

Comparison of Seroma Formation in Modified Radical Mastectomy: Conventional Scalpel Versus Ligasure™ Technique

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ABSTRACT

Objective: This study aims to compare the outcome of scalpel versus LigaSure™ dissection with respect to seroma formation in the skin flaps.

Methods: The study was conducted at the Department of General Surgery, Federal Government Polyclinic Hospital (FGPC), Islamabad. The study spanned over a period of twelve months, i.e. October 2020 to September 2021 which recruited 60 patients with breast cancer which were randomly assigned to two equal groups. Modified radical mastectomy with axillary lymph node dissection was done in all the patients. Group-I underwent traditional scalpel dissection while LigaSure™ dissection was done in the group- II. The primary outcome was to assess the seroma formation. The demographic data along with time required for surgery, duration of drain placement, and hospital stay was recorded. The recorded data was constructed and analyzed using SPSS (version 22.0).

Results: Among 60 enrolled patients, the mean age was 38.3 ± 11.4 and 39.8 ± 9.4 years in group I and II, respectively. A total of 6.7% ($n=2$) patients in group-I and 10% ($n=3$) patients in group-II showed seroma formation in skin flaps after surgery (p -value = 0.640). The mean time required for surgery was 109.9 ± 7.9 and 105.1 ± 8.3 minutes in group-I and group-II, respectively (p -value = 0.027). The average duration of hospital stay in group-I and group-II was 4.8 ± 1.7 and 5.3 ± 1.9 days (p -value=0.335).

Conclusion: Compared to traditional scalpel dissection, the use of LigaSure™ assisted dissection shows no significant benefit in terms of reduced post-operative seroma formation, and duration of hospital stay. However, LigaSure™ assisted dissection significantly reduces the time-of-surgery. In resourceful hospital settings, LigaSure™ assisted dissection can be used to reduce the morbidity associated with longer anesthesia time by reducing the *time-of-surgery*.

Keywords: Mastectomy, Modified Radical, Seroma, Breast cancer, Breast surgery, Operative, Surgical Instrumentation

Authors' Contribution:

^{1,2}Conception; Literature research; manuscript design and drafting; ² Critical analysis and manuscript review; ^{1,2} Data analysis; Manuscript Editing.

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Introduction

Breast cancer is a widely distributed disease and a leading cause of cancer-related deaths in female

population worldwide.^[1] Breast cancer not only contributes to life years lost due to disability-adjusted for global mortality but also bestow a

significant burden to cancer related surgery.^[2] Surgical intervention for breast cancer expands over a spectrum from breast conservation surgery to mastectomy with or without axillary lymph node dissection.^[3,4] Breast surgery is no-exception in terms of post-operative complications; seroma formation being the commonest early nuisance.^[5] Seroma is a serous-fluid collection developing under skin flap or axillary dead space after mastectomy.^[6] The incidence of seroma formation ranges from anywhere between 3-85%.^[7] Seroma formation is a double-edged sword; it not only increases the post-operative morbidity in terms of longer hospital stay, delayed wound healing, and decreased patient satisfaction but at times delay the adjuvant therapy initiation.^[8,9] The cause of seroma formation is multifactorial with electro-thermal local tissue damage during dissection and lymphatic leakage after lymph node resection contributing significantly.^[10] An armamentarium of surgical techniques influence the formation of seroma, thus, leading to widely varying incidence of seroma formation in different studies.^[11] Several techniques are described for modified radical mastectomy (MRM), however, commonly dissection is either carried out by conventional scalpel or by electrocautery method.^[11] The conventional steel-scalpel dissection has advantage over electrocautery in terms of decreased seroma formation but at the cost of increased blood loss, suture knot slippage, and increased time-of-surgery.^[12] Electrocautery has been used widely for dissection purposes in MRM as it significantly reduces blood loss; nevertheless, it is associated with increased incidence of seroma formation due to thermal tissue damage leading to local inflammatory reaction and incomplete lymphatic and vascular occlusion.^[13] Apart from the conventional techniques, newer devices like LigaSure™ (Covidien, CO, USA) are available which use bipolar vessel-sealing system which inflict lower local tissue damage and better vessel sealing capabilities promising safer surgery and reduced

post-operative complications.^[14] LigaSure™ safety, efficacy and time-saving capacity has already been well-examined in different surgical domains including colorectal and thyroid surgeries.^[15,16] Several studies have compared the outcomes of conventional electrocautery and LigaSure™ in modified-radical mastectomy (MRM). However, the literature remains widened on the outcome comparison of steel-scalpel versus LigaSure™ in MRM. The aim of this study is to bridge that gap and compare the effectiveness and outcome of conventional steel-scalpel dissection and LigaSure™ assisted dissection in modified radical mastectomy in terms of post-operative seroma formation.

