

Efficacy of Electrosurgical Vessel Sealer (LigaSure™) Devices in Modified Radical Mastectomy in Primary Breast Carcinoma

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ABSTRACT

Objective: To determine the efficacy of electrosurgical vessel sealer (LigaSure™) devices in modified radical mastectomy in primary breast carcinoma at LUMHS, Jamshoro.

Material and Method:

Study design: Randomized control trial.

Setting: The study was done at Department of General Surgery Liaquat University and Medical Health Sciences (LUMHS) Jamshoro.

Duration of study: Study duration was six months from April 2020 to September 2020.

Methods: All the female patients with Primary Breast Carcinoma of Stage I and II disease were included. The patients were divided into two groups. Patients of group-A were operated with conventional electrocautery device and patients of group B were operated with ligasure devices. All the data regarding age, operative details, postoperative pain, seroma formation, flap necrosis, hospital stay and follow-up was recorded via study proforma.

Results: Total 60 patients of breast carcinoma were studied. Average age of the conventional group (group A) and ligasure group (group B) were 50.3±10.8 years & 47.2±10.2 years respectively (p=0.266). However mean operative time, average blood loss, average weight of tissue and average pain (VAS) were significantly lower among patients of ligasure group as compared to conventional group (p<0.001). 1st to 3rd post-operative day, drain outcome was significantly high in conventional group as compared to ligasure group (p<0.001).

Conclusion: The electrosurgical vessel sealer (LigaSure™) device in modified radical mastectomy was found to be effective, reliable and non-invasive in primary breast carcinoma, in terms of shorter operative time, less pain, less blood loss and shorter Hospital stay.

Keywords: Primary breast carcinoma, Electrosurgical vessel sealer devices, Electrocautery

INTRODUCTION

Breast cancer is among the most prevalent cancers worldwide, which has become a leading cause for tumor mortality in women. Breast cancer survival has improved as a result of advances in research, early diagnosis, and treatment; however breast cancer prevalence has not improved¹. Mastectomy is an option for most females who have had screening and were detected with early-stage of breast cancer². In Pakistan, breast cancer is among the most prevalent cancers, accounting for 38.2 percent of all the cancers and these rates are highest in Asia and most of the females with Breast cancer in Pakistan present late³. Breast cancer that is detected promptly, has a better outcomes.⁴In early-stage (stage 1) breast cancer, at 1, 3, & 5 years after diagnosis, survival rates was 100%.⁴ Despite the fact that surgical care for breast cancers has changed significantly from radical procedures to breast-conserving methods, adapted radical mastectomy using axillary dissection is the most common surgical intervention for locally advanced stage of breast cancer.⁵Lymphedema and seroma are the most common complications of traditional adapted radical mastectomy using axillary dissection with a electrocautery, scalpel, and suture ligation, with rates of 11-85 percent and 2-50 percent, respectively⁶. In contrast, electrocautery has been the most widely used surgical method for dissection as well as hemostasis in conventional mastectomy; though, its large thermal range can cause postoperative complications including flap necrosis, seroma formation, lymphorrhea, prolonged drainage, and wound infection. Adjuvant

therapy, extended hospital stay, and delay in drain removal are all linked to seroma and lymphorrhea development⁷. Bipolar vessel locking system (BVSS) and harmonic scalpel are two new surgical instruments that have been suggested. LigaSure™ is a bipolar electrothermal vessel-sealing device that offers hemostasis through forming a seal by changing the vessel wall's structure and structure of underlying tissues via electrothermal energy and pressure⁸. A bipolar electrothermal vessel sealing method "LigaSure™" has been approved globally for use as a supportive intervention in surgical procedure to enhance hemostasis due to its effectiveness and protection.⁹Although no such studies had found on electrosurgical vessel sealer (LigaSure™) devices in modified radical mastectomy in primary breast carcinoma especially at local level. However this study has been conducted to determine the efficacy of electrosurgical vessel sealer (LigaSure™) devices in modified radical mastectomy in primary breast carcinoma.

MATERIAL AND METHODS

This randomized control trial study was done at department of general surgery LUMHS Jamshoro. Study duration was six months; from April 2020 to September 2020. All the female patients with primary breast carcinoma of Stage I and II disease were included. All the patients of Stage III and IV disease, patients with recurrent disease, patients with co-morbidities and those unfit for anesthesia and those who were not willing to participate in study were excluded.

The patients were divided into two groups by randomization (odd / even). The odd numbers were given to patients operated with ligasure and even numbers were given to patients operated with electrocautery device. All the data regarding age, operative details, postoperative pain, seroma formation, flap necrosis, hospital stay and follow-up was recorded via study proforma. Data was analyzed by using SPSS version 20.

