fascia was excised en bloc with the tumour specimen. Axillary clearance was performed with retraction of pectoralis major along its lateral edge, elevation of pectoralis minor, and dissection extended to level II. Intraoperative blood loss was quantified from the suction canister volume. Drain allocation was disclosed to the operating surgeon only after the mastectomy and axillary clearance had been completed, thereby preventing any divergence in operative technique between the two arms. Patients in Group A received a solitary closed-suction drain positioned in the axilla. Patients in Group B received two closed-suction drains, one sited in the axilla and the second beneath the inferior mastectomy flap. Closed-suction drainage was provided using 14-French (14G) Redivac-type drains connected to vacuum bottles, maintaining a negative pressure of 60 mmHg. Standard postoperative analgesia comprised intravenous paracetamol 1 g every 8 hours together with intravenous ketorolac 30 mg every 12 hours, with intravenous opioid analgesia reserved as rescue medication for breakthrough pain. All outcome assessments were conducted by a single outcome assessor who was not involved in the patients' surgical care.

All data were entered and processed using IBM SPSS Statistics, version 27.0. The Shapiro-Wilk statistic was applied to verify the assumption of normality for continuous variables. Given that the data met normality assumptions and the two arms were independent, the independent-samples test was selected for the between-group comparison of continuous variables. The chi-square test was employed for categorical comparisons; when any expected cell frequency was less than 5, Fisher's exact test was used to preserve the validity of inference. A two-sided p-value of ≤ 0.05 denoted statistical significance.

RESULTS

A total of 64 patients underwent the index procedure and completed the planned follow-up. The mean age was 41.50 ± 9.51 years in the single-drain arm (Group A) and 38.03 ± 7.33 years in the two-drain arm (Group B). Mean body mass index was 23.83 ± 2.99 kg/m² in Group A and 22.99 ± 1.96 kg/m² in Group B. None of the preoperative variables, namely ASA classification, TNM stage, hormone receptor status, menopausal status and use of neoadjuvant chemotherapy, differed significantly between the two arms (Table 1). Intraoperative parameters, including the number of axillary lymph nodes retrieved, resected specimen weight, estimated blood loss and operative duration, were also comparable across the groups.

Table 1: Baseline demographic, preoperative and intraoperative variables in both groups (mean ± SD or n (%)).

Variable	Group A (One Drain) n = 32	Group B (Two Drains) n = 32	p-value
Preoperative variables			
Age (years)	41.50 ± 9.51	38.03 ± 7.33	0.107[a]
BMI (kg/m²)	23.83 ± 2.99	22.98 ± 1.96	0.184[a]
ASA II	24 (75.0%)	25 (78.1%)	1.000[b]
ASA III	8 (25.0%)	7 (21.9%)	
TNM stage			1.000b
II	5 (15.6%)	5 (15.6%)	
III	27 (84.4%)	27 (84.4%)	
Clinical T stage			0.921[b]
T1	2 (6.2%)	3 (9.4%)	
T2	8 (25.0%)	7 (21.9%)	
T3	20 (62.5%)	19 (59.4%)	
T4b	2 (6.2%)	3 (9.4%)	
Clinical N stage			0.837[b]
N1	18 (56.2%)	20 (62.5%)	
N2	9 (28.1%)	7 (21.9%)	
N3	5 (15.6%)	5 (15.6%)	
ER positive	27 (84.4%)	26 (81.2%)	1.000[b]
PR positive	24 (75.0%)	25 (78.1%)	1.000[b]
HER2/neu positive	16 (50.0%)	14 (43.8%)	0.802[b]
Invasive ductal carcinoma (NST)	28 (87.5%)	27 (84.4%)	1.000[b]
Invasive lobular carcinoma	4 (12.5%)	5 (15.6%)	
Postmenopausal	22 (68.8%)	21 (65.6%)	1.000[b]
Neoadjuvant therapy	28 (87.5%)	28 (87.5%)	1.000[b]
Intraoperative variables			
Retrieved lymph nodes	12.94 ± 3.75	12.03 ± 3.36	0.312[a]
Resected specimen weight (g)	527 ± 129	510 ± 121	0.587[a]
Estimated blood loss (mL)	150 ± 28.5	162 ± 31.2	0.115[a]
Operative duration (min)	110 ± 18.4	106 ± 17.6	0.373[a]

