Surgery Section

# Active Drainage versus Passive Drainage after Modified Radical Mastectomy in Patients with Breast Carcinoma: A Randomised Controlled Trial

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## ABSTRACT

**Introduction:** Postoperative seroma formation is a common complication following Modified Radical Mastectomy (MRM), with an incidence ranging from 15-60%. There is a hypothesis that the negative pressure created by the suction drain used in MRM opens the damaged capillaries, preventing them from spontaneously closing and thereby increasing postoperative secretions.

**Aim:** To compare active suction drains with passive drains in MRM in terms of postoperative outcomes.

**Materials and Methods:** A randomised controlled trial with two arms, consisting of 15 patients in each arm, was conducted from November 2018 to March 2020 at the Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital in New Delhi. Patients diagnosed with localised breast carcinoma and scheduled for MRM were invited to participate. Pregnant females, patients with metastatic disease, those lost to follow-up, recurrent breast cancer patients, and those taking anticoagulants and antiplatelet agents were excluded from the study. The outcomes measured were drain output and duration of

hospital stay, and postoperative morbidity, including flap necrosis, surgical site infection, seroma, and volume of seroma aspiration. The data acquired was analysed using the Statistical Package for Social Sciences (SPSS) version 21.0. Quantitative variables were compared using the Independent t-test and Mann-Whitney test as appropriate. Nominal categorical data was compared using the Chi-square or Fisher's-exact test as appropriate.

**Results:** Drain output was higher in the active group than in the passive group, but there was no significant difference in the average daily drain output and the average total output (652 mL versus 540 mL), except for the first two postoperative days. There was no statistically significant difference between the two groups in terms of hospital stay (6.67 days and 6.27 days), duration of drains in situ (6.67 days and 6.27 days), flap necrosis (13.3% vs. 13.3%), seroma formation (26.67% vs. 20%), and surgical site infection (26.67% vs. 20%).

**Conclusion:** The use of suction in drains during MRM surgery is not compulsory and can save costs in resource-poor settings. However, larger sample size studies with multicentre participation should be undertaken before making any recommendations.

## INTRODUCTION

Breast cancer tops the list among female cancers, with an incidence of about 11.1% according to the Global Cancer Observatory 2020 data, surpassing the incidence of lung cancer, which has decreased due to awareness regarding the harmful effects of smoking [1]. The incidence of breast cancer is also increasing in the Indian subcontinent, and advanced-stage breast cancer presentation is a common scenario in this part of the world [2]. Surgical therapy in the form of MRM is the mainstay of treatment for operable breast cancer, augmented by chemotherapy and radiotherapy. Over the time, surgical technique has been refined to decrease the procedure's morbidity while ensuring an oncologically sound surgery.

Postoperative seroma formation is a common complication following MRM, with an incidence ranging from 15-60%. To reduce the occurrence of seroma, drains are routinely used to drain fluid postoperatively and are removed based on the output. The absence of drains has resulted in a very high incidence of seroma formation [3]. Applying suction to the drain helps create negative pressure, which causes the dissected flaps to adhere to the chest wall bed, thus decreasing secretions [4]. However, this theory is challenged by a proposed counter mechanism that states the negative pressure created by the suction drain will open the damaged capillaries during MRM and prevent them from spontaneously closing, thus increasing postoperative secretions [3,5].

The extent of the dissection of breast flaps and axilla, the size of the tumour, lymph node involvement, and Body Mass Index (BMI) also influence the rate of seroma formation. The instrument and the energy source used for the dissection also influence the rate of seroma formation [6]. Using suction or not in the MRM drains is a debatable topic based on the above proposed hypothesis. There is some evidence that using half suction instead of full suction will result in earlier removal of drains and thus a shorter hospital stay, yet no significant increase in the incidence of seroma formation [5]. The use of half suction versus full suction was compared by Chintamani et al., and Bonnema J et al., [5,7]. Full suction versus no suction of drains after breast surgery was compared in an Indian study by Oommen A et al., [8]. The evidence for not having suction pressure in the drains in breast surgery is not robust, and surgeons are often apprehensive about the postoperative morbidities that may occur if suction is removed. Authors have hypothesised that using no suction in the MRM drains will result in earlier removal of the drains and a shorter hospital stay with no increase in postoperative morbidity. The aim of the present study was to compare active suction drains versus passive drains in MRM in terms of postoperative outcomes.

