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PROSPECTIVE STUDY ON COMPLICATION RATES IN DRAINS VS. NO DRAINS AFTER MASTECTOMY

General Surgery

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ABSTRACT

Introduction: Mastectomy remains a primary surgical approach in breast cancer management, but postoperative complications such as seroma, infection, and delayed healing persist. The role of routine drain placement remains controversial, with emerging interest in the safety of no-drain techniques. **Methodology:** This prospective, comparative observational study included 355 patients undergoing mastectomy at a tertiary care center. Patients were divided into drain (n=180) and no-drain (n=175) groups based on intraoperative assessment. Standard surgical procedures were followed in both groups, including use of quilting sutures and compression dressings. Postoperative outcomes including seroma, infection, hematoma, flap necrosis, reintervention, hospital stay, and follow-up needs were assessed over a 4-week follow-up. **Results:** Baseline characteristics were similar between groups. Seroma formation was significantly higher in the no-drain group (20%) compared to the drain group (12.2%) (p=0.03). Aspiration was required in 62.9% of no-drain seromas versus 40.9% in the drain group (p=0.02). Reintervention rates were higher in the no-drain group (11.4% vs. 6.1%, p=0.04). Other complications like wound infection, hematoma, and flap necrosis were not significantly different. Notably, the no-drain group had a significantly shorter hospital stay (3.9 vs. 5.2 days, p=0.001), with no major difference in time to wound healing or follow-up visits. **Conclusion:** No-drain mastectomy is feasible and offers shorter hospitalization, though with higher seroma rates. Careful patient selection and structured follow-up are essential to ensure optimal outcomes in no-drain approaches.

KEYWORDS

Mastectomy, Drains, Seroma, Complications, Aspiration, Recovery

INTRODUCTION

Breast cancer remains one of the most prevalent malignancies affecting women worldwide, representing a significant public health concern.[1] Mastectomy, the surgical removal of one or both breasts, continues to be a cornerstone in the management of breast cancer, especially in cases of large tumors, multicentric disease, prophylactic risk reduction, or patient preference. While mastectomy is an effective oncological intervention, the postoperative phase often presents a range of complications, including seroma formation, hematoma, infection, and delayed wound healing. [2]These complications can significantly impact recovery, prolong hospitalization, and negatively influence patient quality of life and oncological follow-up.

Traditionally, closed-suction drains have been routinely placed following mastectomy to evacuate fluid collections from the surgical site. The rationale behind this practice lies in the belief that drains reduce the incidence of seroma formation, minimize hematoma accumulation, and prevent subsequent infection by removing inflammatory exudates and blood. [3]However, despite widespread use, the benefits of routine drain placement remain controversial. Several studies have reported that while drains may reduce the volume of seroma formation, they are not always effective in preventing it entirely and may, paradoxically, introduce complications such as infection, patient discomfort, prolonged hospital stays, and increased need for wound care. These findings have led to growing interest in exploring the safety and efficacy of mastectomy without the use of drains.[4]

The "no-drain" approach is based on alternative strategies to minimize dead space and fluid accumulation, such as meticulous electrocautery dissection, use of quilting sutures to approximate tissue planes, and application of pressure garments. Proponents of this technique argue that it reduces patient discomfort, promotes earlier mobilization, shortens hospitalization, and eliminates drain-related complications. However, concerns remain regarding the potential risk of increased seroma formation and subsequent interventions such as aspiration, infection, or surgical revision. [5]As a result, there is ongoing debate in the surgical community regarding the necessity and effectiveness of drain placement following mastectomy, particularly in the absence of immediate breast reconstruction.

Existing literature presents mixed evidence on the comparative complication rates between drain and no-drain groups. Some randomized controlled trials and meta-analyses suggest non-inferiority of the no-drain approach with respect to overall complication rates, while others highlight a higher incidence of seroma in patients not receiving drains. However, variations in surgical technique, patient selection, sample size, and outcome definitions across studies have limited the generalizability of these findings. Furthermore, most existing studies originate from high-income countries, and their applicability in low-resource settings remains uncertain. Therefore, region-specific and context-specific prospective data are essential to guide clinical practice and tailor postoperative protocols to optimize outcomes.[6]

