International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Active versus Passive Drainage Following Modified Radical Mastectomy for Breast Carcinoma: A Randomized Controlled Trial

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Received: 07-04-2026
Accepted: 30-05-2026
Available online: 16-06-2026

ABSTRACT

Background: Seroma formation remains one of the most common postoperative complications following modified radical mastectomy (MRM) for breast carcinoma. Closed suction drainage is routinely employed to reduce fluid accumulation; however, the optimal drainage method remains controversial. This study compared the effectiveness of active suction drainage and passive drainage following MRM in terms of postoperative drainage characteristics, complications, and recovery outcomes.

Materials and Methods: This prospective randomized controlled trial was conducted in the Department of General Surgery (Trauma and Emergency), Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar, India. Fifty female patients with operable breast carcinoma undergoing MRM were randomly allocated into two groups: active drainage (n=25) and passive drainage (n=25). Postoperative drain output, duration of drain placement, length of hospital stay, seroma formation, aspirated seroma volume, surgical site infection, and flap necrosis were evaluated. Statistical analysis was performed using SPSS version 25.0, and a p-value <0.05 was considered statistically significant.

Results: Baseline demographic, clinical, and pathological characteristics were comparable between the two groups. Postoperative drain output was similar between the active and passive drainage groups throughout the postoperative period. On postoperative day 1, the mean drain output was 112.4±21.3 mL in the active drainage group and 104.6±20.4 mL in the passive drainage group (p=0.18). On postoperative day 2, the corresponding values were 168.8±28.1 mL and 161.4±30.2 mL, respectively (p=0.37). No statistically significant differences were observed in daily drain output at any postoperative time point. Although cumulative drain output was higher in the active drainage group (800.3±128.6 mL) than in the passive drainage group (745.4±115.2 mL), the difference was not statistically significant (p=0.11). The duration of drain placement, length of hospital stay, seroma formation, surgical site infection, flap necrosis, and aspirated seroma volume were also comparable between the groups (p>0.05 for all comparisons).

Conclusions: Conclusions: Passive drainage demonstrated postoperative outcomes similar to active suction drainage following modified radical mastectomy, with no statistically significant differences in drain output, duration of drainage, hospital stay, seroma formation, or wound-related complications. Passive drainage may therefore serve as a simple and practical alternative for postoperative management after MRM.

Keywords*:* Breast carcinoma; Modified radical mastectomy; Active drainage; Passive drainage; Seroma; Surgical site infection.