## MATERIALS AND METHODS

A randomised controlled trial with two arms was conducted from November 2018 to March 2020 at Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi,

India. This was a single-centre study with balanced randomisation (1:1) and used a parallel group design. The study was not blinded. The Institutional Ethics Committee (IEC) approved the study prior to its commencement, with approval number TP (MD/MS) (47/2018)/IEC/PGIMER/RMLH/880. All patients were enrolled in the study after obtaining their written informed consent. The proceedings of the study are reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Since the study was a pilot study, the sample size was set at 30 based on the central theorem of logistics, with equal randomisation of subjects into each group. A minimum sample size of 30 patients (15 in each group) was selected.

**Inclusion criteria:** Patients diagnosed with localised breast carcinoma and planned to undergo MRM in the outpatient department of surgery were invited to participate in the study. Those who consented were enrolled in the study until the required sample size was reached (consecutive sampling).

**Exclusion criteria:** Pregnant females were not included in the study. Patients found to have metastatic disease were excluded. Patients lost to follow-up during the 30-day post-drain removal period were considered as exclusions. Male breast cancers were omitted from the study. Patients taking anticoagulants and antiplatelet agents were exempted from the study. Patients with recurrent breast carcinoma were also excluded from the study.

A total of 39 patients were evaluated for the study, of whom six patients were excluded due to metastasis on further evaluation. One male breast cancer patient was excluded from the study. One patient was excluded as she was pregnant, and one patient did not consent to participate in the study [Table/Fig-1].
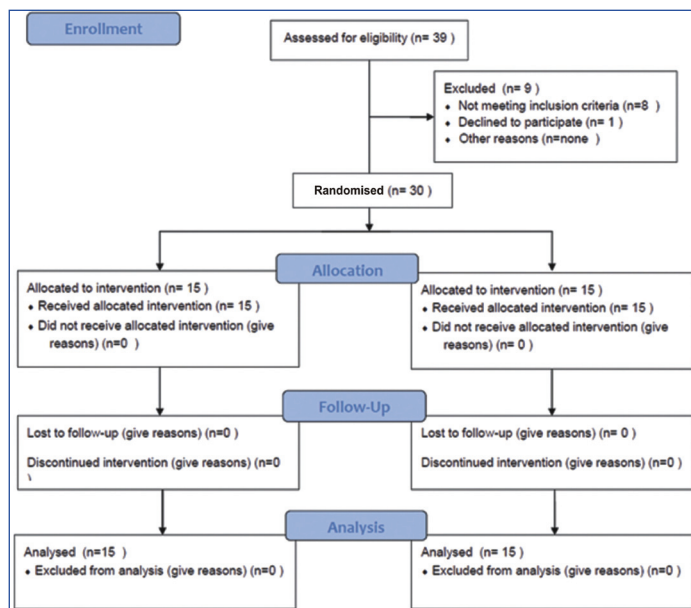


[Table/Fig-1]: CONSORT 2010 flow diagram.

All patients presenting to the outpatient department of our institute with symptoms and a history suggestive of breast malignancy were evaluated according to the protocol, which included a triple assessment consisting of history and physical examination, imaging, and pathological assessment. Breast carcinoma was confirmed through core-needle biopsy, and patients meeting the inclusion and exclusion criteria were invited to participate in the study. Clinical staging of the tumour was performed according to the American Joint Committee on Cancer staging system [9]. All patients with locally advanced breast carcinoma (Stage III) and early breast carcinoma (Stage I and II) with symptoms suggestive of metastasis were evaluated using Contrast-Enhanced Computed Tomography (CECT) of the chest, abdomen, and pelvis, as well as a bone scan, to rule out metastatic disease. Patients with metastasis were excluded from the study.

Patients were given preoperative neoadjuvant dose-dense chemotherapy consisting of cyclophosphamide, doxorubicin (adriamycin), and paclitaxel, with or without trastuzumab, depending on the HER2/neu receptor status. After two weeks from the completion of the last chemotherapy cycle, patients underwent a preanaesthetic check-up and were scheduled for MRM under general anaesthesia.