Methodology

A comparative analytical study was conducted at the Department of General Surgery, Federal Government Polyclinic Hospital (FGPC), Islamabad spanning over a time-course of one year from October, 2020 till September, 2021. The study population included female patients presenting with early breast carcinoma (stage I and II, as per AJCC staging system) with age group of 35-65 years. The exclusion criteria were locally advanced breast carcinoma (stage III and IV, as per AJCC staging system), body mass index (BMI) >30kg/m² or <18kg/m², diabetes mellitus, uncontrolled hypertension, patients who received neoadjuvant treatment, patients planned for revision surgery, previous breast-surgery, and low-compliance for follow-up. The study recruited a total of sixty (*n*=60) patients meeting the selection criteria which were randomly allocated in two equal groups (I & II) using table of random numbers and non-probability consecutive sampling technique. All the selected patients underwent a standardized subjective and objective examination, as recommended, and a thorough preoperative anesthesia department evaluation with necessary baseline investigations. Patients then underwent standard surgical intervention i.e. modified radical mastectomy

(MRM) with level II axillary lymph node dissection under general anesthesia. All the surgeries were performed by the same apt surgical team led by consultant surgeon. In Group-I (scalpel dissection group) skin flap raising, breast tissue dissection from pectoral fascia, and axillary dissection was done with conventional steel-scalpel blade no. 15. Hemostasis was secured with Vicryl® 3/0 where required. In Group II (LigaSure™ assisted dissection group) skin flap raising, breast tissue dissection from pectoral fascia, and axillary dissection was done with LigaSure™. In all patients two negative suction drains of Fr 16 (one in skin flap and other in axilla) were placed and their output monitored daily. All patients received same post-operative management. Drain was removed once output became less than 30 ml/24 hours. Patients were discharged once deemed fit by consultant surgeon and called for follow-up every week for a month. The primary outcome was to assess seroma formation in the skin-flap. A structured questionnaire was used to record the secondary outcomes like time-of-surgery, hospital stay, drain output, and drain removal. Seroma at skin-flap site was managed with multiple aspirations, pressure dressings or open drainage of wound. The research was conducted with approval of Institutional Ethical and Research Review Board. Data were entered and analyzed using SPSS (version 22.0). Quantitative variables like age (years), time-of-surgery (minutes), drain output(ml/24hours), and duration of hospital stay (days) were represented as mean ± standard deviation (SD). The occurrence of seroma formation in both groups was compared using the chi-square test as a measure of study outcome. Independent t-test was applied to compare quantitative variables. A *p-value* ≤0.05 was deemed significant.

Results

Among 60 enrolled patients, the mean age was 38.3 ± 11.4 and 39.8 ± 9.4 years in group I and II, respectively. A total of 6.7% (n=2) patients in

Group-I and 10% (n=3) patients in group-II showed seroma formation in skin flaps after surgery (*p-value* = 0.640). The mean time required for surgery was 109.9 ± 7.9 and 105.1 ± 8.3 minutes in Group-I and group-II, respectively (*p-value* = 0.027). The average duration of hospital stays in Group-I and group-II was 4.8 ± 1.7 and 5.3 ± 1.9 days (*p-value*=0.335).

VARIABLE	SCALPEL DISSECTION GROUP-I	LIGASURE DISSECTION GROUP-II	P-VALUE*
SEROMA FORMATION	<i>n</i> = 30 (100%)	<i>n</i> = 30 (100%)	
PRESENT	2 (6.7%)	3 (10%)	0.640*
ABSENT	28 (93.3%)	27 (90%)	

**p* ≤ 0.05 was considered significant. Calculated by chi-square test.

VARIABLES	SCALPEL DISSECTION GROUP Mean ± S.D	LIGASURE DISSECTION GROUP Mean ± S.D	P-VALUE*
AGE (Years)	38.3 ± 11.4	39.8 ± 9.1	0.566
DURATION OF SURGERY (Mins)	109.9 ± 7.9	105.1 ± 8.3	0.027
DURATION OF FLAP DRAIN (Days)	3.8 ± 1.7	4.3 ± 1.9	0.335
QUANTITY OF FLAP DRAIN (ml)	208.5 ± 110.1	234.8 ± 123.7	0.387
DURATION OF HOSPITAL STAY (Days)	4.8 ± 1.7	5.3 ± 1.9	0.335

* *p* ≤ 0.05 was considered significant. Calculated by independent t test.

