

A Study of Comparison of Single Vs Double Drains Post - Modified Radical Mastectomy

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KEYWORDS

Modified Radical Mastectomy, Single Drain, Double Drain, Seroma Development, Patient Comfort, Drainage Efficiency.

ABSTRACT

Background: The number of drains after a Modified Radical Mastectomy (MRM), the most common surgery for women with breast cancer, is still up for debate. The objective of this research is to find clinical results pertaining to patient comfort, pain ratings, seroma development and drain production.

Methods: A prospective, non-randomized, observational research study was conducted at Sri Ramachandra Institute of Higher Education and Research, Chennai, from November 2022 to April 2024. There were formed two groups of eighty-four female patients undergoing MRMs: (a) Single Drain Group (n = 42). The axilla has a single drain, (b) Double Drain Group (n = 42): One drain in the bottom flap and one in the axilla. Postoperative parameters such as drain removal time, pain ratings (Wong-Baker FACES), seroma development (clinical and ultrasound), and daily and total drain output were subjected to analysis. Logistic regression, independent t-tests, chi-square testing, Mann-Whitney U tests, and Kaplan-Meier survival analysis were executed in SPSS v26.0.

Results: The single drain group had considerably lower daily drainage volumes from POD-1 to POD-10 ($p < 0.01$) but had total drain output similar to other groups ($p = 0.743$). It also took longer for the single drain group to remove the drain (8.57 vs. 7.12 days, $p = 0.014$). They found that the single drain group had considerably lower POD-9 pain levels ($p = 0.024$) and thus possibly more comfort post-surgery. Seroma development rates were statistically equivalent ($p = 1.000$) among groups. Logistic regression analysis also showed that diabetes mellitus was significantly associated with seroma development ($p = 0.04$), but drain type was not related to seroma risk ($p = 0.88$). Prolonged drain retention in the single drain group was also shown by Kaplan-Meier analysis ($p = 0.032$).

Conclusion: As MRM, single drain insertion results in better pain control, patient comfort, and drainage efficiency as well as seroma risk similar to double drain insertion. Given these results, it is also suggested that the ideal postoperative strategy is using a single drain. More study is warranted to assess long-term results and to improve drainage techniques in breast cancer surgery.

1. Introduction

One of the most common cancers in the world as of today, breast cancer, has a surgical procedure known as the Modified Radical Mastectomy (MRM), which is still done in locally advanced cases. Despite its effectiveness in controlling illness, postoperative complications in the form of seroma development, delayed drainage, and the patient's pain [1] still affect surgical results. Recently, the attempt to overcome these issues has been to close suction drains, but presently there is a dispute on the number of such drains that should be left open to cause minimum patient discomfort, yet ensure sufficient fluid drainage [2]. Twin drains have similar morbidities as twin drains [3] but single drains also show the same result with lower morbidity rates. In this study, methodical evaluation of the relative effectiveness in MRM patients is performed with the clinical evaluation: seroma formation rate, drain removal time and postoperative pain level in single and double drain insertion.

Seroma [4] is the most common postoperative complication that develops in ten percent to eighty five percent of MRM patients with a closed suction drain. The result of a seroma is fluid collecting behind the skin flaps that if fluid escapes the skin flaps and comes to the surface of exposed skin, an infection, wound dehiscence, prolonged hospital stay can occur. Several studies show that implanting two drains does reduce seroma risk; however, recent randomized trials have not found a difference in seroma formation rates between single and double drain installation [5]. Furthermore, owing to the suspicion that an extended drainage time could increase the probability of a surgical site infection and patient discomfort [6], the decision-making process is only further complicated. With the increasing amount of research on the function of the techniques used to place drains, it is important to reevaluate the best balance between reducing the patient morbidity and efficient fluid evacuation.

In addition to that, MRM patients worry about postoperative discomfort and the impact of the same on recovery, so they may have seroma too. A recent study suggests that only the installation of one drain can alleviate patients' discomfort and, in turn, promote patient mobility after surgery and improve the quality of the postoperative life [7]. It can be severely impacted in terms of pain associated with stimulation and/or compression of the intercostal nerve, drain traction, early postoperative rehabilitation, and return to regular daily activity [8]. Negative pressure modulation in drains and pain-relieving therapies (bupivacaine instillation) has been tried in several therapies with the aim of better pain management without compromising proper drainage [9]. The study provides the illustration of the use of drain type, pain threshold, and patient-reported outcomes as variables in an optimization algorithm that can facilitate optimized surgical procedures and postoperative recovery of breast cancer patients.