INTRODUCTION

Breast cancer is the most commonly diagnosed malignancy among women worldwide and remains a leading cause of cancer-related morbidity and mortality. According to the Global Cancer Observatory (GLOBOCAN) 2020 estimates, breast cancer accounted for approximately 11.7% of all newly diagnosed cancer cases globally, surpassing lung cancer and becoming the most frequently diagnosed cancer worldwide [1]. The burden of breast cancer is steadily increasing in low- and middle-income countries, including India, where changing lifestyle patterns, urbanisation, delayed childbearing, and improved life expectancy have contributed to a rising incidence of the disease. Despite advances in screening and awareness programmes, a significant proportion of Indian patients continue to present with locally advanced breast cancer, necessitating mastectomy-based surgical treatment [2]. Surgery remains the cornerstone of curative treatment for operable breast carcinoma and is often integrated with chemotherapy, radiotherapy, hormonal therapy, and targeted therapy as part of a multidisciplinary treatment approach. Modified Radical Mastectomy (MRM) continues to be one of the most commonly performed surgical procedures in many tertiary care centres across India, particularly in patients with large tumours, multicentric disease, locally advanced breast cancer, or when breast-conserving surgery is not feasible. Although refinements in surgical techniques have reduced perioperative morbidity and improved oncological outcomes, postoperative complications continue to pose challenges for both surgeons and patients. Among the various postoperative complications following MRM, seroma formation remains the most frequent and clinically significant. Seroma is defined as the accumulation of serous fluid within the dead space created after breast and axillary tissue dissection. The reported incidence ranges from 15% to 60%, depending on patient characteristics, surgical techniques, and postoperative management protocols. Although often considered a minor complication, seroma can lead to patient discomfort, wound tension, flap necrosis, delayed wound healing, infection, repeated aspirations, prolonged hospital stay, delayed initiation of adjuvant therapy, and increased healthcare costs. Consequently, prevention of seroma formation remains an important objective in breast cancer surgery [3]. The pathophysiology of seroma formation is multifactorial and incompletely understood. It is believed to result from inflammatory exudation combined with disruption of lymphatic and vascular channels during breast and axillary dissection. The extensive dead space created following MRM facilitates the accumulation of fluid, particularly during the early postoperative period. To minimise this complication, surgical drains are routinely employed to evacuate fluid collections and promote adherence of the skin flaps to the underlying chest wall. Several studies have demonstrated that omission of drains is associated with substantially higher rates of seroma formation, highlighting their importance in postoperative management [3]. Conventionally, closed active suction drainage systems are widely used following MRM. The theoretical advantage of active drainage lies in the generation of negative pressure, which facilitates continuous evacuation of fluid, reduces dead space, and promotes flap adherence, thereby reducing the likelihood of seroma formation [4]. However, the routine use of suction drainage has been questioned. An alternative hypothesis proposes that excessive negative pressure may prevent the spontaneous closure of disrupted lymphatic channels and small blood vessels, thereby increasing postoperative drainage volume and prolonging the duration of drain placement. Such prolonged drainage may contribute to patient discomfort, delayed mobilisation, increased risk of infection, and longer hospitalisation [3,5]. Several factors influence postoperative fluid accumulation and seroma formation following MRM. These include patient-related factors such as age, obesity, body mass index (BMI), and comorbidities, as well as disease-related factors including tumour size, nodal status, and stage of presentation. Surgical factors such as the extent of axillary dissection, creation of skin flaps, duration of surgery, and the type of energy source used during dissection also play important roles in determining postoperative drainage and seroma formation [6]. Given the multifactorial nature of seroma development, the optimal drainage strategy remains a subject of ongoing debate. Previous investigators have attempted to optimise postoperative drainage by modifying suction pressure levels. Chintamani et al. and Bonnema J et al. compared half-suction and full-suction drainage systems and reported earlier drain removal and reduced hospital stay without a significant increase in postoperative complications [5,7]. Similarly, Oommen A et al. evaluated the outcomes of full-suction versus non-suction drainage following breast surgery in an Indian setting [8]. Although these studies have provided valuable insights, the available evidence remains limited, and consensus regarding the superiority of active or passive drainage has not been established. Consequently, considerable variation exists in clinical practice, with many surgeons continuing to favour active suction drainage because of concerns regarding postoperative seroma and wound-related complications.

In resource-constrained healthcare settings, such as those in many parts of India, strategies that reduce postoperative drain duration, improve patient comfort, facilitate earlier discharge, and decrease treatment costs without compromising surgical outcomes are of considerable clinical importance. Tertiary care referral centres frequently manage a large volume of breast cancer patients, many of whom travel long distances for treatment and follow-up. Therefore, identifying an effective and economical postoperative drainage method could have significant implications for patient care and healthcare resource utilisation. Given the limited evidence regarding passive drainage in the Indian population and the absence of clear recommendations favouring one drainage method over another, this study was undertaken to compare active suction drainage and passive drainage following modified radical mastectomy for breast carcinoma. Therefore, the present randomized controlled trial was undertaken to compare active versus passive drainage following modified radical mastectomy for breast carcinoma and to assess their impact on postoperative outcomes.

MATERIALS AND METHODS

Study Design and Setting

This prospective, parallel-group, randomized controlled trial was conducted in the Department of General Surgery (Trauma and Emergency), Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar, India, over a period of one year. The study aimed to compare postoperative outcomes between active suction drainage and passive drainage following Modified Radical Mastectomy (MRM) in patients with breast carcinoma. The study protocol was approved by the Institutional Ethics Committee of IGIMS, Patna. Written informed consent was obtained from all participants prior to enrolment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Sample Size Calculation

The sample size was calculated using G*Power software version 3.1.9.7. Assuming a two-sided significance level (α) of 0.05, a study power ($1-\beta$) of 80%, and a moderate effect size (Cohen's d = 0.80) for detecting differences in postoperative outcomes between the two groups, the minimum required sample size was estimated to be 25 patients per group. Accordingly, a total of 50 patients were enrolled and randomly allocated in a 1:1 ratio to the active drainage group (n=25) and the passive drainage group (n=25).

Inclusion Criteria

Patients fulfilling all of the following criteria were included in the study:

- Histopathologically confirmed breast carcinoma diagnosed by core needle biopsy.
- Female patients aged ≥18 years.
- Patients with operable breast carcinoma planned for Modified Radical Mastectomy.
- Clinical stage I, II, or III disease without evidence of distant metastasis.
- Patients willing to provide written informed consent and comply with follow-up requirements.