Discussion

The incidence of seroma formation after breast surgery is so common that it is now perceived as a

side-effect of the surgery rather than a complication; nevertheless, it continues to be a nuisance for the surgeon and the patient. Despite being the leading complication after modified radical mastectomy, little is known about the inciting risk factors so far; but the surgical technique often plays pivotal role for its development.^[17,18] It is believed that during early phase of wound healing, acute inflammatory response due to the surgical trauma cause exudate accumulation and seroma formation.^[19] It is advocated that meticulous surgical technique to minimize leakage from dissected blood vessels and lymphatics may help reduce the incidence of seroma formation post-operatively.^[20] With the advent of electrothermal vessel sealing devices, the conventional steel-scalpel dissection is readily replaced by monopolar and bipolar diathermy along-with newer devices like LigaSure™ and harmonic scalpel.^[21] Across the literature multiverse, a limited plausible investigation is done to compare the conventional steel-scalpel technique to modern techniques like LigaSure™.^[23] The literature describes use of conventional steel-scalpel with lower incidence of seroma formation post-operatively compared to traditional electrothermal techniques.^[19,23] However, it comes at the cost of greater blood loss and increased time-of-surgery.^[24,25] The use of LigaSure™ bipolar vessel sealing system has shown significant improvement in terms of reduced post-operative complications, especially seroma formation, over the traditional electrocautery methods of dissection in modified radical mastectomy; nevertheless, its cost-effectiveness is debatable in a resource limited setting.^[14,19] Individual studies conducted by Chavan *et al.* and Masud *et al.* shows lower rates of seroma formation with scalpel dissection compared to electrosurgery dissection.^[23,25] Recently, a systemic-review and meta-analysis conducted by Watanabe J *et al.* surprisingly advocates little benefit of electrosurgical bipolar vessel sealing

system over the conventional techniques in terms of seroma formation and drained fluid volume.^[26] Our results are in accordance with this systemic review, showing no significant benefit of LigaSure™ bipolar vessel sealing device over the conventional steel-scalpel dissection technique. Isozaki *et al.* also shows comparable results of conventional scalpel dissection with the modern bipolar vessel sealing devices.^[27] Our results are comparable to this; however, our study shows a clear-cut advantage of LigaSure™ assisted dissection in reducing the time-of-surgery.

The literature shows some gaps in terms of plausible comparison of conventional steel-scalpel dissection technique with modern bipolar vessel sealing devices like LigaSure™. Our study not only endeavor in bridging this gap but also bring-forth a perspective from low-income resource country.^[22] The early post-operative complications associated with modified radical mastectomy sometimes brings unnecessary delays in continued management of the disease by delaying the start of adjuvant systemic therapy.^[28] On that account, recognition of risk factors leading to complications, like seroma formation in MRM, must be meticulously identified and preventive measures like cost-effective surgical techniques maybe adopted to improve the outcome in healthcare system.

Conclusion

Compared to conventional steel-scalpel dissection, the use of LigaSure™ assisted dissection shows no significant benefit in terms of reduced post-operative seroma formation, and duration of hospital stay. However, LigaSure™ assisted dissection significantly reduces the time-of-surgery. In resourceful hospital settings, LigaSure™ assisted dissection can be used to reduce the morbidity associated with longer anesthesia time by reducing the *time-of-surgery*. Nevertheless, the scope of such research is limited in a developing country;

therefore, the authors recommend further clinical trials.

Limitations:

The main limitation of study is the relatively small sample size, which restricts the applicability of the findings. Perioperative bleeding was not taken into consideration as an outcome variable, which is another study drawback. We advise doing additional, larger-scale, randomized controlled clinical trials to compare both approaches. We also advise contrasting additional risks connected with both methods, such as hematoma formation and bleeding.

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