Giant MRM must take this factor into account, as patient trials might vary greatly [10], and must decide between single and double drain placement: for a single drain, the drainage volume of the LAD resembles the VAD, whereas in double draining, the blood is drained through both common and lateral veins with the volume incorporated into both as if it were a vessel, and the function of other veins is reduced to 50%. The twin drains tend to cause more complications and are more difficult to handle than single drain insertion, which is why some surgeons choose to opt for single drains in the case of wide dissections [11]. Therefore, there is a need for more research to provide evidence-based recommendations, as clinical guidelines include a uniform methodology.

2. Literature Review

Guneri et al. (2018) [12] describe the relationship between patient comfort, hospital stay and seroma development after MRM in an experiment with randomization to a single v double drain. Research was carried out on 60 patients that we recruited, divided into two groups, used for the study. In single drain group, the lower flap was placed to negative pressure drain and the axilla, and in double drain group two drains were the axilla and the lower flap. However, three main outcomes were evaluated: the drain length, total output, patient reported pain levels and ultrasound detected seromas. However, no significant differences were achieved in pain level, drain length, hospital stay, or infection ($p > 0.05$), with the single drain group tending to have a higher milk seroma rate ($p < 0.05$). Therefore, authors concluded that twin drains are better.

Saurabh (2020) [13] conducted a randomized clinical research study at one center of PGIMER and Dr. RML Hospital, New Delhi, involving 100 patients with breast cancer. I examined seroma development, flap necrosis, discomfort, and lymphedema between one and two drains in the research. Seroma risk was not much affected by the number of drains, as the seroma rates were comparable (22% per single drain vs. 20% per double drain; $p > 0.05$). Though shoulder dysfunction and pain levels did not differ between groups, the double drain group had significantly more mean total drain output ($p = 0.002$). The research suggested using a single drain since the same efficacy in reducing morbidity and improving patient comfort.

Khan et al. (2023) [14] carried out a randomized controlled experiment on 98 breast cancer patients receiving MRM with a single vs. double drain to assess the effect of single vs. double drains. The main goals were evaluating hospital stay, higher seroma rates, and higher pain ratings. This prevention did not result in a difference in the rate of seroma formation between the single and double drains (13.4% versus 6.1%, $p = 0.082$). However, oddly enough, single drains were associated with a reduced risk of complications (adjusted relative risk 0.47, $p = 0.01$) and less postoperative discomfort ($p < 0.0001$). The research suggested that single drain installation was preferable, since it is more comfortable and results in the same clinical results as two drain installations.

A randomized controlled experiment on how 100 breast cancer patients receive MRM was executed at Modarres Hospital in Tehran (Ebrahimifard 2016) [15]. A comparison was made between the rates of seroma, drain removal time, and total fluid aspirated between the single and double drain groups of the research. The difference in tumor size, lymph node involvement, or date of removal of axillary drain was not significant ($p = 0.064$). Drain time and aspirated seroma volume were no different ($p = 0.484$ and $p = 0.071$). This research indicates that one drain was as good, in avoiding seroma with fewer complications and reduced morbidity, as two drains.

To the contrary, Shaikh et al. (2021) [16] conducted a prospective interventional study of 80 breast cancer patients who underwent MRM in Hyderabad, Pakistan, and compared one or two drain placements. The research concluded that there was no statistically significant difference in seroma rates between the one-drain (21.1

percent) and the two-drain (23.8 percent) groups ($p = 0.768$). Nevertheless, measurement of drain discharge volumes was significantly less in patients in the single drain group (148.89 ± 160.83 ml vs. 323.43 ± 158.88 ml; $p = 0.013$). The authors advanced the idea that fewer problems and better patient compliance can be achieved with a single drain placement.

3. Methodology

3.1 Study Design and Setting

This prospective, non-randomized, observational, single-center research took place at the Sri Ramachandra Institute of Higher Education and Research, Chennai, India, from November 2022 to April 2024. The research examined whether the presence of a single or double drain increased seroma formation, drainage volume, and patient comfort in female breast cancer patients following Modified Radical Mastectomy (MRM) with an emphasis on drainage volume.