Exclusion Criteria

Patients were excluded if they had:

- Male breast carcinoma.
- Pregnancy or lactation.
- Evidence of distant metastatic disease at presentation.
- Recurrent breast carcinoma.
- Previous breast or axillary surgery on the affected side.
- Coagulation disorders or current use of anticoagulant/antiplatelet medications.
- Active local or systemic infection.
- Severe uncontrolled medical comorbidities rendering them unfit for surgery.
- Incomplete follow-up or withdrawal of consent during the study period.

Preoperative Evaluation

All patients underwent a comprehensive preoperative evaluation, including detailed clinical history, physical examination, routine laboratory investigations, chest radiography, ultrasonography and/or mammography, and histopathological confirmation by core needle biopsy. Tumour staging was performed according to the American Joint Committee on Cancer (AJCC) staging system [9]. Patients with suspected advanced disease underwent appropriate metastatic workup, including contrast-enhanced computed tomography and other imaging modalities as indicated. Neoadjuvant chemotherapy was administered to selected patients with locally advanced breast carcinoma according to institutional protocols. Surgery was performed after completion of neoadjuvant treatment and appropriate pre-anaesthetic evaluation.

Randomization and Allocation Concealment

Eligible patients were randomly assigned in a 1:1 ratio to either the active drainage group (Group A) or the passive drainage group (Group B) using a computer-generated randomization sequence created by an independent investigator who was not involved in patient recruitment, surgical management, or outcome assessment. Simple randomization was performed using random number generation software. Allocation concealment was ensured through the use of sequentially numbered, opaque, sealed envelopes (SNOSE), which were prepared by a research assistant independent of the study team. The envelopes were opened only after completion of the modified radical mastectomy and immediately before drain placement, thereby ensuring concealment of treatment allocation until the point of intervention.

Group A (Active Drainage)

Patients received a closed suction drainage system connected to a negative-pressure reservoir.

Group B (Passive Drainage)
Patients received the same drainage system without application of suction, allowing passive drainage by gravity.

Surgical Procedure
All patients underwent Modified Radical Mastectomy under general anaesthesia by experienced consultant surgeons following a standardised operative protocol. The procedure included removal of the entire breast tissue along with the nipple-areola complex and axillary lymph node dissection. Haemostasis was meticulously secured before wound closure.

A 16-Fr closed drainage tube with two limbs was placed at the completion of surgery, with one limb positioned beneath the mastectomy flap and the second within the axillary cavity. In the active drainage group, suction was applied immediately after wound closure, whereas no suction was applied in the passive drainage group.

Postoperative Management
Drain output was measured every 24 hours using a calibrated measuring container and recorded until drain removal. Standard postoperative analgesia, antibiotics, wound care, and physiotherapy were provided according to institutional protocols. Drains were removed when the output was less than 30 mL during a 24-hour period for two consecutive days. Patients were discharged following satisfactory clinical recovery and drain removal.

Follow-up and Outcome Assessment
All patients were followed up at postoperative day 7, day 15, and day 30 following drain removal.

Primary Outcome Measures
- Total postoperative drain output (mL).
- Duration of drain placement (days).
- Length of postoperative hospital stay (days).

Secondary Outcome Measures
- Seroma formation.
- Volume of aspirated seroma (mL).
- Surgical site infection.
- Flap necrosis.
- Wound-related complications requiring intervention.

Seroma was diagnosed clinically as a fluctuant fluid collection beneath the mastectomy flap or within the axillary region. Symptomatic seromas were managed by sterile aspiration followed by compression dressing. The volume of aspirated fluid was recorded. Surgical site infection was diagnosed according to the Centres for Disease Control and Prevention (CDC) criteria. Flap necrosis was identified by the presence of partial or complete skin flap devitalization requiring conservative or surgical management.

Statistical Analysis
Data were entered into Microsoft Excel and analysed using the Statistical Package for the Social Sciences (SPSS), version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate. Categorical variables were presented as frequencies and percentages. The normality of data distribution was assessed using the Shapiro–Wilk test. Comparisons between the two study groups were performed using the Independent Student's t-test for normally distributed continuous variables and the Mann–Whitney U test for non-normally distributed variables. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. A p-value of less than 0.05 was considered statistically significant for all analyses.