RESULTS

Total 60 patients of breast carcinoma were studied, followed by 27 in conventional group and 33 in ligasure group. Average age of conventional group patients was 50.3±10.8 years and ligasure group patients' mean age was 47.2±10.2 years; (p<0.266). However, mean operative time, average blood loss, average weight of tissue and average pain (VAS) were significantly lower among patients ligasure group as compared to conventional group (p<0.001), as showed in table.1

1st to 3rd post-operative day, drain outcome was significantly high in conventional group as compared to ligasure group; (p<0.001). However, post-operative hospital stay was also decreased in ligasure group as compared to conventional group; (p<0.001), as showed in table.2

Table 1: Descriptive statistics of age, operative time, blood loss, tissue weight and VAS n=60

Variables	Study group	N	Mean±SD	p-value
Age (years)	Group A	27	50.3±10.8	0.266
	Group B	33	47.2±10.2	
Operative time (Minutes)	Group A	27	132.7±19.7	0.0001
	Group B	33	76.3±10.7	
Loss of blood (ml)	Group A	27	239.2±39.6	0.0001
	Group B	33	120.7±43.3	
Weight of tissue excised (g)	Group A	27	348.8±50.4	0.001
	Group B	33	298.0±58.7	
VAS score	Group A	27	5.18±0.7	0.0001
	Group B	33	2.4±1.0	

Group A= Modified radical mastectomy (conventional)
Group B= Modified radical mastectomy (ligasure)

Table 2: Descriptive statistics of drain outcome, flap necrosis & hospital stay n=60

Drain outcome	Study groups	N	Mean±SD	p-value
1 st Post-operative day	Group A	27	166.3±56.16	0.0001
	Group B	33	70.6±43.17	
2 nd Post-operative day	Group A	27	100.3±44.07	0.0001
	Group B	33	39.6±33.28	
3 rd Post-operative days	Group A	27	67.2±37.42	0.0001
	Group B	33	18.9±17.51	
Signs of flap necrosis	Group A	27	01.8±0.32	0.219
	Group B	33	01.9±0.17	
Hospital stay	Group A	27	05.8±1.19	0.0001
	Group B	33	03.9±1.14	

Group A= Modified radical mastectomy (conventional)
Group B= Modified radical mastectomy (ligasure)

DISCUSSION

Breast cancer is very common among women in Pakistan and unfortunately, in our country patients present at late stage due to lack of awareness and traditional false beliefs.³Mastectomy only or accompanied

by reconstruction, either primary or secondary, are two surgical options for managing breast tumours. However, this study has assessed effectiveness of electrosurgical vessel sealer (LigaSure™) devices in modified radical mastectomy in primary breast carcinoma and LigaSure™ was found to be significantly effective in terms of lesser operative time period, less pain, less blood loss and shorter period of Hospital stay by taking electrocautery device as control. Similarly, Cortadellas T et¹⁰ observed that LigaSure™ in axillary surgery will minimize hospital stay and surgical time, allowing for early drain extraction without raising postoperative complications. LigaSure™ was correlated with lesser blood loss, lesser complications, and decreased postoperative pain in a meta-analysis of prospective randomized controlled trials contrasting LigaSure™ with either clamping with harmonic scalpel or electrocauterization / suture-ligation in different surgical procedures.^{10,11} However, in surgical procedure of breast cancer, variations in duration of surgery, total volume of drained fluid, and drain duration were not statistically significant in a reported prospective randomised controlled clinical trials comparing LigaSure™ and traditional axillary dissection.^{10,12}

In this study, mean age of conventional group patients was 50.3±10.8 years and ligasure group patients' mean age was 47.2±10.2 years; (p<0.266). On the other hand, Shaukat A et al³ reported that mean age in group A and group B were 45.8±18.2 and 50.1±18.2 years, respectively.

In this study, 1st to 3rd post-operative day, the drain outcome was significantly high in conventional group as compared to ligasure group; (p<0.001). Likewise, Shaukat A et al³ reported that in group A and group B mean drain volumes were 500.1±60.8 ml and 665.3±84.9 ml respectively; (p <0.0001). Consistently, in this study mean post-operative drains volume in ligasure group was significantly lower (p<0.0001). For axillary dissection, Seki T et al¹³ compared the safety and efficacy of LigaSure™ Small Jaw (the latest bipolar vessel sealing system) (BVSS) with conventional procedure and the researchers proposed that BVSS is more effective procedure as compared to traditional axillary dissection techniques. In breast surgical procedure, Botoncea M et al¹⁴ evaluated the efficiency of LigaSure™ Small Jaw BVSS and they found that in breast surgery, LigaSure™ device reduces the operative time. Panhofer P et al¹⁵ also reported that the aspirations frequency (≤ 2 times) was lesser in patients managed with LigaSure™. While in contrast to this study, in 2007, Antonio M et al¹⁶ reported that in patients managed with LigaSure™ vs conventional dissection, the mean duration was 70.7 ± 24.66 minutes vs. 70.6 ± 22.47 minutes respectively; (p=0.98). While in 2011 Cortadellas T et¹⁰ reported that the length of hospitalization and drain volume were lesser in LigaSure group. Similarly, in this study, post-operative hospital stay was also decreased in ligasure group in comparison to conventional group; (p<0.001). Although, Manouras et al⁵ documented that the mean duration of in-hospital stay among ligasure patients versus historical controls were 3.7 days versus 2.4-10.1 days respectively. While in contrast to our finding, Botoncea M et al¹⁴ reported that use of LigaSure™ devices in breast surgery failed to reduce the hospital stay duration or the drainage duration or quantity. On the other hand,

Panhofer P et al¹⁵ also reported that the hospital stay period was reduced by 1 day when LigaSure™ was used.