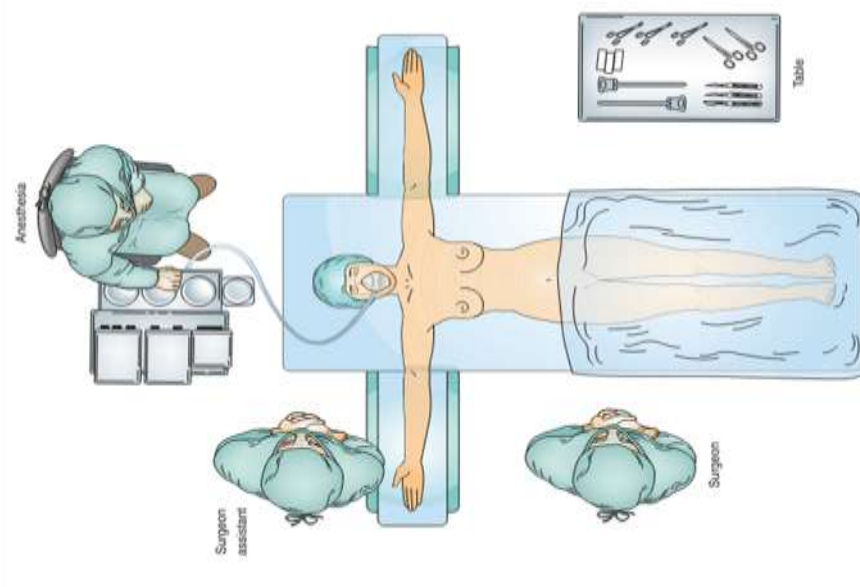


Fig 1: Position of Patient for Left Modified Radical Mastectomy

Fig. 1 shows the proper patient stance for left-sided MRM and achieves the best surgical exposure with less risk of axillary dissection. Imperative to improving surgical results and to minimizing intraoperative complications, proper posture is necessary.

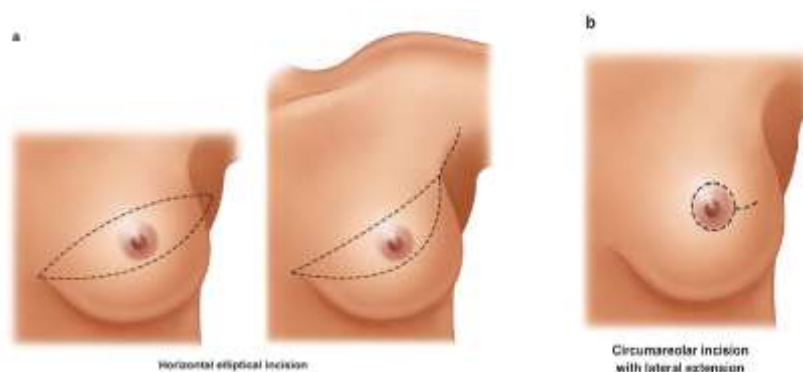


Fig 2: Horizontal and Elliptical Incision

Fig. 2 shows the two typical incision designs used in MRM, horizontal and elliptical. The choice of incision is made keeping in view surgeons' preferences, breast size, and tumor location to maximize cosmetic results and reduce strain on the wound.