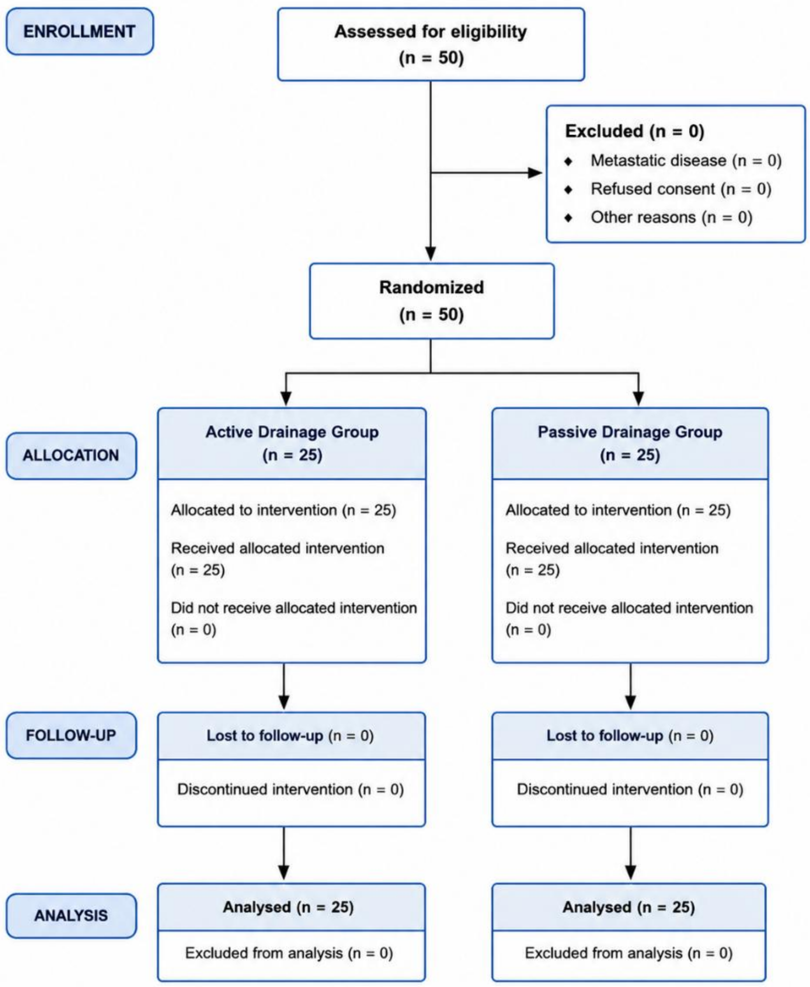

Figure 1: CONSORT 2010 flow diagram showing participant recruitment, randomization, follow-up, and analysis in the active drainage and passive drainage groups following modified radical mastectomy.

RESULTS

The baseline clinicodemographic and disease characteristics of the study participants are summarised in Table 1. The mean age of patients in the active drainage group was 50.24±6.12 years, compared to 51.68±7.05 years in the passive drainage group, with no statistically significant difference between the groups (p=0.442). The majority of patients belonged to the 46–50 years age group (30.0%).

The mean body mass index (BMI) was comparable between the active and passive drainage groups (21.14±3.18 kg/m² vs. 21.82±3.44 kg/m², respectively; p=0.476). Similarly, the prevalence of hypertension, diabetes mellitus, and hypothyroidism did not differ significantly between the two groups (p>0.05 for all comparisons).

With respect to tumour characteristics, the distribution of tumour laterality was identical in both groups, with 50% of patients having right-sided disease and 50% having left-sided disease (p=0.777). T3 tumours constituted the majority of cases (54.0%), followed by T2 tumours (38.0%) and T4b tumours (8.0%), with no significant difference between the study groups (p=1.000). Likewise, nodal staging was comparable, with N1 disease being the most frequent presentation (68.0%), followed by N0 (26.0%) and N2 disease (6.0%) (p=0.812). The mean number of resected lymph nodes was similar in the active and passive drainage groups (15.92±2.43 vs. 16.36±2.18, respectively; p=0.504). Overall, the two groups were well matched with respect to baseline demographic, clinical, and pathological characteristics.

Table 1. Comparison of baseline clinicodemographic and disease characteristics between the active and passive drainage groups.

Parameters	Category	Active Drainage (n=25)	Passive Drainage (n=25)	Total (n=50)	p-value
Age	**≤45**	06	05	11	0.918