During the surgery, a modified Stewart incision was used with a prescribed margin of two centimeters around the tumour, including the nipple-areola complex, to ensure oncological clearance. Flaps were raised using scissors, and axillary dissection was performed to remove Level-I and II lymph nodes, along with the fibrofatty tissue, using electrocautery. Level-III lymph nodes were detached if clinically involved. Following the completion of the dissection, a 16Fr suction drain with two limbs was placed, with one limb beneath the flaps and the other limb in the axilla. The incision was then closed.

Patients were randomised using the opaque sealed envelope method, which was opened in the Operating Theatre (OT) by a resident. One arm, labelled as group A (active suction group), had suction applied to the drains, while the other arm, labelled as group-B (passive drainage group), had no suction applied. All surgeries were performed by the same surgical team, consisting of one senior consultant surgeon, senior registrar, and a junior resident, to ensure uniformity in the surgical technique.

In the postoperative period, drain output was measured daily using a volumetric jar, and the data was recorded. Drains were removed when the output was less than 30 mL per day for two consecutive days. All patients were followed-up after drain removal on the 7th, 15th, and 30th days to conduct a clinical examination and note any seroma formation. Symptomatic seromas were treated by aspiration followed by compression dressing.

The primary outcomes studied in this research are as follows: drain output per day (calculated each day using a measuring jar), duration of drain in-situ, hospital stay, flap necrosis, surgical site infection, seroma formation, and volume of seroma aspirated (calculated by measuring the aspirated seroma in the syringe).

## STATISTICAL ANALYSIS

The data acquired was analysed using SPSS version 21.0 (IBM SPSS Statistics, International Business Machines Corporation, New York). Categorical variables were presented as numbers and percentages (%), while continuous variables were presented as mean±Standard Deviation (SD) and median. The normality of the data was tested using the Shapiro-Wilk test. A p-value of <0.05 was considered statistically significant. The statistical tests used are as follows: quantitative variables were compared using the Independent t-test and Mann-Whitney test as appropriate. The nominal categorical data was compared using the Chi-square or Fisher's exact test, as appropriate.

## RESULTS

All the patients in the study were female patients with breast cancer; no male breast cancer patients were included. The mean age of patients in the active and passive drainage groups was 49.8±5.24 years and 51.27±8.11 years, respectively, with no statistically significant difference. The mean BMI of the two groups was 20.59±3.24 and 21.57±3.5 kg/m$^2$, respectively [Table/Fig-2].

The median daily output on different postoperative days was compared between the two groups. There was a significant difference between the groups on the first and second postoperative days in terms of the volume of drain output, with the passive group having lesser drain output. However, there was no significant difference in drain output between the two groups on the remaining postoperative days. The total average drain output combined for all days in the active and passive groups was 652 mL and 540 mL, respectively, with no statistically significant difference between them [Table/Fig-3].

| Parameter | Active drainage n (%) | Passive drainage n (%) | Total n (%) | p-value | Test performed |
|---|---|---|---|---|---|
| **Age in years** | | | | | |
| ≤45 | 4 (26.67) | 4 (26.67) | 8 (26.67) | 1.000 | Fisher Exact test |
| 46-50 | 5 (33.33) | 4 (26.67) | 9 (30) | | |
| 51-55 | 2 (13.33) | 2 (13.33) | 4 (13.33) | | |
| >55 | 4 (26.67) | 5 (33.33) | 9 (30) | | |
| Mean±SD | 49.8±5.24 | 51.27±8.11 | 50.53±6.75 | 0.561 | t test; 0.588 |
| **Body Mass Index (BMI) (kg/m²)** | | | | | |
| <18.5 (Underweight) | 4 (26.67) | 3 (20) | 7 (23.33) | 1.000 | Fisher-Exact test |
| 18.4-24.9 (Normal) | 9 (60) | 10 (66.67) | 19 (63.33) | | |
| 25-29.9 (Overweight) | 2 (13.33) | 2 (13.33) | 4 (13.33) | | |
| Mean±SD | 20.59±3.24 | 21.57±3.5 | 21.08±3.35 | 0.432 | t-test; 0.796 |
| **Hypertension** | | | | | |
| No | 14 (93.33) | 9 (60) | 23 (76.67) | 0.080 | Fisher-Exact test |
| Yes | 1 (6.67) | 6 (40) | 7 (23.33) | | |
| **Diabetes mellitus** | | | | | |
| No | 14 (93.33) | 11 (73.33) | 25 (83.33) | 0.330 | Fisher-Exact test |
| Yes | 1 (6.67) | 4 (26.67) | 5 (16.67) | | |
| **Hypothyroid** | | | | | |
| No | 15 (100) | 14 (93.33) | 29 (96.67) | 1.000 | Fisher-Exact test |
| Yes | 0 | 1 (6.67) | 1 (3.33) | | |
| **Side of breast cancer** | | | | | |
| Left CA breast | 8 (53.33) | 7 (46.67) | 15 (50) | 0.715 | Chi-square test, 0.133 |
| Right CA breast | 7 (46.67) | 8 (53.33) | 15 (50) | | |
| **T stage** | | | | | |
| T2 | 6 (40) | 5 (33.33) | 11 (36.67) | 1.000 | Fisher-Exact test |
| T3 | 8 (53.33) | 8 (53.33) | 16 (53.33) | | |
| T4b | 1 (6.67) | 2 (13.33) | 3 (10) | | |
| **N stage** | | | | | |
| N0 | 5 (33.33) | 4 (26.67) | 9 (30) | 0.700 | Fisher-Exact test |
| N1 | 9 (60) | 11 (73.33) | 20 (66.67) | | |
| N2 | 1 (6.67) | 0 | 1 (3.33) | | |
| **Number of lymph nodes harvested** | | | | | |
| Mean±SD | 15.56±2.06 | 16.12±2.31 | | 0.489 | t-test |