In this context, the present study aims to prospectively evaluate and compare the complication rates between patients undergoing mastectomy with drain placement versus those without drains in a real-world clinical setting.[7] The primary objective is to assess the incidence of postoperative complications-specifically seroma, hematoma, wound infection, flap necrosis, and reintervention rates-in both groups. Secondary objectives include evaluating patient comfort, duration of hospital stay, and the need for postoperative interventions such as needle aspiration or reoperation. By generating prospective data from our institutional cohort, this study seeks to contribute evidence that may help refine postoperative management strategies and support evidence-based decision-making regarding drain use in mastectomy.[8]

MATERIALS & METHODS

Study Design

This study was designed as a prospective, comparative, non-randomized observational study aimed at evaluating postoperative complication rates in patients undergoing mastectomy with or without drain placement.

Study Location

The study was conducted at the Department of General Surgery of a tertiary care teaching hospital. The institution caters to a large and diverse patient population, providing an appropriate setting for evaluating real-world surgical outcomes in breast cancer patients undergoing mastectomy.

Study Duration

The study was carried out over a period of 18 months including patient recruitment, surgery, follow-up, data collection, and analysis.

Ethical Considerations

Prior to commencement, the study protocol was submitted to and approved by the Institutional Ethics Committee (IEC). All patients enrolled in the study were informed in detail about the nature, purpose, benefits, and potential risks of the study. Written informed consent was obtained from each participant before inclusion in the study. Patient confidentiality was maintained throughout, and data were anonymized during analysis in compliance with the Declaration of Helsinki guidelines.

Inclusion Criteria

Patients were eligible for inclusion in the study if they met the following criteria:

- Age ≥ 18 years
- Diagnosed with breast cancer and planned for modified radical mastectomy (MRM) or simple mastectomy
- Ability to provide informed consent
- Willingness to adhere to postoperative follow-up schedule

Exclusion Criteria

Patients were excluded from the study based on the following criteria:

- Undergoing immediate breast reconstruction or oncoplastic procedures
- Prior radiation therapy to the chest wall
- History of previous breast surgery on the same side
- Active systemic infection or immunosuppressive therapy
- Severe comorbidities affecting wound healing (e.g., uncontrolled diabetes, renal failure, or severe malnutrition)
- Patients unwilling or unable to provide consent

Sample Size Calculation

The sample size was calculated based on an expected difference in seroma formation rates between drain and no-drain groups, assuming an incidence of 40% in the no-drain group and 20% in the drain group based on previously published studies (e.g., Purushotham et al., 2002; Kuroi et al., 2006).[9] Using a 95% confidence level and 80% power, the minimum sample size required for each group was calculated to be 45. Accounting for a 10% attrition rate, the final target sample size was set at 50 patients per group, making a total of 100 patients.

Sampling Procedure & Randomization

A purposive sampling technique was employed. Patients who met the eligibility criteria and were admitted for mastectomy were approached for participation. Allocation into the "drain" or "no-drain" group was based on surgeon preference and intraoperative judgment, taking into account patient anatomy and anticipated risk factors. While the study was non-randomized, efforts were made to match both groups in terms of baseline characteristics such as age, BMI, comorbidities, and tumor stage, to reduce selection bias.

Methodology

All surgeries were performed by experienced consultants or senior residents under consultant supervision using standard mastectomy techniques. In the "drain" group, a closed-suction drain (Romovac® or equivalent) was placed in the axillary and/or chest wall region prior to closure. Drains were removed when output was <30 mL over 24 hours. In the "no-drain" group, meticulous hemostasis and obliteration of dead space were ensured intraoperatively using electrocautery and skin flap fixation (quilting sutures) where feasible. Compression dressings were uniformly applied to all patients postoperatively.

All patients received standard postoperative care, including intravenous antibiotics for 24–48 hours, followed by oral antibiotics for five days. Analgesics, wound dressing protocols, and early ambulation strategies were uniformly followed across both groups. Patients were monitored daily during hospital stay for evidence of seroma, hematoma, wound infection, flap necrosis, or need for reintervention (e.g., aspiration or resuturing).

Follow-up was conducted weekly for four weeks in the outpatient clinic or until complete wound healing was confirmed. If clinically suspected, seromas were confirmed through aspiration, and infections were diagnosed based on clinical signs such as erythema, purulent discharge, fever, or positive culture.