		(24.0%)	(20.0%)	(22.0%)	
	46–50	08 (32.0%)	07 (28.0%)	15 (30.0%)	
	51–55	05 (20.0%)	06 (24.0%)	11 (22.0%)	
	>55	06 (24.0%)	07 (28.0%)	13 (26.0%)	
	Mean ± SD	50.24 ± 6.12	51.68 ± 7.05	50.96 ± 6.57	0.442
BMI (kg/m²)	**<18.5**	04 (16.0%)	03 (12.0%)	07 (14.0%)	1.000
	18.5–24.9	17 (68.0%)	18 (72.0%)	35 (70.0%)	
	25–29.9	04 (16.0%)	04 (16.0%)	08 (16.0%)	
	Mean ± SD	21.14 ± 3.18	21.82 ± 3.44	21.48 ± 3.30	0.476
Hypertension	**Yes**	04 (16.0%)	06 (24.0%)	10 (20.0%)	0.725
	No	21 (84.0%)	19 (76.0%)	40 (80.0%)	
Diabetes Mellitus	**Yes**	03 (12.0%)	04 (16.0%)	07 (14.0%)	1.000
	No	22 (88.0%)	21 (84.0%)	43 (86.0%)	
Hypothyroidism	**Yes**	01 (4.0%)	02 (8.0%)	03 (6.0%)	1.000
	No	24 (96.0%)	23 (92.0%)	47 (94.0%)	
Side of Cancer	**Right**	12 (48.0%)	13 (52.0%)	25 (50.0%)	0.777
	Left	13 (52.0%)	12 (48.0%)	25 (50.0%)	
T Stage	**T2**	10 (40.0%)	09 (36.0%)	19 (38.0%)	1.000
	T3	13 (52.0%)	14 (56.0%)	27 (54.0%)	
	T4b	02 (8.0%)	02 (8.0%)	04 (8.0%)	
N Stage	**N0**	07 (28.0%)	06 (24.0%)	13 (26.0%)	0.812
	N1	16 (64.0%)	18 (72.0%)	34 (68.0%)	
	N2	02 (8.0%)	01 (4.0%)	03 (6.0%)	
Number of Resected Lymph Nodes	**Mean ± SD**	15.92 ± 2.43	16.36 ± 2.18	16.14 ± 2.30	0.504

Postoperative Drain Output

The comparison of postoperative drain output between the active and passive drainage groups is presented in Table 2. The mean drain output was consistently comparable between the two groups throughout the postoperative period. On postoperative day 1, the mean drain output was 112.4±21.3 mL in the active drainage group and 104.6±20.4 mL in the passive drainage group, with no statistically significant difference ($p=0.18$). Similarly, on postoperative day 2, the mean drain output was 168.8±28.1 mL and 161.4±30.2 mL in the active and passive drainage groups, respectively ($p=0.37$).

From postoperative day 3 onwards, daily drain output remained similar between the two groups, and no statistically significant differences were observed at any postoperative time point ($p>0.05$ for all comparisons). In both groups, drain output showed a gradual decline over the postoperative period. The cumulative drain output was higher in the active drainage group (800.3±128.6 mL) compared with the passive drainage group (745.4±115.2 mL); however, this difference was not statistically significant ($p=0.11$). These findings suggest that passive drainage provides postoperative fluid evacuation comparable to that achieved with active suction drainage following modified radical mastectomy.

Table 2. Comparison of postoperative drain output (mL) between the active drainage and passive drainage groups following modified radical mastectomy.

Postoperative Days	Active Drainage (Mean±SD)	Passive Drainage (Mean±SD)	Total	p-value
Day 1	112.4±21.3	104.6±20.4	108.5±20.9	0.18
Day 2	168.8±28.1	161.4±30.2	165.1±29.1	0.37
Day 3	148.2±55.4	143.7±46.8	146.0±51.1	0.76
Day 4	105.6±42.7	108.4±33.1	107.0±38.2	0.79
Day 5	68.4±26.3	73.8±22.5	71.1±24.4	0.44
Day 6	48.6±23.4	49.2±20.8	48.9±22.1	0.92
Day 7	39.8±18.5	40.1±14.4	40.0±16.5	0.95
Day 8	42.5±16.8	42.2±12.0	42.4±14.4	0.94
Day 9	36.0±6.5	22.0±8.0	29.0±7.3	0.85
Day 10	30.0±0.0	-	30.0±0.0	-
Total	800.3±128.6	745.4±115.2	772.9±123.1	0.11

[All measurements were taken in millilitres (mL)]

Postoperative Outcomes and Complications

Postoperative outcomes and complications are shown in Table 3 and Figure 2. The mean duration of hospital stay was 6.67±1.45 days in the active drainage group and 6.27±1.10 days in the passive drainage group, with no significant difference between the groups (p=0.620). Flap necrosis occurred in 3 patients (12%) in each group, while the remaining patients had no evidence of flap necrosis (p=1.000). Surgical site infection was observed in 7 patients (28%) in the active drainage group and 5 patients (20.00%) in the passive drainage group, with no statistically significant difference (p=1.000). Seroma formation was noted in 6 patients (24%) in the active drainage group and 5 patients (20.00%) in the passive drainage group (p=1.000). Among patients who developed seroma, the mean aspirated seroma volume was 362.5±170.17 mL in the active drainage group and 400.0±50.0 mL in the passive drainage group (p=0.372). The mean duration of drain placement was 6.67±1.45 days in the active drainage group and 6.27±1.10 days in the passive drainage group, which was not statistically significant (p=0.620). Overall, passive drainage demonstrated postoperative outcomes comparable to active drainage, with no significant differences in hospital stay, drain duration, seroma formation, surgical site infection, flap necrosis, or aspirated seroma volume.

