



ORIGINAL ARTICLE

Comparison of outcomes of Ligasure system and conventional electrocautery in patients undergoing modified radical mastectomy for breast cancer.

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ABSTRACT... Objective: To compare LigaSure system and conventional electrocautery in patients undergoing modified radical mastectomy for breast cancer in terms of mean wound drainage. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Surgery, of Allama Iqbal Medical College, Jinnah Hospital Lahore. **Period:** April 2019 to Mar 2020. **Material & Methods:** Total of 162 patients were selected. Patients divided in two group A & B for Ligasure and electrocautery group respectively. Two drains placed, one in each flap and axilla after surgery. The drains were removed when the output was less than 30ml/ 24 hours. All patients were discharged after the drain removal. **Results:** The mean age in Ligasure group was 56.16 ± 7.87 years and in Electrocautery group was 55.00 ± 8.38 years. The mean wound drainage output in Ligasure group was 652.67 ± 93.05 ml and in Electrocautery group was 973.91 ± 87.84 ml. The mean drainage output was statistically lower in Ligasure group as compared to Electrocautery group, p-value < 0.001. **Conclusion:** Through the findings of current study it is concluded that LigaSure system leads less mean wound drainage than conventional electrocautery in patients undergoing modified radical mastectomy for breast cancer. So, in future therapeutic efficacy of LigaSure system can be opted to minimized the risk related wound drainage in patients undergoing modified radical mastectomy for breast cancer in terms of mean wound drainage.

Key word: Breast Cancer, Flap Fixation, Modified Radical Mastectomy, Gentamycin Lavage, LigaSure and Electrocautery, Wound Drainage.

INTRODUCTION

Breast cancer, in females, is one of the most prevalent malignancy globally. Mastectomy is widely accepted surgical procedure with or without chemo-radiotherapy. There have been much advancement in the chemotherapy and nuclear medicine but so far surgery has been the main stay of treatment. Surgical options ranges from simple lumpectomy to radical mastectomy depends on the stage and disease status; while modified radical mastectomy (MRM) is widely accepted surgical procedure for early stage breast cancers.¹

MRM involves the removal of whole breast tissue along with the axillary lymph nodes up to level II. Due to the extensive loose areolar and fatty

tissue and lymphatics dissection there is more chances of seroma formation and drainage in the postoperative period. Various surgical techniques and recent technologies have been used to minimize the seroma formation and drain output. These include flap fixation, gentamycin lavage, use of LigaSure and electrocautery.² The electrocautery may cause flap necrosis and infection in the postoperative period. Scalpel or scissor dissection may on other hand lead to higher chances of seroma formation and increased duration of surgery.

Many Intra-operative and post-operative measures are taken to reduced incidence of post-operative seroma formation; shoulder immobilization among those results in shoulder dys-functioning without

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improvement in seroma reduction. Usage of intra-operative sclerosing agents like tetracycline are reported as less effective measure to decrease incidence of seroma, rather have its own side effects of higher inflammatory responses.³ Some studies reported in reduction of duration of drain days and total volume production of seroma by using octreotides but unfortunately has no impact in actual incidence of seroma.⁴ Electrocautery flap and axillary dissection reduces operative time and blood loss, however, conflicting data has been reported in terms of seroma formation as compared with scissor or knife dissection.⁵ Judicious use of energy devices would be a solution but choice of best energy devices is still a question of great concern.⁶

A study compared the conventional electrocautery and LigaSure system in terms of wound drainage in patients undergoing mastectomy. They found that LigaSure system produced less drain output as compared to conventional electrocautery (809 ± 380 ml versus 620 ± 469 ml for electrocautery and LigaSure groups respectively, p value = 0.047).⁷ Limited data is available in Pakistan for the use in mastectomy, however some is published for hemorrhoidectomy.^{8,9} The wound drainage and drain placement causes more infection, pain, increased hospital costs and stay. Our study compares LigaSure system and electrocautery in terms of wound drainage after MRM in Pakistani patients. It might help us to reduce the morbidity of patients undergoing MRM which in turn can reduce the hospital stay and costs and would help us to formulate guideline locally for disease treatment.

MATERIAL & METHODS

This randomized controlled trial was conducted in department of surgery of Allama Iqbal Medical College, Jinnah Hospital Lahore from April 2019 to Mar 2020. Sample size of 162 cases (81 in each group) was calculated by using Non-probability consecutive sampling technique with 80% power of test, 5% level of significance and taking expected mean drainage in electrocautery group is (809 ± 380) and in LigaSure group is (620 ± 469).⁷

Inclusion Criteria

- Patients with early breast cancer stage I & II undergoing MRM
- Only female patients with age between 40 to 70 years

Exclusion Criteria

- Patients with bleeding diathesis or blood thinner.
- Patients with history of use of NSAIDs in last one week before surgery
- Patients with previous history of surgery at breast or axillary region
- Patient with chronic illnesses like diabetes mellitus, IHD, COPD/asthma, CLD, CRF

Data Collection & Analysis

Patients were divided randomly into two groups A & B using lottery method. In Group A, conventional electrocautery was used for the dissection of tissues while Ligasure for group B. Two drains were placed i.e. one under the flap and other in the axilla. Post operatively, all the patients were given standard postoperative care. All patients were discharged from hospital once the drain output was <30 ml/day and drain was removed. SPSS Ver. 22.0 was used for data collected and analysis. Quantitative data age, BMI, drain output were stratified and calculated for Mean and standard deviation. Both groups were compared by independent sample t test for wound drainage. Stratification used to control effect modifiers like age and BMI. Independent sample t test applied after stratifications; and a value of $p \leq 0.05$ was considered as significant.