[a] independent samples t-test
[b] Fisher's exact test

Cumulative drain output over the postoperative period averaged 423 ± 84.7 mL in Group A and 460 ± 79.6 mL in Group B; although the two-drain arm evacuated a numerically greater volume, the difference did not reach statistical significance (p = 0.074). The mean day of drain removal was comparable: 5.62 ± 2.20 days in Group A and 5.42 ± 2.05 days in Group B (p = 0.721). With respect to the primary outcome, postoperative seroma occurring at any time during the 30 days following surgery, eight patients (25.0%) in the single-drain arm and six patients (18.8%) in the two-drain arm were affected. The 6.2-percentage-point difference between the arms did not reach statistical significance (Fisher's p = 0.763; Figure 1). Haematoma was documented in one patient (3.1%) in each arm. Flap necrosis occurred in two patients (6.2%) in Group A and one patient (3.1%) in Group B. The mean visual analogue scale pain score on the first postoperative day was significantly lower in Group A than in Group B (3.8 ± 1.2 vs 4.6 ± 1.4, p = 0.018), with single-drain patients reporting reduced pain intensity (Table 2).

Table 2: Comparison of outcome variables between groups within 30 days postoperatively.

Outcome variable	Group A (One Drain)	Group B (Two Drains)	p-value
Total drain output (mL)	423 ± 84.6	460 ± 79.6	0.074a
Drain removal day	5.62 ± 2.20	5.42 ± 2.05	0.721[a]
VAS pain score (0–10)	3.8 ± 1.2	4.6 ± 1.4	0.018[a]
Seroma formation	8 (25.0%)	6 (18.8%)	0.763[b]
Haematoma	1 (3.1%)	1 (3.1%)	1.000[b]
Flap necrosis	2 (6.2%)	1 (3.1%)	1.000[b]

a independent samples t-test
b Fisher's exact test

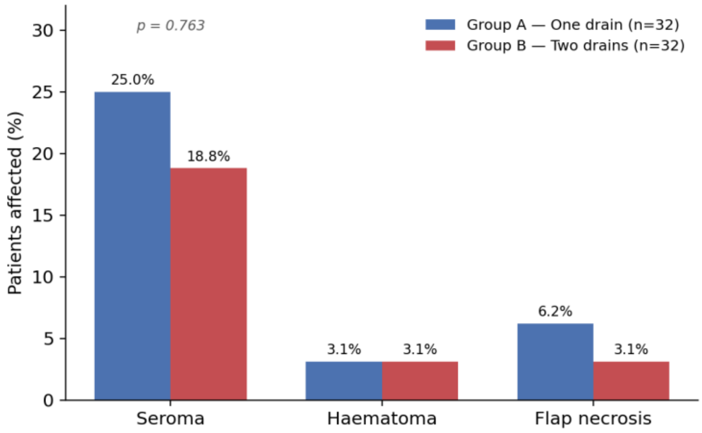

Figure 1. *Incidence of postoperative complications within 30 days, by drain group. Seroma, haematoma and flap necrosis did not differ significantly between the single-drain (Group A) and two-drain (Group B) arms (seroma 25.0% vs 18.8%, p = 0.763).*

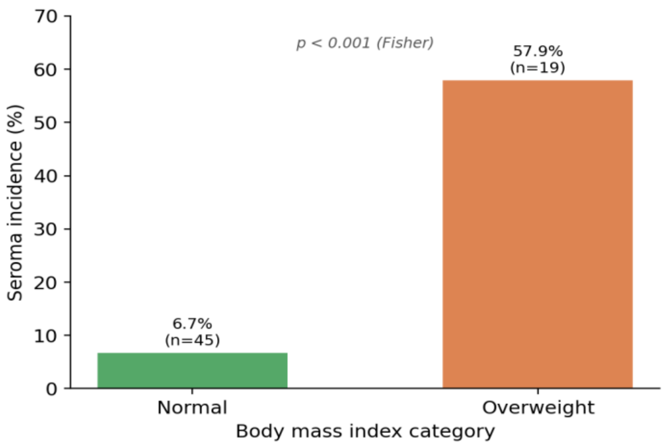

Figure 2. Seroma incidence stratified by body mass index category in the pooled cohort. Overweight patients had a markedly higher seroma rate than normal-weight patients (57.9% vs 6.7%, p < 0.001), identifying BMI as a significant risk modifier independent of drain number.