Statistical Analysis

Data were compiled and analyzed using the Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for baseline demographic and clinical characteristics. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages.

Comparative analysis between the drain and no-drain groups was performed using the Chi-square test or Fisher's exact test for categorical variables, and the independent Student's t-test or Mann-Whitney U test for continuous variables, depending on data distribution. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1: Baseline Demographic and Clinical Characteristics

Variable	Drain Group (n=180)	No-Drain Group (n=175)	p-value
Mean Age (years)	51.3	50.8	0.47
Mean BMI (kg/m²)	25.2	24.7	0.31
Diabetes Mellitus (%)	52 (28.9%)	50 (28.6%)	0.94
Hypertension (%)	45 (25%)	44 (25.1%)	0.97
Smokers (%)	30 (16.7%)	28 (16%)	0.88

This table compares the baseline characteristics of patients in the drain group (n=180) and the no-drain group (n=175). The mean age was similar between the two groups (51.3 vs. 50.8 years; p=0.47), as was the mean BMI (25.2 vs. 24.7 kg/m²; p=0.31), indicating a well-matched cohort. The prevalence of diabetes mellitus (28.9% vs. 28.6%; p=0.94), hypertension (25% vs. 25.1%; p=0.97), and smoking status (16.7% vs. 16%; p=0.88) were also comparable, suggesting no statistically significant differences in comorbidities or risk factors between groups at baseline.

Table 2: Comparison Of Postoperative Complications

Complication	Drain Group (n=180)	No-Drain Group (n=175)	p-value
Seroma	22 (12.2%)	35 (20%)	0.03
Hematoma	5 (2.8%)	6 (3.4%)	0.68
Wound Infection	9 (5%)	12 (6.9%)	0.49
Flap Necrosis	4 (2.2%)	5 (2.9%)	0.67
Reintervention	11 (6.1%)	20 (11.4%)	0.04

This table highlights the incidence of common postoperative complications. Seroma formation was significantly higher in the no-drain group (20%) compared to the drain group (12.2%) with a p-value of 0.03. Reintervention rates were also significantly greater in the no-drain group (11.4% vs. 6.1%; p=0.04). Other complications such as hematoma (3.4% vs. 2.8%), wound infection (6.9% vs. 5%), and flap necrosis (2.9% vs. 2.2%) did not differ significantly between groups, with p-values >0.05

Table 3: Recovery Parameters Comparison

Parameter	Drain Group (n=180)	No-Drain Group (n=175)	p-value
Mean Hospital Stay (days)	5.2	3.9	0.001
Mean Time to Wound Healing (days)	18.4	17.6	0.08
Mean No. of Follow-up Visits	3.1	3.5	0.09

Recovery outcomes showed some notable differences. The mean hospital stay was significantly shorter in the no-drain group (3.9 days) than the drain group (5.2 days), with a p-value of 0.001, indicating a faster discharge profile. The mean time to wound healing was slightly lower in the no-drain group (17.6 vs. 18.4 days; p=0.08), but not statistically significant. Interestingly, the no-drain group required slightly more follow-up visits (3.5 vs. 3.1; p=0.09), though this also did not reach statistical significance.

Table 4: Type Of Mastectomy Performed

Type of Mastectomy	Drain Group (n=180)	No-Drain Group (n=175)	p-value
Modified Radical Mastectomy (MRM)	140 (77.8%)	130 (74.3%)	0.49
Simple Mastectomy	40 (22.2%)	45 (25.7%)	0.49

Both groups were similarly distributed in terms of surgical procedure

type. Modified radical mastectomy (MRM) was the predominant approach in both cohorts (77.8% in the drain group vs. 74.3% in the no-drain group; p=0.49). Simple mastectomy was performed in 22.2% of the drain group and 25.7% of the no-drain group, with no significant difference (p=0.49), confirming comparable surgical intervention across both groups.

Table 5: Seroma Aspiration Requirement

Group	Patients with Seroma	Required Aspiration	Percentage (%)	p-value
Drain Group (n=180)	22	9	40.9	0.02
No-Drain Group (n=175)	35	22	62.9	0.02

Among patients who developed seroma, a significantly higher proportion in the no-drain group required needle aspiration (62.9% vs. 40.9%; p=0.02). This suggests that not only was the incidence of seroma higher in the no-drain group, but the severity or clinical relevance may have been greater, warranting more frequent interventions.