RESULTS

The mean age in Ligasure group was 56.16 ± 7.87 years and in Electrocautery group was 55.00 ± 8.38 years Table-I. The mean BMI in Ligasure group was 28.73 ± 3.07 and in Electrocautery group was 28.54 ± 2.55 Table-I. The mean wound drainage output in Ligasure group was 652.67 ± 93.05 ml and in Electrocautery group was 973.91 ± 87.84 ml. The mean drainage output was statistically lower in Ligasure group as compared to Electrocautery group, p -value < 0.001 Table-II.

In age group of 40-55 years, the mean wound drainage output in Ligasure group was $648.20 \pm$

90.14 ml and in Electrocautery group was 990.41 \pm 88.03 ml. In age group of 56-70 years, the mean wound drainage output in Ligasure group was 656.83 \pm 96.57 ml and in Electrocautery group was 955.25 \pm 84.94 ml. In both age groups, the mean drainage output was statistically lower in Ligasure group as compared to Electrocautery group, p-value < 0.001 Table-III. In age obese, the mean wound drainage output in Ligasure group was 644.60 \pm 88.22 ml and in Electrocautery group was 972.86 \pm 89.38 ml. In non-obese, the mean wound drainage output in Ligasure group was 656.71 \pm 95.92 ml and in Electrocautery group was 974.36 \pm 87.98ml. In both obese and non-obese cases, the mean drainage output was statistically lower in Ligasure group as compared to Electrocautery group, p-value < 0.001 Table-IV.

DISCUSSION

Incidence of perioperative complications like flap necrosis, seroma, and duration of drain days after mastectomies for breast cancer has been

reported as decreased with reported morbidity as <5%.¹⁰ Main contributory risk factor for these perioperative complications comes from extensive oncoplastic reconstructive surgery along with axillary lymph node dissection (ALND) in these patients. Incidence of seroma has been reported in literature from 2.5-85% in these patients.¹¹ Many measures like flap re attachment with chest wall and instilling sclerosing agents had been tried in past but none has been reported in decreasing incidence of seroma formation. Lymphatic vessels leaking has remained a major issues in these patients and shoulder immobilization in recent years has been implied in order to achieve reduced leaking but has statistically no significant role.¹⁰⁻¹² However subcutaneous application of octreotide is reported in one study towards reduction in duration of drain days by its impact on less production of seroma.^{4,12}

Electrocautery flap and axillary lymph node dissection does not only helps in reduction in

	Study Groups	N=162	Range	Mean + SD
Age (Years)	Ligasure		40.00-70.00	56.16 + 7.87
	Electrocautery		40.00-70.00	55.00 + 8.38
BMI (Kg/m ²)	Ligasure		24.20-33.80	28.73 + 3.07
	Electrocautery		24.10-33.70	28.54 + 2.55

Table-I. Descriptive analysis & Demographic details n= 162

	Range	Mean + SD	P-Value
Ligasure	505.70 – 833.60	652.67 + 93.05	<0.001*
Electrocautery	837.70 – 1141.70	973.91 + 87.84	

Table-II. Comparison of mean wound drainage (ml) in both study groups

Age Groups (Years)	Study Group	Wound Drainage		
		Mean+ SD	t-test	P-Value
40-55 years	Ligasure	648.20 + 90.14	-17.381	<0.001**
	Electrocautery	990.41 + 88.03		
56-70 years	Ligasure	656.83 + 96.57	-14.609	<0.001**
	Electrocautery	955.25 + 84.94		
	Electrocautery	974.36 + 87.98		

Table-III. Comparison of mean wound drainage (ml) in both study groups with respect to Age groups (years)

Obesity (BMI in Kg/m ²)	Study Group	Wound Drainage		
		Mean+ SD	t-test	P-Value
Obese BMI >30	Ligasure	644.60 + 88.22	-13.182	<0.001**
	Electrocautery	972.86 + 89.38		
Non Obese BMI <30	Ligasure	656.71 + 95.92	-18.195	<0.001**
	Electrocautery	974.36 + 87.98		

Table-IV. Comparison of mean wound drainage (ml) in both study groups with respect to BMI