[Table/Fig-2]: Comparison of the two randomised groups with respect to various preoperative parameters.

| Drain output (mL) | Active drainage | Passive drainage | Total | p-value | Test performed |
|---|---|---|---|---|---|
| **Postoperative day 1** | | | | | |
| Mean±SD | 109.33±20.17 | 86±19.93 | 97.67±23 | 0.006 | Mann-Whitney test; 48 |
| Median (IQR) | 100 (100-120) | 80 (75-100) | 100 (100-120) | | |
| Range | 70-140 | 60-120 | 60-140 | | |
| **Postoperative day 2** | | | | | |
| Mean±SD | 164±25.01 | 136±29.47 | 150±30.4 | 0.011 | Mann-Whitney test; 52 |
| Median (IQR) | 170 (150-180) | 140 (110-155) | 150 (122.5-170) | | |
| Range | 120-200 | 100-200 | 100-200 | | |
| **Postoperative day 3** | | | | | |
| Mean±SD | 144±59.62 | 132±42.96 | 138±51.42 | 0.616 | Mann-Whitney test; 100.5 |
| Median (IQR) | 150 (90-200) | 130 (100-165) | 140 (100-177.5) | | |
| Range | 60-250 | 70-200 | 60-250 | | |

| | Active | Passive | Total | p-value | Test performed |
|---|---|---|---|---|---|
| **Postoperative day 4** | | | | | |
| Mean±SD | 102±44.91 | 86±29.47 | 94±38.2 | 0.45 | Mann-Whitney test; 94.5 |
| Median (IQR) | 100 (65-140) | 80 (65-100) | 80 (62.5-115) | | |
| Range | 50-200 | 30-140 | 30-200 | | |
| **Postoperative day 5** | | | | | |
| Mean±SD | 64.67±28.25 | 59.29±21.29 | 62.07±24.84 | 0.675 | Mann-Whitney test; 95.5 |
| Median (IQR) | 60 (40-95) | 60 (42.5-70) | 60 (40-80) | | |
| Range | 30-100 | 30-100 | 30-100 | | |
| **Postoperative day 6** | | | | | |
| Mean±SD | 45.83±24.66 | 39.17±22.34 | 42.5±23.27 | 0.575 | Mann-Whitney test; 62.5 |
| Median (IQR) | 50 (27.5-57.5) | 40 (20-52.5) | 50 (20-52.5) | | |
| Range | 10-80 | 10-80 | 10-80 | | |
| **Postoperative day 7** | | | | | |
| Mean±SD | 38.57±21.16 | 33.33±13.66 | 36.15±17.58 | 0.766 | Mann-Whitney test; 19 |
| Median (IQR) | 30 (20-55) | 30 (22.5-45) | 30 (20-50) | | |
| Range | 20-70 | 20-50 | 20-70 | | |
| **Postoperative day 8** | | | | | |
| Mean±SD | 40±17.32 | 30±0 | 36±13.42 | 0.542 | Mann-Whitney test; 2 |
| Median (IQR) | 50 (35-50) | 30 (30-30) | 30 (30-50) | | |
| Range | 20-50 | 30-30 | 20-50 | | |
| **Postoperative day 9** | | | | | |
| Mean±SD | 35±7.07 | - | 35±7.07 | No p-value | No test performed |
| Median (IQR) | 35 (32.5-37.5) | - | 35 (32.5-37.5) | | |
| Range | 30-40 | - | 30-40 | | |
| **Postoperative day 10** | | | | | |
| Mean±SD | 30±0 | - | 30±0 | No p-value | No test performed |
| Median (IQR) | 30 (30-30) | - | 30 (30-30) | | |
| Range | 30-30 | - | 30-30 | | |

