

Original Research Article

A comparative prospective randomized study of LigaSure versus electrocautery for axillary dissection in modified radical mastectomy with half pressure suction drain: impact on seroma formation

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ABSTRACT

Background: Seroma formation remains the most frequent complication following modified radical mastectomy (MRM). The choice of dissection technique plays a role in its incidence. This study compared LigaSure with conventional electrocautery for axillary dissection in terms of seroma formation and related outcomes.

Methods: A prospective randomized study was conducted on 50 female patients with unilateral FNAC/Biopsy proven breast carcinoma undergoing MRM, at Aadhar health institute, Hisar, Haryana. Patients were randomized into two groups: group A (electrocautery, n=25) and group B (LigaSure, n=25). Standardized half-pressure negative suction drains were placed in all cases. Outcomes compared in terms of operative time, daily drain output, duration of drainage, incidence of seroma formation, and number of seroma aspirations.

Results: The mean operative time, was shorter in the LigaSure group, though not significant statistically. Drain output up to postoperative day 3 was significantly lower in the LigaSure group ($p < 0.05$), but from POD 4 to POD14, cumulative drain output was statistically non-significant. Seroma incidence was reduced with LigaSure (28%) compared to electrocautery (32%), though not statistically significant. The seroma aspirations were also lower in the LigaSure group in number, but non-significant.

Conclusions: LigaSure reduces operative time and drainage volume, with a trend toward fewer seroma formation compared to electrocautery. Although the difference in seroma incidence did not reach statistical significance, LigaSure appears to be a safer and more efficient option for axillary dissection in MRM.

Keywords: Modified radical mastectomy, LigaSure, Electrocautery, Axillary dissection, Seroma

INTRODUCTION

Modified radical mastectomy (MRM) is a standard procedure for operable breast carcinoma.¹ While effective, it is associated with postoperative complications, among which seroma formation is most frequent, with reported rates ranging from 15-85%. Seroma delays wound healing, predisposes to infection, and prolongs recovery.² In recent years, various surgical devices have been evaluated to reduce seroma formation,

with LigaSure and electrocautery being two prominent devices for axillary dissection.³⁻⁵

This study aimed to compare LigaSure and electrocautery in axillary dissection during MRM, focusing on their effect on seroma formation.

METHODS

This was a prospective randomized controlled study conducted on 50 patients, with FNAC proven unilateral

breast carcinoma, in the Department of General Surgery, Aadhar Health Institute, Hisar, Haryana, over a period of 18 months, from March 2023 to September 2024.

After taking approval from Institutional Ethical Committee and individual patient consent, each patient underwent detailed history taking, clinical examination, investigations as per per forma before selection. Patients were randomized into group A (electrocautery, n=25) and group B (LigaSure, n=25).

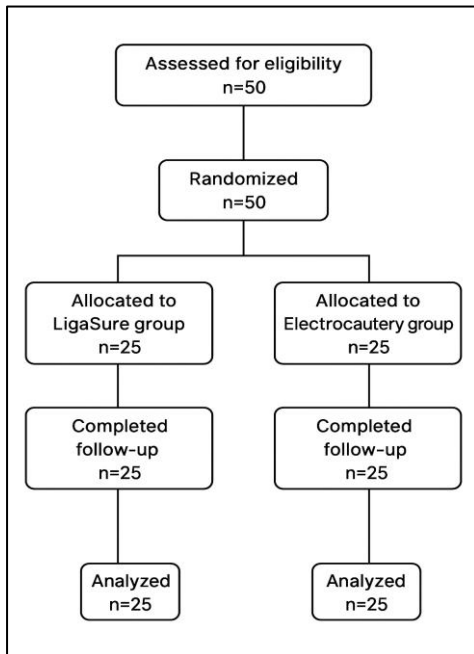


Figure 1: Clinical examination.

Inclusion criteria

Patients aged 18-70 years, and FNAC/biopsy proven breast cancer were included.

Exclusion criteria

Patients with metastatic disease, prior axillary surgery, BMI >35 Kg/m², severe comorbidities, B/L breast carcinoma were excluded.

Surgical technique

Standard MRM with level I-II axillary clearance was performed and two negative suction drains placed with half pressure (one in axilla: posterior, one below skin flap: anterior).

Primary outcomes

The primary outcomes were operative time, drain output, duration of drainage.

Secondary outcomes

The secondary outcomes were seroma incidence, number of seroma aspirations.

Data analyzed with t test/Chi-square; p<0.05 significant.

RESULTS

Both groups were comparable in terms of age group, BMI, baseline laboratory values. Mean operative time was comparable between both groups (p=0.569). Daily drain output till POD 3 was significantly lower in LigaSure group (p=0.0445, 0.0334, 0.0353 respectively). Drain output from POD 4 to POD 14, cumulative drain output (POD 1-14) was non-significant (p>0.05) in between both groups (994.5±412.5ml in electrocautery group, 796.4±408.3ml in LigaSure group). Seroma incidence 20% (LigaSure) vs. 36% (electrocautery), not statistically significant (p=0.758). Mean number of repeated seroma aspirations was lower in LigaSure, but non-significant (p=0.585).