Table 3. Comparison of postoperative complications and recovery parameters between the active and passive drainage groups following modified radical mastectomy.

Parameters	Category	Active Drainage (n=25)	Passive Drainage (n=25)	Total (n=50)	p-value
Duration of hospital stay (days)	**Mean ± SD**	6.67±1.45	6.27±1.10	6.47±1.28	0.620
Flap necrosis	**Present**	03 (12%)	03 (12%)	06 (12%)	1.000
	Absent	22 (88%)	22 (88%)	44 (88%)	
Surgical site infection	**Present**	07 (28%)	05 (20.00%)	12 (24%)	1.000
	Absent	18 (72%)	20 (80.00%)	38 (76%)	
Seroma formation	**Present**	06 (24%)	05 (20.00%)	11 (22%)	1.000
	Absent	19 (76%)	20 (80.00%)	39 (78%)	
Volume of seroma aspirated (mL)	**Mean ± SD**	362.5±170.17	400±50.00	378.57±125.36	0.372

Number of days of drain in situ	Mean ± SD	6.67±1.45	6.27±1.10	6.47±1.28	0.620

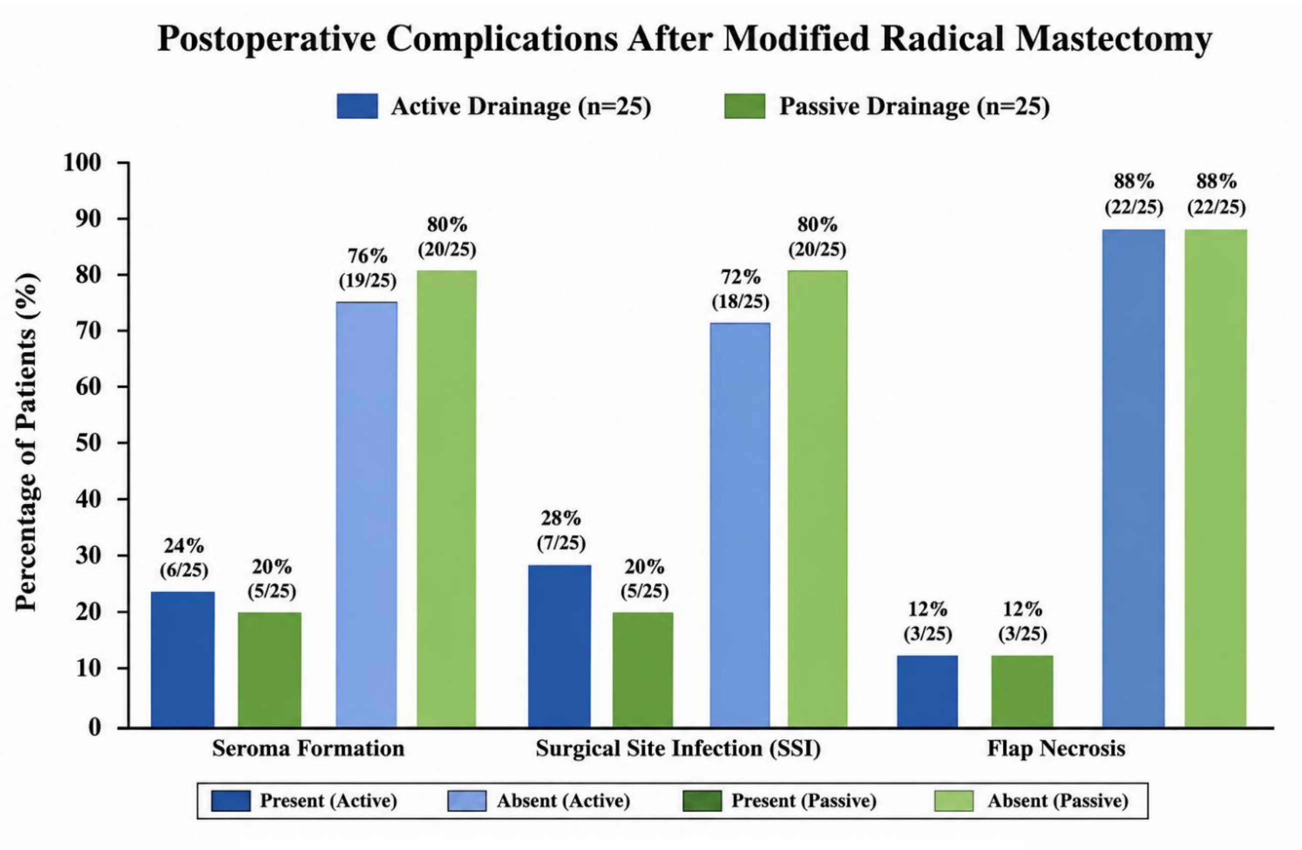

Figure 2. Comparison of Postoperative Complications Between Active and Passive Drainage Groups Following Modified Radical Mastectomy

DISCUSSION

Postoperative seroma formation remains one of the most frequent complications following modified radical mastectomy and continues to be a major concern for breast surgeons. Despite numerous modifications in operative techniques and postoperative management protocols, the optimal strategy for minimising fluid accumulation and promoting wound healing remains controversial. Effective drainage is important not only for reducing postoperative morbidity but also for improving patient comfort, facilitating recovery, and reducing healthcare costs. In resource-constrained settings, where prolonged hospitalisation imposes additional economic burdens on both patients and healthcare systems, identifying a simple and effective drainage method has significant clinical relevance.

The duration for which surgical drains remain in place often determines the length of postoperative hospitalisation, as many centres prefer drain removal before discharge. In developing countries such as India, home management of drains is not routinely practised because of limited patient education, inadequate access to follow-up care, and socioeconomic constraints [10]. Furthermore, prolonged drain placement may increase patient discomfort and may potentially contribute to wound-related complications, including surgical site infections [11,12]. Therefore, strategies that allow safe postoperative recovery without increasing complications are of considerable clinical importance.

Previous studies have evaluated different drainage techniques following breast surgery. Thoren L compared suction drainage with corrugated rubber drainage after mastectomy and reported no significant difference in postoperative outcomes between the two approaches [13]. Similarly, Whitfield PC and Rainsbury RM observed no significant difference in seroma formation when comparing suction drainage with closed siphon drainage systems [14]. It is also well recognised that postoperative seroma formation is influenced by multiple factors, including the extent of tissue dissection, surgical technique, energy devices used during surgery, and flap fixation methods, in addition to the drainage system employed [6,13,15].