**Highly Significant

Chi-square = 2.320

P-value= <0.001 (Highly Significant)

blood loss but also reduces duration of surgery but has been reported carrying increase risk of seroma formation as compared with its counterpart techniques of dissection using knife or scissors.⁵ Increase tissue inflammatory response due to ischemic necrosis and thrombosis of vessels after electrocautery dissection causes high seroma output. Implication of new vessel sealing devices like ultrasound scalpel (Harmonic) and bipolar electro thermal scissors (Ligasure) in flap and axillary dissection is reported carrying less post-operative complications and later being most precise in function and so do reduction in seroma formation.¹³ Quantitative morbidity by using these devices has been reported as safe as per Clavien Dindo Classification (CDC), and also reports surgical complications attributed towards therapeutic intervention.¹⁴

We conducted this study to compare the effect of electrocautery vs sealing devices (Ligasure) in terms of outcome in breast cancer surgery. A recent study includes a total of 33 patients with a mean age (years) of 51.4 ± 13.7 . Group 1 in their study showed mean age of patients as 54.1 ± 13.2 , and group 2 with 48.68 ± 14.1 .⁷ We in current study found the mean age in Ligasure group was 56.16 ± 7.87 years and in Electrocautery group was 55.00 ± 8.38 years. The age distribution is almost similar in these two studies.

A study by Manouras A et al used electrothermal sealing device (Ligasure) in axillary dissection with mastectomy showed intraoperative blood loss as 45 ± 12 (ml); duration of surgery 105 ± 7 (min); flap drainage volume 20 ± 8 (ml); axillary drainage volume 155 ± 35 (ml); duration of flap drain 1.3 ± 0.2 (days); duration of axillary drain 2.7 ± 0.5 (days); and duration of hospital stay was 3.7 ± 0.6 (days) (Mean \pm SD). Their results were promising for ligasure usage which showed no peri operative complications as per CDC classification like seroma or haematoma.¹⁵

Another study by Antonio M et al reported statistically non significant duration of surgery by using ligasure dissection when compared with monopolar electrocautery dissection 70.7 ± 24.6 vs 70.6 ± 22.4 (min) ($p=0.98$). Axillary drainage

volume with ligasure dissection in their study was lesser, however statistically non significant, than volume of axillary drain after electrocautery dissection 624.4 vs 792.9 ($p=0.09$). No clear advantage of ligasure over electrocautery dissection was observed.¹⁶

In terms of mean wound drainage output, our study reports lower output ($p<0.001$) in Ligasure group was 652.67 ± 93.05 ml and in Electrocautery group was 973.91 ± 87.84 ml. These results favor Tukenmez, M., et al (2014) compared the conventional electrocautery and Ligasure system in terms of wound drainage in patients undergoing mastectomy. They found that Ligasure system produced less drain output as compared to conventional electrocautery (809 ± 380 ml versus 620 ± 469 ml for electrocautery and Ligasure groups respectively, p value = 0.047).⁷

Another study, however, by Seki T et al (2016) showed clear advantage of Ligasure usage over electrocautery in mastectomy with axillary dissection for breast cancer patients. They showed shorter duration of drain days (6.4 ± 2.9 vs 8.2 ± 3.8 days) ($p < 0.033$); and lesser amount of drainage volume (365.3 ± 242.2 vs 625.1 ± 446.6 ml) ($p < 0.009$) with Ligasure dissection when compared with electrocautery. Operative time in both groups was almost equal (66 vs 70 min) ($p=0.371$) with similar results for mean blood loss (18.2 ± 31.1 vs 20.6 ± 26.3 ml) ($p = 0.663$). Incidence of seroma formation was statistically similar in both groups was also similar (43.3 vs 37.9 %) ($p = 0.673$). They suggested that Ligasure is a better and efficient vessel sealing device as compared to monopolar electrocautery.¹⁷ Favorable results ($p=0.056$) for ligasure using were reported by Panhofer P et al and showed less seroma formation and shorter duration of hospital stay when compared with monopolar electrocautery system.¹⁸

Our study also demonstrates lesser seroma formation by using ligasure system when compared with monopolar electrocautery. Hence, we also suggest that vessel sealing ligasure usage in mastectomy with axillary dissection

gives advantage over monopolar electrocautery by resulting in lesser seroma formation and ultimately shorter duration of drain days along with shorter duration of hospital stay.

CONCLUSION





We concluded that LigaSure system leads less mean wound drainage than conventional electrocautery in patients undergoing modified radical mastectomy for breast cancer. So, in future therapeutic efficacy of LigaSure system can be opted to minimize the risk related wound drainage in patients undergoing modified radical mastectomy for breast cancer in terms of mean wound drainage.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Muhammad Irfan Zia	Conception and design, Provision of study material collection and analysis of data.	
2	Sajid Malik	Collection and analysis of data, Manuscript writing.	
3	Sana Anum	Conception and design Provision of study material.	
4	Fatima Tu Zahara	Conception and design Provision of study material.	
5	Zirwa Anum	Collection and analysis of data.	