DISCUSSION

The rising incidence of breast carcinoma in Pakistan, combined with the predominance of locally advanced disease at presentation, continues to make modified radical mastectomy a frequently performed oncological procedure. Postoperative seroma is one of the major causes of morbidity in this group of patients. This complication can be reduced with suction drainage, but the number of drains to use remains controversial. The seroma incidence was 25.0% in the single-drain arm and 18.8% in the two-drain arm in the present cohort. This difference was not statistically significant ($p = 0.763$). Baseline demographic characteristics and TNM staging were similar between the two arms. To reduce performance bias, all procedures were performed by surgeons with 5 or more years of operative experience, and the allocation of drains was revealed only to the operating surgeon after the mastectomy and axillary clearance were completed. This result is supported by the published literature. Shaikh et al. reported no significant difference in seroma rates between single- and double-drainage (21.1% and 23.8%, respectively) [13]. In a similar study, Khan et al. reported a marginally higher incidence of seroma (13.4% vs 6.1%; $p = 0.07$) and a significant difference in postoperative pain (mean 2.5 vs 5.22; $p < 0.001$) between single-drain and double-drain patients [14]. This was further extended by Bhagchandani et al., who reported that single axillary drain and flap quilting resulted in a lower seroma rate than the conventional axillary-plus-pectoral drain arrangement (23% vs 58%) in a 76-patient trial, with the added benefit of a shorter hospital stay [15]. The combined results of these trials and the current results suggest that a second drainage is not of significant value in controlling seroma.

The incidence of seroma after MRM has been reported in different ranges in various publications. In a prospective cohort from Brazil, Fabro et al. reported a seroma rate of 71.1%, accounting for most patients who developed a seroma and required 2 or more aspirations [9]. The incidence of seroma in the present series was compared with that reported in a study conducted at a tertiary centre in Rawalpindi, Pakistan, which found seroma in 23% of patients managed with a single drain [16]. This large difference in seroma rates across different parts of the world could be explained by variations in case definition, detection methods, the extent of axillary lymphadenectomy, patient BMI, or the protocol for drain management. Case-mix differences between our two arms were not statistically significant and therefore are unlikely to explain the lack of difference in seroma rate.

The anatomical rationale for the placement of two drains is based on the idea that there are two distinct dead spaces in the axilla after lymphadenectomy and between the mastectomy flap and the chest wall, and thus, a second drain placed below the flap, if it were placed, should drain this subfascial space more effectively. The findings from the present study do not support this. Although the addition of a sub-flap drain in Group B produced a numerically greater cumulative output (460 ± 79.6 vs 423 ± 84.7 mL, $p = 0.074$), this did not translate into any reduction in seroma formation, and the day of drain removal was similar between the arms. The extra volume captured by the second drain, therefore, appears to reflect the presence of the additional drain itself rather than a genuine reduction in dead-space exudate. Intraoperative haemostatic technique during axillary clearance may have a greater effect on postoperative drains than the number of drains. Gambardella et al. showed that using advanced bipolar energy devices for tissue reduction instead of electrocautery decreased the rate of dead-space exudate from 64% to as low as 16%, indicating that dead-space exudate rate is more affected by intraoperative tissue dissection techniques and tissue handling than by the geometry of postoperative drainage methods [17]. The extra drain also came at a cost. The mean first-day postoperative pain scores were significantly higher in Group B (VAS 4.6 ± 1.4) than in Group A (3.8 ± 1.2; $p = 0.018$), most likely due to irritation at the additional skin exit site and the increased dressing burden.

On post hoc analysis, seroma was substantially more frequent in overweight patients than in those of normal weight (57.9% vs 6.7%, $p < 0.001$; Figure 2). This is similar to Fabro et al., who found that obesity and axillary lymphadenectomy were independent risk factors for seroma, and to Borg et al., who found that an elevated BMI ≥26.5 kg/m^2 increased the risk of seroma [18]. Risk factors were also summarised in a literature review by Mrad et al., who conducted a meta-analysis across breast surgery, and these risk factors were consistent with those reported in the literature, including BMI, diabetes mellitus, and hypertension [19]. BMI thus constitutes a clinically significant risk modifier. As BMI was balanced between our two arms, it did not confound the between-group comparison.