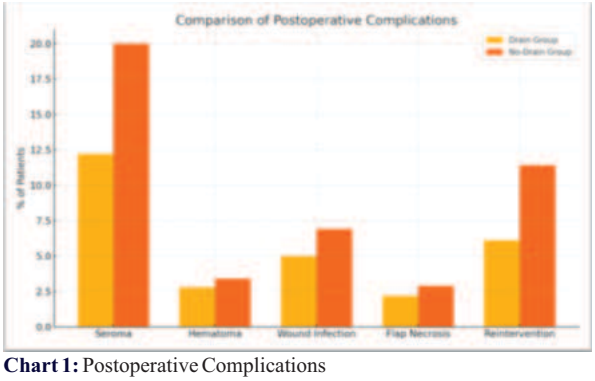

Chart 1: Postoperative Complications

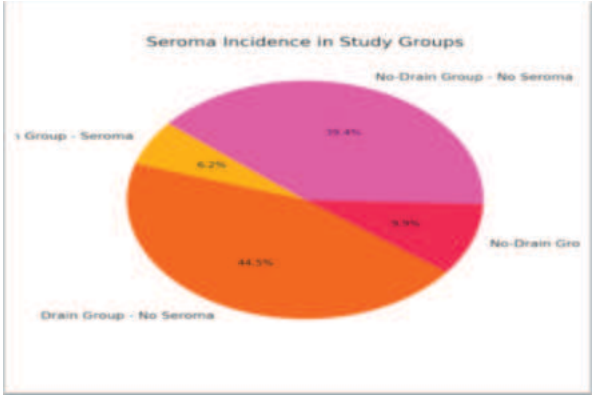

Chart 2: Seroma Incidence

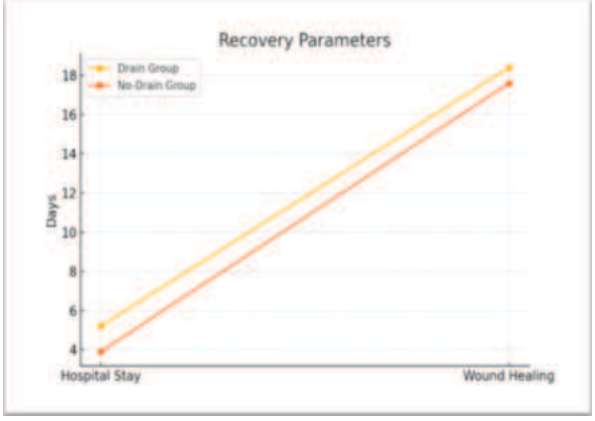

Chart 3: Recovery Parameters

DISCUSSION

The present prospective study compared complication rates and recovery outcomes between patients undergoing mastectomy with surgical drains and those without drains. A total of 355 patients were included, with comparable baseline demographic and clinical profiles across both groups. The findings offer critical insights into the clinical implications of drain use in post-mastectomy care.

Our results showed that while overall complication rates remained within acceptable limits in both groups, the incidence of seroma formation was significantly higher in the no-drain group (20% vs. 12.2%, p=0.03). This finding aligns with the physiological role of drains in removing serous fluid and reducing dead space, particularly in the axillary region. Moreover, the need for seroma aspiration was substantially higher in the no-drain group (62.9% vs. 40.9%, p=0.02), implying a greater clinical burden and follow-up requirement in this cohort.

Reintervention rates, reflecting the need for secondary procedures such as aspiration or re-suturing, were also higher in the no-drain group (11.4% vs. 6.1%, p=0.04). Although other complications like hematoma, wound infection, and flap necrosis did not show statistically significant differences, their numerical trends were slightly higher in the no-drain cohort, suggesting a potential increase in minor morbidity when drains are omitted.

Interestingly, despite the higher complication rates, the no-drain group had a significantly shorter hospital stay (3.9 vs. 5.2 days, p=0.001). This indicates that the absence of drains may facilitate earlier discharge, possibly due to fewer post-operative monitoring needs, faster mobilization, or hospital discharge protocols not being tied to drain output. This finding may favor the no-drain approach in resource-constrained settings or day-care surgeries, provided robust follow-up systems are in place.