[Table/Fig-3]: Comparison of drain output (mL) between active and passive drains.

The average hospital stay in the active and passive groups was 6.67±1.45 days and 6.27±1.1 days, respectively, with no statistically significant difference between them. The average amount of serous fluid aspirated from the seroma in the active and passive groups was 362.5±170.17 mL and 400±50 mL, respectively, with no significant difference [Table/Fig-4].

| Duration of hospital stay (days) | Active drainage n (%) | Passive drainage n (%) | Total n (%) | p-value | Test performed |
|---|---|---|---|---|---|
| **Duration of hospital stay (days)** | | | | | |
| Mean±SD | 6.67±1.45 | 6.27±1.1 | 6.47±1.28 | 0.62 | Mann-Whitney test; 101 |
| **Flap necrosis** | | | | | |
| Absent | 13 (86.67) | 13 (86.67) | 26 (86.67) | 1 | Fisher-Exact test |
| Present | 2 (13.33) | 2 (13.33) | 4 (13.33) | | |
| **Surgical site infection** | | | | | |
| Absent | 11 (73.33) | 12 (80) | 23 (76.67) | 1 | Fisher-Exact test |
| Present | 4 (26.67) | 3 (20) | 7 (23.33) | | |
| **Seroma formation** | | | | | |
| Absent | 11 (73.33) | 12 (80) | 23 (76.67) | 1 | Fisher-Exact test |
| Present | 4 (26.67) | 3 (20) | 7 (23.33) | | |

| Volume of seroma aspirated (mL) | | | | | |
|---|---|---|---|---|---|
| Mean±SD | 362.5±170.17 | 400±50 | 378.57± 125.36 | 0.372 | Mann-Whitney test; 3.5 |
| Number of days of drain in situ | | | | | |
| Mean±SD | 6.67±1.45 | 6.27±1.1 | 6.47±1.28 | 0.62 | Mann-Whitney test; 101 |

**[Table/Fig-4]:** Comparison of the two groups with respect to various postoperative parameters.

## DISCUSSION

Seroma prevention is one of the most debated topics in MRM surgery, with various surgical techniques and refinements proposed to reduce seroma incidence. The length of the drains in situ ultimately determines the duration of hospital stay, as patients are usually not discharged until the drains are removed. However, the practice of discharging patients with drains is not common in India, particularly in government hospitals where a significant portion of patients are illiterate and come from low socio-economic backgrounds [10]. Improper handling of drains can also serve as a source of surgical site infection [11,12]. In this context, early removal of drains is the only method to decrease hospital stay, which also reduces the overall cost of the procedure.

The use of suction drains has been compared with corrugated rubber drains in patients undergoing simple mastectomy by Thoren L, and no difference was observed in the study [13]. In a randomised trial by Whitefield PC and Rainsbury RM comparing suction and closed siphon drainage, no statistically significant difference was found in the rate of seroma formation [14]. Seroma formation is also influenced by various factors such as the extent of dissection, type of energy device used, and whether flap fixation is performed or not [6,13,15].

In the present study, drain output was higher in the active group compared to the passive group, but there was no significant difference in the median daily drain output except for the first two postoperative days. A study by Oommen A et al., reported a significant difference in the daily drain output between the active and passive drain groups, with the passive group showing lower output. However, in the same study, no significant difference was observed when comparing the total drain output between the two groups [8]. Findings from the study by Ezeome ER and Adebamowo CA were similar to the present study regarding drain output [16].

Regarding the number of days drains were in situ and the duration of hospital stay, no significant difference was found between the two groups in the present study. This aligns with the findings of Oommen A et al., where no significant difference in hospital stay was observed [7]. Similarly, in the study by Ezeome ER and Adebamowo CA there was no significant difference in the duration of hospital stay between the active and passive drainage groups [16].