CONCLUSION

The electrosurgical vessel sealer (LigaSure™) devices in modified radical mastectomy in primary breast carcinoma, found to be effective, reliable and non-invasive in terms of shorter operative time, less pain, less blood loss and shorter hospital stay. However this was a small sample size and single unit study, therefore further large scale studies are recommended on this subject.

REFERENCES

- White MC, Kavanaugh-Lynch MM, Davis-Patterson S, Buermeyer N. An expanded agenda for the primary prevention of breast cancer: Charting a course for the future. *Int J Environ Res Public Health* 2020;17(3):714.
- Moo TA, Sanford R, Dang C, Morrow M. Overview of breast cancer therapy. *PET clinics*. 2018;1;13(3):339-54.
- Shaukat A, Anjum MA. Comparison of Axillary Lymph Node Dissection by Using Ligasure Vessel Sealing System Vs Conventional Thread Ligation in Patients Undergoing Modified Radical Mastectomy for Carcinoma of Breast. *Annals of Punjab Medical College*. 2020 Sep 30;14(3):254-8.
- Li J, Guan X, Fan Z, Ching LM, Li Y, Wang X, Cao WM, Liu DX. Non-Invasive Biomarkers for Early Detection of Breast Cancer. *Cancers*. 2020 Oct;12(10):2767.
- Manouras A, Markogiannakis H, Genetzakis M, Filippakis GM, Lagoudianakis EE, Kafiri G, Filis K, Zografos GC. Modified radical mastectomy with axillary dissection using the electrothermal bipolar vessel sealing system. *Archives of Surgery*. 2008 Jun 16;143(6):575-80.
- Parveen S, Qureshi S, Sarwar O, Damani SR. Modified radical mastectomy with axillary clearance using harmonic scalpel. *Pak J Surg*. 2012;28(3):168-71.
- Seki T, Hayashida T, Takahashi M, Jinno H, Kitagawa Y. A randomized controlled study comparing a vessel sealing system with the conventional technique in axillary lymph node dissection for primary breast cancer. *Springerplus*. 2016 Dec;5(1):1-8.
- Chang YW, Kim HS, Jung SP, Woo SU, Lee JB, Bae JW, Son GS. Comparison of skin-sparing mastectomy using LigaSure™ Small Jaw and electrocautery. *World journal of surgical oncology*. 2017;15(1):1-5.
- Ugo M, Amore A, Lucia B, Corrado C. Electrothermal Bipolar Vessel Sealing System Dissection Reduces Drainage Fluid Output or Time to Drain Removal Following Axillary and Ilio-Inguinal Node Dissection in Melanoma Patients: A Pilot Study. *Journal of Cancer Therapy*. 2018 Sep 5;9(09):613.
- Cortadellas T, Córdoba O, Espinosa-Bravo M, Mendoza-Santin C, Rodríguez-Fernández J, Esgueva A, Álvarez-Vinuesa M, Rubio IT, Xercavins J. Electrothermal bipolar vessel sealing system in axillary dissection: a prospective randomized clinical study. *International Journal of Surgery*. 2011 Jan 1;9(8):636-40.
- Macario A, Dexter F, Sypal J, Cosgriff N, Heniford BT. Operative time and other outcomes of the electrothermal bipolar vessel sealing system (LigaSure™) versus other methods for surgical hemostasis: a meta-analysis. *Surgical innovation*. 2008 Dec;15(4):284-91.
- Antonio M, Pietra T, Domenico LG, Massimo D, Ignazio R, Antonio N, Luigi C. Does LigaSure™ reduce fluid drainage in axillary dissection? A randomized prospective clinical trial. *Ecancermedalscience*. 2007;1.
- Seki T, Hayashida T, Takahashi M, Jinno H, Kitagawa Y. A randomized controlled study comparing a vessel sealing system with the conventional technique in axillary lymph node dissection for primary breast cancer. *Springerplus*. 2016 Dec;5(1):1-8.
- Botoncea M, Surgical Clinic No. 1, Emergency Clinical County Hospital of Târgu Mureş, George Emil Palade University of Medicine, Pharmacy, Science and Technology of Târgu Mureş, Romania. *Austin J Pathol Lab Med*. 2019; 6(1): 1026.
- Panhofer P, Rothe S, Schütz M, Grohmann-Izay B, Dubsy P, Jakesz R, Gnant M, Fitzal F. Morbidity reduction using the vessel sealing device LigaSure™ in breast cancer surgery. *European Surgery*. 2015 Aug;47(4):150-6.
- Antonio M, Pietra T, Domenico LG, Massimo D, Ignazio R, Antonio N, Luigi C. Does LigaSure™ reduce fluid drainage in axillary dissection? A randomized prospective clinical trial. *Ecancermedalscience*. 2007;1.