In the present study, postoperative drain output was comparable between the active and passive drainage groups throughout the postoperative period. Although the active drainage group demonstrated numerically higher drain output on certain postoperative days, these differences were not statistically significant at any time point. Similarly, the cumulative drain output was higher in the active drainage group; however, the difference did not reach statistical significance. These findings suggest that the application of negative suction does not confer a significant advantage in terms of postoperative fluid evacuation following modified radical mastectomy. The comparable drainage profiles observed in both groups indicate that passive drainage is equally effective in managing postoperative fluid accumulation. Our findings are consistent with those reported by Oommen A et al., who observed no significant differences in overall postoperative outcomes between active and passive drainage systems following modified radical mastectomy [8]. Similarly, Ezeome ER and Adebamowo CA demonstrated that closed simple drainage achieved outcomes comparable to closed suction drainage, with no significant differences in drainage-related complications or recovery parameters [16]. Collectively, these studies support the view that passive drainage provides adequate postoperative fluid evacuation without compromising patient safety or clinical outcomes.

Another important observation of the present study was the absence of a significant difference in the duration of drain placement and length of hospital stay between the two groups. The mean duration of drain placement and hospital stay was slightly lower in the passive drainage group; however, the difference was not statistically significant. These findings indicate that omission of suction does not prolong recovery or delay discharge after modified radical mastectomy. Comparable results have been reported by Oommen A et al., who also found no significant difference in hospital stay between active and passive drainage groups [8]. Similar conclusions were drawn by Ezeome ER and Adebamowo CA, who demonstrated equivalent durations of hospitalisation irrespective of drainage modality [16].

With regard to postoperative complications, the incidence of flap necrosis, surgical site infection, and seroma formation was comparable between the active and passive drainage groups in the present study. Importantly, passive drainage did not increase the risk of wound-related complications despite the absence of negative suction. These findings support the hypothesis that passive drainage can provide adequate postoperative fluid evacuation while maintaining similar safety outcomes. The results are in agreement with those reported by Oommen A et al. and Ezeome ER and Adebamowo CA, both of whom observed no significant differences in postoperative complications between active and passive drainage systems [8,16].