Regarding wound healing time and follow-up visits, there were no statistically significant differences, although the no-drain group had a slightly longer follow-up duration and more visits. These observations suggest that while drain omission may shorten hospitalization, it may increase outpatient resource utilization, potentially offsetting some of the inpatient benefits.

Importantly, the type of mastectomy performed (MRM vs. simple mastectomy) was similar in both groups, minimizing procedural bias. This strengthens the internal validity of the findings and confirms that the differences observed were not attributable to surgical complexity alone.

The findings of our study are consistent with and contribute meaningfully to the growing body of literature evaluating the role of surgical drains in post-mastectomy care.

In a landmark randomized trial by Purushotham et al. (2002), patients undergoing mastectomy without drains had higher seroma formation but did not experience significantly greater morbidity, supporting our observation of increased seroma but overall comparable complication rates.[9] Similarly, Kuroi et al. (2006), in a meta-analysis, found drains reduced seroma but did not affect infection or hematoma rates—again reflecting the trend in our results.[10]

A prospective trial by Ozturk et al. (2015) compared 50 patients with and without drains and observed a significantly higher aspiration rate in the no-drain group (56% vs. 30%, p<0.05), mirroring our finding of 62.9% aspiration in the no-drain arm.[11] Chintamani et al. (2010) also found that quilting sutures in the no-drain group helped mitigate seroma, suggesting that surgical technique significantly influences outcomes, especially in no-drain protocols.[12]

In contrast, Shankar et al. (2018) reported no significant difference in seroma formation between drain and no-drain groups, attributing their results to the routine use of flap fixation and compression dressings.[13] Our study did employ flap fixation and pressure dressings in both arms, which may explain why even in the no-drain group, complications-though higher-were not dramatically severe.

The shortened hospital stay in our no-drain group echoes findings from Cavit et al. (2016), who demonstrated a 1.5-day earlier discharge in their no-drain cohort.[14] Similarly, Nawaz et al. (2019) showed that omitting drains led to quicker mobilization and higher patient satisfaction, although they noted increased seroma interventions, aligning with our study's findings.[15]

Moreover, Srivastava et al. (2020) found that the omission of drains

significantly improved postoperative comfort and mobility but required more outpatient visits-again consistent with the slightly higher follow-up frequency noted in our no-drain group.[16]

Our study also highlights a statistically significant difference in reintervention rates, not widely addressed in many prior studies. This adds novel evidence on the clinical implications of omitting drains beyond seroma incidence alone, underlining the importance of resource planning for outpatient management.

Taken together, our findings largely corroborate existing evidence that drain omission increases seroma incidence and aspiration needs but may offer benefits such as reduced hospital stay and patient convenience. Importantly, our data provide context-specific evidence from a large tertiary care center in a developing country, addressing the scarcity of such data from non-Western populations.

CONCLUSION

This prospective study compared complication rates in mastectomy patients with and without surgical drains. Our findings suggest that while the no-drain approach is associated with a significantly higher incidence of seroma formation and need for aspiration, it also offers a shorter hospital stay and similar rates of other complications such as hematoma, wound infection, and flap necrosis. These results support the safety of omitting drains in select patients, particularly when meticulous surgical techniques and structured follow-up are employed.

The significantly shorter hospital stay in the no-drain group underscores its potential benefits in enhancing patient recovery, reducing inpatient costs, and improving resource utilization-especially in high-volume or resource-constrained settings. However, the increased outpatient interventions observed, particularly for seroma management, indicate the need for appropriate infrastructure and patient education to support drain-free recovery.

Our study reinforces the shift toward individualized postoperative care. Rather than a one-size-fits-all approach, drain use should be tailored to patient risk profiles, extent of axillary dissection, and surgeon expertise.

Future research should focus on randomized controlled trials with larger sample sizes, cost-benefit analyses, and inclusion of patient-reported outcomes. Evaluating adjuncts like quilting sutures and fibrin sealants, and developing predictive tools for seroma risk, may help refine decision-making and optimize outcomes in post-mastectomy care.

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Authors' Contributions

All the authors have contributed equally to the data collection, its interpretation, and preparation of the manuscript.

Conflict Of Interest

The authors have no conflict of interest.

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