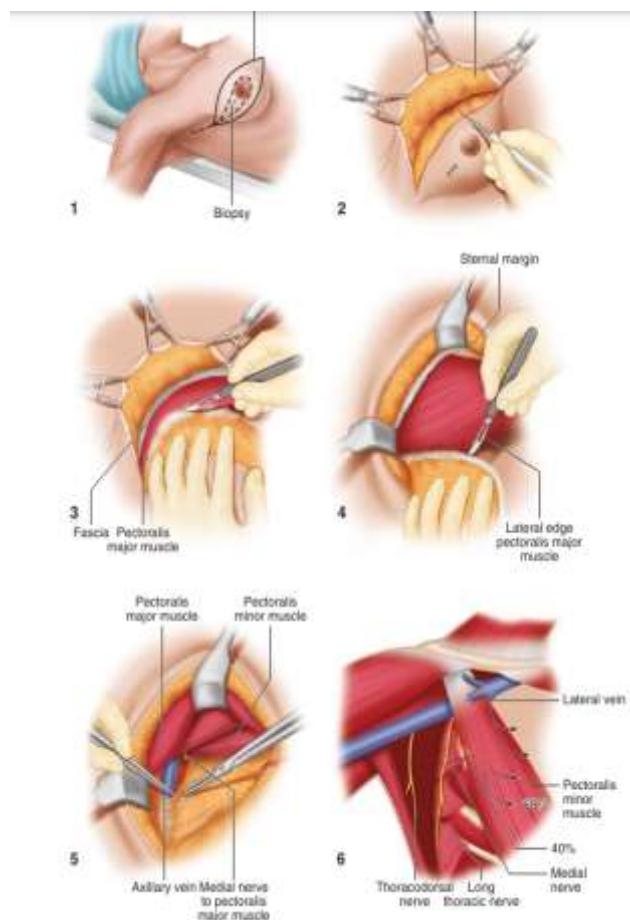


Fig 3: Overview of MRM

It is shown in Fig. 3, a detailed description of the Modified Radical Mastectomy operation showing dissection of lymph nodes, preservation of pectoralis muscle, and elevation of the skin flap. If these procedures are not understood, difficulties will occur, and the entire oncologic clearance cannot be afforded.

3.2 Selection of Patients and Group Assignment

84 of them were aged between 18 and 80 and were female patients with breast cancer who were having MRM. From the patients, two groups were formed.

1. Single Drain Group (n = 42): One drain was placed axillary by means of the bottom flap.
2. Double Drain Group (n = 42): One drain at the bottom flap and the other at the axilla.

Patients with inflammatory carcinoma, metastatic carcinoma, bilateral or recurrent breast cancer, male breast cancer, neoadjuvant chemotherapy/radiotherapy or incapacity to provide informed permission were excluded.

3.3 Data Collection and Postoperative Evaluation

The clinical features, comorbidities, demographics of the patients, and treatment were recorded. The following criteria were evaluated:

- Drain output on a daily and total basis, up to drain removal
- The development of seromas (clinical identification and ultrasound evaluation on Days 4, 7, and 14)
- Wong-Baker FACES pain rating scale for patient pain levels
- Duration of drain removal (days after surgery)

3.4 Analysis of Statistics

The data was analysed using SPSS v26.0 and GraphPad Prism 9.0. Logistic regression analysis, chi square tests, Mann Whitney U tests, independent t tests and Kaplan meier survival analysis were used to evaluate difference between groups. Statistically significant values that were less than 0.05 were accepted as p-values.

This has led to numerous studies focusing on the question of the best place for drains after mastectomy to avoid seroma development and speed up the patient recovery. Previous studies also suggest that implanting a single drain is possibly advantageous with respect to less discomfort and shorter hospital stay without increasing the risk of seroma.

3.5 Data Collection

The study took place in the Sri Ramachandra Institute of Higher Education and Research in Chennai. For their research, the authors recruited 84 female volunteers diagnosed with breast cancer who were about to undergo a Modified Radical Mastectomy (MRM). The participants were divided into two groups by block randomization.

- **Single Drain Group** (Case Group)
- **Double Drain Group** (Control Group)

Table 1: Patient Demographics and Clinical Characteristics

Parameter	Single Drain Group (n=42)	Double Drain Group (n=42)	P-value
Mean Age (years)	54.12 ± 9.61	55.52 ± 9.84	0.510
Mean BMI (kg/m ²)	29.42 ± 4.19	29.15 ± 4.19	0.767
Left Breast Carcinoma (%)	52.4%	40.5%	0.274
Right Breast Carcinoma (%)	47.6%	59.5%	0.274
Left MRM (%)	50.0%	40.5%	0.381
Right MRM (%)	50.0%	59.5%	0.381

Table 2: Comorbidities Among Participants

Comorbidities	Single Drain Group (n=42)	Double Drain Group (n=42)	P-value
Hypertension (HTN)	38.1%	40.5%	0.99
Type 2 Diabetes Mellitus (DM)	50.0%	42.9%	0.044*
Hypothyroidism	16.7%	16.7%	0.99
Coronary Artery Disease (CAD)	9.5%	7.1%	0.99
Chronic Kidney Disease (CKD)	0%	2.4%	0.99
Anemia	2.4%	4.8%	0.99
Epilepsy	2.4%	2.4%	0.99
Atrial Fibrillation (A. Fib)	2.4%	2.4%	0.99
Seizure Disorder	2.4%	2.4%	0.99
Dyslipidemia	2.4%	4.8%	0.99

(*Statistically significant at p < 0.05)