The absence of significant differences in postoperative drain output, duration of drain placement, length of hospital stay, and wound-related complications suggests that the routine application of negative suction may not be essential following modified radical mastectomy. From a clinical perspective, these findings are important because passive drainage systems are simpler to manage and do not require continuous suction devices. In resource-limited healthcare settings, where affordability and ease of postoperative care are important considerations, passive drainage may provide a practical alternative without compromising patient safety or recovery outcomes.

Taylor JC et al. compared breast cancer patients managed with and without postoperative drains and found no increase in seroma formation, aspiration requirements, or wound infections in patients managed without drains, although hospital stay was longer in patients with drains [17]. While a formal cost-analysis was beyond the scope of the present study, passive drainage eliminates the need for suction reservoirs and associated equipment, thereby reducing treatment expenses. This may be particularly beneficial in high-volume public hospitals and resource-limited healthcare settings. Ezeome ER and Adebamowo CA similarly concluded that passive drainage represents a more cost-effective alternative without compromising patient safety [16].

Chintamani et al. compared full suction with half suction drainage and reported significantly reduced drain output and shorter hospital stay in the half-suction group without an increase in postoperative complications [5]. These findings further suggest that higher levels of suction may not necessarily confer additional clinical benefits. Saratzis A et al. demonstrated that the number of drains used after mastectomy had no significant effect on seroma formation, although patients with fewer drains experienced greater comfort and improved postoperative satisfaction [18]. Collectively, these findings reinforce the concept that less aggressive drainage strategies may be sufficient for postoperative management following breast surgery.

The timing of drain removal has also been extensively investigated. Studies by Yii M et al. and Parikh HK et al. demonstrated that early drain removal did not significantly increase seroma formation or seroma volume when compared with conventional prolonged drainage protocols [19,20]. Similarly, Baas-Vrancken Peeters MJ et al. reported that short-duration drainage following axillary lymph node dissection was not associated with an increased risk of wound complications [21]. These findings support the notion that prolonged drainage may not always be necessary and that individualised drainage protocols can be safely adopted.

Freitas-Junior R et al. evaluated axillary dissection with and without drainage and observed comparable safety profiles between the groups, although patients managed without drainage experienced higher rates of wound dehiscence and aspiration procedures [22]. In contrast, Lal M et al. reported shorter hospitalisation in patients managed with half suction drainage but observed a higher incidence of seroma formation, findings that differed from those reported by Chintamani et al. [5,23]. Such variations across studies may reflect differences in sample size, surgical techniques, patient characteristics, and postoperative management protocols.

The clinical significance of the present study lies in demonstrating that passive drainage provides postoperative outcomes comparable to active suction drainage without increasing the risk of seroma formation or wound-related complications. Given its simplicity, lower cost, and ease of use, passive drainage may represent a practical alternative to active suction drainage, particularly in resource-limited healthcare settings such as government tertiary care hospitals. Adoption of passive drainage could reduce equipment-related expenses while maintaining equivalent clinical outcomes.

Limitations of the study: The present study has certain limitations that should be acknowledged. First, it was conducted at a single tertiary care centre, which may limit the generalizability of the findings to other healthcare settings. Second, although the sample size was larger than in several previous studies, it remained relatively modest and may not have been sufficient to detect small differences in uncommon postoperative complications. Although no statistically significant differences were observed between the study groups, the relatively small sample size may have limited the statistical power to detect modest differences in postoperative complications such as seroma formation, surgical site infection, and flap necrosis. Third, the study was not blinded, which could have introduced observer-related bias during postoperative assessment. Fourth, follow-up was limited to the early postoperative period, and long-term outcomes such as chronic seroma formation, patient satisfaction, quality of life, and cosmetic results were not evaluated. Finally, a formal cost-effectiveness analysis was not performed, although passive drainage is expected to be economically advantageous. Future multicentric studies with larger sample sizes, longer follow-up durations, and detailed economic evaluations are warranted to further validate these findings.

CONCLUSIONS

In this randomized controlled trial, no statistically significant differences were observed between active suction drainage and passive drainage with respect to postoperative drain output, duration of drain placement, length of hospital stay, seroma formation, surgical site infection, flap necrosis, or aspirated seroma volume following modified radical mastectomy. These findings suggest that passive drainage provides effective postoperative fluid evacuation and may serve as a simple and practical alternative to active suction drainage in patients undergoing MRM.

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