In terms of flap necrosis, seroma formation, and surgical site infection, no significant difference was observed between the active drainage and passive drainage groups in the present study. This indicates that the absence of suction drainage did not increase postoperative wound complications. These findings were consistent with the studies conducted by Oommen A et al., and Ezeome ER and Adebamowo CA [8,16].

In a study by Taylor JC et al., patients with breast cancer who underwent surgery were compared with and without drains. There was no significant increase in the incidence of seroma formation, required aspirations, surgical site infections, or reinfection rates in the two groups [17]. However, the group with drains had a significantly longer duration of hospital stay. Although cost-effective analysis was not conducted in the present study, it is evident that the cost associated with using suction apparatus in drains would be saved. In the study by Ezeome ER and Adebamowo CA the authors concluded that passive drainage was a cost-effective approach compared to active drainage [16]. This is particularly beneficial in settings where resources are limited to cater to a larger population.

In a study by Chintamani et al., comparing full suction with half suction, there was a significant reduction in drain output in the half suction group compared to the full suction group, with no increase in the incidence of complications and a shorter hospital stay [5]. The total number of drains used had no effect on the incidence of seroma formation, as shown in various studies. Saratzis A et al., compared patients with three drains, two drains, and one drain, and found no statistically significant difference in seroma rates between the groups, with patients having a single drain experiencing less discomfort [18]. The early removal of drains, rather than waiting until the drain output decreases, has also been studied. In the studies by Yii M et al., and Parikh HK et al., there was no statistically significant difference in the incidence of seroma or seroma volume when drains were removed early [19,20]. Baas-Vrancken Peeters MJ et al., compared 24 hours drainage with traditional long-term drainage in patients undergoing axillary lymph node clearance and concluded that 24 hours drainage was not associated with an excess increase in postoperative wound complications [21]. In the study by Freitas-Junior R et al., comparing patients undergoing axillary lymph node clearance with and without drainage, although safety rates were similar between the two groups, the incidence of wound dehiscence and the number of aspirations were higher in the group without drainage [22]. Lal M et al., in their study comparing full suction versus half suction, found that the half suction group had a shorter hospital stay and a higher incidence of seroma formation, which contrasts with the study by Chintamani et al., [5,23]. A comparison between various studies is presented in [Table/Fig-5] [5,7,8,16,23].

| Study | Pub. year | Sample size | Comparison | Results |
|---|---|---|---|---|
| Present study | 2023 | 30 | Full versus No suction | No significant difference in drain output, hospital stay and seroma rate. |
| Oommen A et al., [8] | 2018 | 100 | Full versus No suction | No significant difference in drain output and hospital stay. |
| Lal M et al., [23] | 2017 | 50 | Full versus Half suction | Half suction group had lesser hospital stay. Seroma formation was more in half suction group. |
| Ezeome ER [16] | 2008 | 50 | Full versus No suction | No significant difference in drain output and hospital stay. |
| Chintamani et al., [5] | 2005 | 85 | Full versus Half suction | No significant difference in seroma formation. Significant decrease in the hospital stay. |
| Bonnema J et al., [7] | 1997 | 141 | High vacuum versus low vacuum | No significant differences in the drain fluid volume and wound complications. |

**[Table/Fig-5]:** Comparison of outcomes of various studies regarding suction drains in Modified Radical Mastectomy (MRM) [5,7,16,23].

The strength of the present study lies in its study design, which is a non blinded randomised controlled trial. Both arms of the study were comparable in terms of parameters that influence drain output. The operating technique was standardised in the study, minimising bias.

### Limitation(s)

The study has several limitations, including a small sample size. Additionally, being a single-centre study conducted in a tertiary centre, the study was susceptible to centripetal bias.

## CONCLUSION(S)

The techniques used in breast cancer surgery are constantly evolving to minimise morbidity and facilitate early return to normal life for patients. The absence of suction in drains used for MRM was not statistically significantly associated with differences in overall drain output or duration of hospital stay, and it does not increase the incidence of complications. Based on these findings, the authors conclude that the use of suction in drains is not mandatory and

can potentially save costs, especially in resource-limited settings. However, it is important to conduct studies with larger sample sizes and multicentre participation before making any definitive recommendations.

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