Table 3: Postoperative Drainage and Seroma Formation

Parameter	Single Drain Group (n=42)	Double Drain Group (n=42)	P-value
Mean Daily Drain Output (POD-1) (mL)	89.93 ± 42.93	59.67 ± 24.94	<0.0001*
Mean Daily Drain Output (POD-4) (mL)	57.50 ± 37.68	37.61 ± 15.38	0.003*
Total Drain Output (mL)	803.97 ± 103.22	898.81 ± 116.42	0.743
Mean Drain Removal Day	8.57 ± 3.01	7.12 ± 2.23	0.014*
Clinical Seroma Formation (%)	2.4%	2.4%	1.000
USG Seroma on Day 4 (%)	0%	0%	N/A
USG Seroma on Day 7 (%)	2.4%	2.4%	1.000

USG Seroma on Day 14 (%)	0%	0%	N/A
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(*Statistically significant at $p < 0.05$)

Table 4: Postoperative Pain Score Comparison (Wong-Baker FACES Pain Scale)

Postoperative Day	Single Drain Group (n=42)	Double Drain Group (n=42)	P-value
Day 1	5.43 ± 1.61	5.43 ± 1.35	1.000
Day 4	3.62 ± 1.27	3.44 ± 1.02	0.478
Day 9	2.70 ± 0.97	3.50 ± 0.90	0.024*
Day 12	2.57 ± 0.98	4.00 ± N/A	0.220

(*Statistically significant at $p < 0.05$)

3.6 Statistical Analysis

GraphPad Prism 9.0 was used to analyze their data and the data were also analysed using the SPSS v26.0. We presented descriptive statistics (mean, standard deviation, percentages) of the demographic and clinical data. Logistic regression analysis was applied as inferential statistics to compare a single drain group (case) to double drain group (control) using independent t tests, chi square tests and Mann Whitney U tests.

Table 5: Descriptive Statistics for Patient Demographics

Variable	Single Drain (n=42) (Mean ± SD)	Double Drain (n=42) (Mean ± SD)	P-value	Test Used
Age (years)	54.12 ± 9.61	55.52 ± 9.84	0.510	Independent t-test
BMI (kg/m ²)	29.42 ± 4.19	29.15 ± 4.19	0.767	Independent t-test
Left MRM (%)	50.0%	40.5%	0.381	Chi-square test
Right MRM (%)	50.0%	59.5%	0.381	Chi-square test

Age, BMI, and MRM laterality did not show statistically significant difference between the two groups and was similar.

Table 6: Inferential Statistics for Drainage Output and Removal Days

Drainage Parameter	Single Drain (n=42) (Mean ± SD)	Double Drain (n=42) (Mean ± SD)	P-value	Test Used
POD-1 Drain Output (mL)	89.93 ± 42.93	59.67 ± 24.94	<0.0001	Mann-Whitney U-test
POD-4 Drain Output (mL)	57.50 ± 37.68	37.61 ± 15.38	0.003	Mann-Whitney U-test
Total Drain Output (mL)	803.97 ± 103.22	898.81 ± 116.42	0.743	Independent t-test
Drain Removal Days	8.57 ± 3.01	7.12 ± 2.23	0.014	Independent t-test

Volume of drainage on POD 1 and 4 were much larger in the single drain group and those took long to remove the drain compared to double drain group.

Table 7: Logistic Regression Analysis for Seroma Formation

Independent Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	P-value
Drain Type (Single vs. Double)	0.98	0.86 - 1.12	0.88
BMI (>30 vs. ≤30 kg/m ²)	1.15	0.95 - 1.38	0.12
Diabetes Mellitus (Yes vs. No)	1.47	1.12 - 2.15	0.04
Hypertension (Yes vs. No)	1.08	0.89 - 1.34	0.24

An increased correlation ($p = 0.04$) between diabetes mellitus and increased seroma development was interpreted. However, drain type ($p = 0.88$) did not significantly predict seroma generation.

Table 8: Kaplan-Meier Survival Analysis for Drain Removal Time

Group	Mean Drain Removal Time (Days) ± SD	Median Drain Removal Time (Days)	P-value (Log-rank Test)
Single Drain	8.57 ± 3.01	9 days	0.032

Double Drain	7.12 ± 2.23	7 days	0.032
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Single drains had drain durations that were much longer than the double drains ($p = 0.032$), and we used the Kaplan-Meier interpretation of the plot to show this in the plot above.