Table 1: Age distribution across the study groups.

| Age (in years) | Group A | Group B | Total |
|-----------------------------------|-----------|-----------|-----------|
| ≤40 | 4 | 6 | 10 |
| 41-50 | 7 | 6 | 13 |
| 51-60 | 8 | 10 | 18 |
| 61-70 | 5 | 4 | 9 |
| Total | 24 | 26 | 50 |
| Pearson chi-square=0.731, p=0.866 | | | |

Table 2: Comparison of drain output (POD 1-POD 7).

| POD | Group A (mean±SD) | Group B (mean±SD) | P value |
|-------|-------------------|-------------------|---------|
| POD 1 | 133.0±76.0 | 92.4±46.3 | 0.0445 |
| POD 2 | 122.5±55.0 | 88.8±45.1 | 0.0334 |
| POD 3 | 116.0±53.0 | 84.8±39.5 | 0.0353 |
| POD 4 | 97.0±45.0 | 78.8±40.3 | 0.1660 |
| POD 5 | 86.0±36.8 | 73.6±38.3 | 0.2760 |

Continued.

| POD | Group A (mean±SD) | Group B (mean±SD) | P value |
|-------|-------------------|-------------------|---------|
| POD 6 | 94.0±83.9 | 66.8±35.9 | 0.1880 |
| POD 7 | 72.0±26.9 | 62.8±31.8 | 0.2991 |

Table 3: Comparison of drain output (POD 8 to POD 14).

| POD | Group A (mean±SD) | Group B (mean±SD) | P value |
|--------|-------------------|-------------------|---------|
| POD 8 | 65.5±28.0 | 56.8±31.5 | 0.3325 |
| POD 9 | 57.0±21.3 | 48.4±27.9 | 0.2479 |
| POD 10 | 47.5±21.5 | 42.8±25.9 | 0.5095 |
| POD 11 | 38.5±19.3 | 35.6±22.9 | 0.6472 |
| POD 12 | 28.0±12.0 | 27.6±19.2 | 0.9323 |
| POD 13 | 21.5±8.8 | 21.6±15.5 | 0.9783 |
| POD 14 | 16.0±7.5 | 15.6±10.0 | 0.8794 |

Table 4: Total drain output (POD 1 to POD 14).

| Group | Mean±SD (ml) |
|----------|--------------|
| Group A | 994.5±412.5 |
| Group B | 796.4±408.3 |
| P=0.1155 | |

Table 5: Comparison of cumulative drain outputs between LigaSure and electrocautery.

| Cumulative drain outputs by POD | | | |
|---------------------------------|-------------|-------------|-------------|
| Group | POD 1-7 | POD 8-14 | POD 1-14 |
| A | 720.5±317.4 | 274.0±109.2 | 994.5±412.5 |
| B | 548.0±271.5 | 248.4±144.4 | 796.4±408.3 |
| P value | 0.0611 | 0.5021 | 0.1155 |

Table 6: Incidence of seroma formation.

| Groups | Number of patients developing seroma | Percentage of patients developing seroma |
|--------|--------------------------------------|--|
| A | 8 | 32 |
| B | 7 | 28 |

Table 7: Number of aspiration procedures for seroma.

| Number of aspirations | Group A | Group B | Total |
|-----------------------|---------|---------|-------|
| 0 | 17 | 18 | 35 |
| 1 | 2 | 4 | 6 |
| 2 | 4 | 3 | 7 |
| 3 | 1 | 0 | 1 |
| 4 | 1 | 0 | 1 |
| Total | 25 | 25 | 50 |

Pearson chi-square=2.938, p=0.585.

DISCUSSION

This study compares the effect of LigaSure vs. electrocautery on post MRM seroma formation.

Postoperative drain output acts as critical indicator of extent of lymphatic or vascular dissection and their sealing. Zia et al reported that patients in LigaSure group had considerably reduced drain output as compared to conventional electrocautery.⁶ In our study, drains were removed on POD 7 (anterior) and POD 14 (posterior),

irrespective of drain output. LigaSure group had statistically significant lower drain output in early postop period (POD 1-3), but later this difference became insignificant even in terms of cumulative drain output. In contrast to our study, Tukenmez et al showed smaller drain volume and shorter duration of drainage after axillary lymph node dissection (ALND) using LigaSure when compared to electrocautery and suture ligation.⁷

Incidence of seroma formation was lower in LigaSure group (28%) as compared to electrocautery (32%), yet

statistically non-significant ($p=0.758$). There was no statistical difference in frequency of multiple aspirations, but it was less in LigaSure group numerically. Similar to our results, Antonio et al reported in his prospective randomized trial, no improvement in terms of duration of drainage and drained fluid amount by using LigaSure compared to electrocautery.⁸ On the other hand, Cortedellas et al reported a reduction in postoperative seroma aspirations and total amount of aspirated fluid when applying LigaSure as compared to electrocautery.⁹

Newer surgical devices have shown better outcomes regarding intra- and postoperative complications. Many studies show decrease in operative time, perioperative complications by using LigaSure.¹⁰

Seroma formation is most common complication post MRM and its multifactorial, influenced by surgical technique, lymphatic disruption, and inflammatory response. It affects patient's recovery, healthcare cost, quality of life and delay in adjuvant treatment.^{25,28,29,31}

In this study, age group was from 18-70 years, avoiding the age-related factors, that could skew the postoperative outcomes. All 50 participants were female, which is consistent with high incidence of breast cancer in females. Both groups were comparable in terms of baseline investigations, BMI.

LigaSure was associated with shorter operative time and reduced drainage volume, though seroma incidence reduction was not statistically significant, trends favor LigaSure. A clear advantage could not be demonstrated in this study of LigaSure over electrocautery.

This study has few limitations, including small sample size, shorter duration of follow up, which may explain lack of statistical significance.

CONCLUSION

LigaSure is a safe and effective alternative to electrocautery for axillary dissection in MRM in terms of better early postoperative damage control, it does not significantly reduce the overall risk of seroma formation or the number of seroma aspirations required. Both techniques showed comparable effectiveness in terms of operative duration, total drain output and reducing trend of drain output. Hence, the selection between LigaSure and electrocautery should consider factors; such as surgeon preference, equipment availability, and individual patient characteristics, rather than expectations of seroma prevention alone.

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