A concern frequently raised against routine two-drain placement is that the additional exit site may provide a portal for ascending infection, thereby increasing surgical site infection rates and delaying wound healing. The present data did not corroborate this concern. Rates of surgical site infection were comparable in both arms, and the mean day of drain removal was similar between groups (5.62 vs 5.42 days, $p = 0.721$). Wen et al. conducted a multicentre, three-arm randomised trial and demonstrated that lowering the drain removal threshold to 20 mL per 24 hours improved quality of life and reduced seroma events without increasing complications, indicating that removal criteria may be modified safely [20]. The network meta-analysis of Spiekerman van Weezelenburg et al. compared ten different techniques for seroma prevention following axillary clearance and concluded that continuing drainage until 24-hour output falls under 50 mL on two successive days produces the lowest rate of clinically significant seroma, with no incremental benefit from energy devices, padding, tissue adhesives or absorbent patches [21]. A UK national practice survey conducted by Fairhurst et al. reported that 85% of breast surgeons routinely place drains after mastectomy, while two-thirds of respondents felt that a formal randomised trial remained necessary to guide practice [10]. Roy et al., in a prospective dual-arm study from India, similarly observed that single-drain placement permitted earlier drain removal and improved patient compliance, with comparable seroma rates between groups [22]. A systematic review by Shima et al. confirmed that prolonged drainage is associated with reduced seroma risk, supporting the practice of retaining the drain until the 24-hour output falls below 50 mL rather than early removal [23]. Pharmacological adjuncts have also been investigated in our region. Fatima et al. reported that a single intravenous dose of hydrocortisone administered at induction reduced seroma incidence from 31.58%, and Ahmed et al. demonstrated that tranexamic acid reduced both drain output and seroma incidence after MRM [24, 25]. These low-cost adjuncts can be combined with single-drain placement in resource-limited settings without altering the basic operative technique. Blinding of the operating surgeon to drain allocation until completion of the mastectomy and axillary clearance further minimised performance bias between the two arms.

A quasi-experimental design was used, with patients allocated by arrival order rather than randomization. Although three surgeons performed procedures in both groups using the same equipment, minor variations in surgical technique may have occurred. The sample size of 64 patients was adequate for the primary outcome but limited the ability to detect differences in uncommon complications. Follow-up was restricted to 30 days, so late or persistent seroma and other long-term outcomes were not assessed. Larger multicentre studies with extended follow-up are recommended.

CONCLUSION

In the surgical management of breast carcinoma, postoperative wound drainage remains an integral step for minimising seroma formation after modified radical mastectomy, since unresolved seroma contributes to patient morbidity and may delay the initiation of adjuvant chemotherapy. In the present cohort, a single axillary drain proved equivalent to dual-drain placement in controlling seroma. The single-drain approach also yielded lower postoperative pain scores and is more cost-effective, supporting its adoption as the preferred drainage strategy for routine surgical practice.

Authors Contribution

Dr. Fahad Qayyum: Conceived and designed the study, developed the protocol, supervised study conduct, performed data analysis and interpretation, drafted the manuscript, approved the final version, and accepts responsibility for the integrity and accuracy of the work.

Prof. Farooq Ahmed Rana: Contributed to study design and interpretation of results, provided scientific supervision, critically reviewed and revised the manuscript for important intellectual content, approved the final version, and accepts responsibility for the integrity and scientific validity of the work.

Dr. Muhammad Saud Iqbal: Participated in study design, patient recruitment, data collection including postoperative drain output, seroma volume, pain assessment, and length of hospital stay, contributed to manuscript revision, approved the final version, and accepts responsibility for the accuracy of the work.

Dr. Muhammad: Participated in patient recruitment and data collection, maintained study records and follow-up data, measured outcome variable of pain, contributed to data interpretation and manuscript drafting, approved the final version, and accepts responsibility for the integrity of the work.

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