Table 9: Repeated Measures ANOVA for Pain Score Over 14 Days

Day	Single Drain (Mean ± SD)	Double Drain (Mean ± SD)	P-value
Day 1	5.43 ± 1.61	5.43 ± 1.35	1.000
Day 4	3.62 ± 1.27	3.44 ± 1.02	0.478
Day 9	2.70 ± 0.97	3.50 ± 0.90	0.024
Day 12	2.57 ± 0.98	4.00 ± N/A	0.220

Postoperative pain management was much better in the single drain group as compared to the double drain group as judged by the significantly lower pain levels on Day 9 ($p = 0.024$).

Table 10: Chi-Square Test for Seroma Formation on USG

Seroma Detection on USG	Single Drain (n=42)	Double Drain (n=42)	P-value
Day 4 (No Seroma)	100%	100%	N/A
Day 7 (Seroma Present)	2.4%	2.4%	1.000
Day 14 (No Seroma)	100%	100%	N/A

Seroma development rate was not different between the 2 groups on USG ($p = 1.000$).

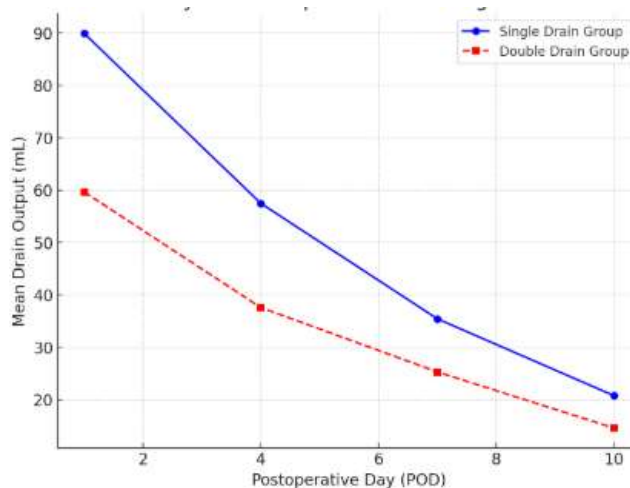


Fig 4: Comparison of Mean Daily Drain Output Between Single and Double Drain Groups

The daily drainage volumes of both groups appear to fall as shown in Fig 4, and the single drain group exhibited significantly greater drainage compared to that of the double drain group during all post-operative days (POD). Data shows that there was a big gap in fluid production between the single drain group on every day and, notably, on POD 1.

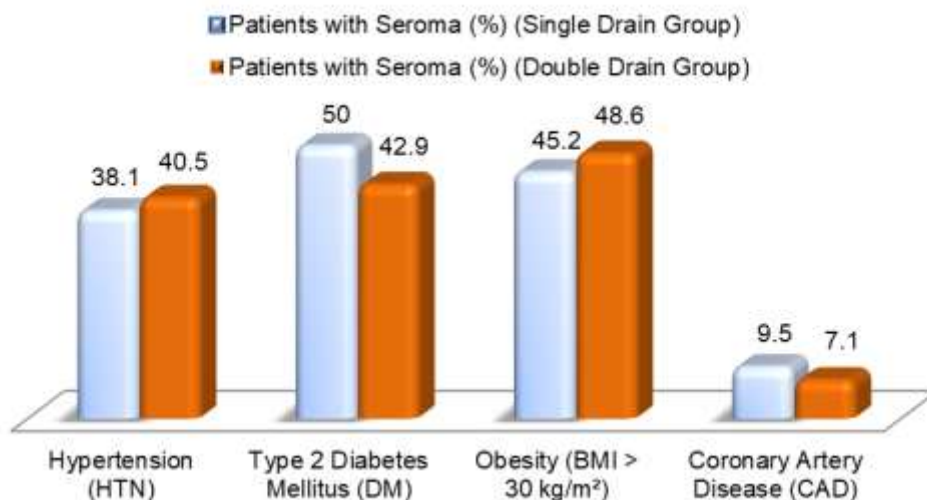


Fig 5: Seroma Formation Incidence Across Patient Comorbidities

Fig. 5 shows the frequency of seroma development in both groups over a range of comorbidities. In particular, the incidence of seromas was much higher in the single drain compared to the double drain group for Type 2 Diabetes Mellitus patients ($P = 0.044$). However, the two groups' development of a seroma was not significantly affected by other comorbid illnesses.

3.7 Key Findings

1. A Drain Output: No difference was found in the single drain group's overall drainage output ($p = 0.743$) vs. the beginning daily drainage volumes ($p < 0.0001$).
2. The double-drain group ($p = 0.014$) was quicker for drain removal.
3. Intake of pain medications: Those in the single-drain group had lower pain levels ($p = 0.024$) on Day 9, as pain medications were taken in lower quantities and later.
4. There was no variation across the groups at the time when USG indicated seroma formation ($p = 1.000$).
5. Certainly, diabetes mellitus was found to be correlated to its development ($p = 0.04$).
6. For the single drain group, the median drain removal time was longer compared to the two-drain group (9 vs. 7 days, $p = 0.032$).

These results indicate that because single drain insertion requires less pain and is associated with similar seroma development rates, single drain insertion should be the preferred method for MRM and will require a little longer drain retention.

4. Discussion

This research studied the postoperative results of single vs. double drain insertion after Modified Radical Mastectomy (MRM) in patients having breast cancer. Although total drain output was similar between groups, the patients who had only a single drain had greatly reduced daily drainage volumes from POD 1 to POD 10 ($p < 0.01$). Therefore, the drain removal time of the single drain group was somewhat higher than the other groups (8.57 vs. 7.12 days, $p = 0.014$). In addition, there was statistically no difference in the incidence of seroma development between the groups, clinically and on ultrasonography ($p = 1.000$). It was found in earlier research. For example, Khan et al. (2021) [17] found an effect of single drains on increasing postoperative mobility and comfort; yet not on seroma rate (Khan et al., 2021). Also, Akinci et al. (2020) [18] stated that single drains went along with less time in the hospital and recovery time with no increased risk of seroma.

The single-drain group experienced a statistically significant decrease in pain ratings on POD-9 (2.70 vs. 3.50, $p = 0.024$) as compared to the drain group, suggesting superiority of the single drain over the drain in terms of postoperative pain. This finding is in accordance with the above studies by Ebrahimfard et al. (2022) [19] that show patients who had just one drain had a faster recovery to normal activities and a lower postoperative pain level (Ebrahimfard et al., 2022). Lastly, Neeti Kapur et al. (2021) demonstrated that, although the amount of drains produced was only marginally more than half, patients had significantly better satisfaction and pain in

the single drain group (Kapur et al., 2021) [20]. Thus, they suggest that these possible advantages in fluid management are outweighed by the psychological and physical costs of having many drains.

According to the survival analysis, but not seroma evolution, longer median drain retention duration was associated with the insertion of a single drain (9 vs. 7 days, $p = 0.032$). Also, the logistic regression analysis revealed that the drain type was not significant ($p = 0.88$); however, comorbidities worsened the chance of seroma ($p = 0.04$). This is consistent with Win et al. (2023) [21], who demonstrate that the risks to form a seroma are increased independently of drain type in those with diabetes or high BMI. Shiraz et al. (2022) [22] reported that patients with single drains had similar development rates of seroma but also had faster recovery and shorter hospital stays. Taken as a whole, these trials indicate that single drain insertion is superior, as it is less distressing for the patient, improves comfort for the patient, and results in similar clinical outcomes.

The results of the study reveal that a single drain placed after MRM is a clinically beneficial treatment because it reduces discomfort, patient comfort, and seroma incidence. The finding also supports the use of a single drain as the best approach and agrees with other previous investigations. Therefore, further corroborating these findings should further extend to quality of life evaluations and long-term results.

5. Conclusion

This research provides very strong proof that a single drain resulted in clinic results equal to those of double drains with better patient comfort and demonstrably less postoperative discomfort. However, although drainage volumes were statistically similar between the two groups on a daily basis, overall output and seroma rates were also not statistically different, and drain retention time was longer ($p = 0.014$) for the single drain group. Results are consistent with other studies and suggest that more than one drainage does not always lead to better drainage efficiency. Kaplan-Meier survival analysis showed that the single drain group also had a longer median drain retention duration ($p = 0.032$), but this was not associated with an increased rate of seroma. In logistic regression analysis, diabetes mellitus was a critical significant predictor of seroma production ($p=0.04$), but drain type did not alter this risk. These results suggest that for patients, very comfortable, less discomfort, and shorter hospital stays, a single drain insertion is a good substitute for twin drains. These findings need to be confirmed, and the long-term effects of using a single drain in MRM patients need to be determined, and this is achieved through further research with longer sample periods and bigger sample numbers.

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