

Research Article

Comparing a vessel sealing system with the conventional technique in axillary lymph node dissection for primary breast cancer



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Abstract

Background: The goal of this research was to evaluate the effectiveness and safety of the most recent bipolar vascular sealing system (BVSS; LigaSure™ Small Jaw) in axillary dissection compared to the standard procedure. **Methods:** this is a prospective study was conducted under the observation of south Egypt cancer institute, Egypt. The study conducted on total of 90 breast cancer patients were split into two groups and given either standard dissection surgery with a scalpel plus monopolar cautery (CONV group; n = 45) or surgery with a vessel sealing equipment (BVSS group; n = 45). **Results** showed a statistically significant difference between the two groups in the mean given quantity of drainage liquids ($(850 \pm 97$ vs. 372.7 ± 152 mL; P value = <0.001) and the mean number of weeks until drain removal (10.6 ± 1.9 vs. 6.2 ± 0.8 days; P value = 0.001). Seroma prevalence was comparable in the two groups (15% vs. 11.1%), P = 0.53. Axillary dissections took longer (37.3 ± 5.5 minutes and 28.8 ± 4.4 minutes) and resulted in more blood loss (215.6 ± 50.9 ml and 147.8 ± 33.6 ml; P value = <0.001) than other type of surgical procedures.

Our findings indicate that compared to the standard methods of axillary dissection, BVSS is the superior tool.

Keywords: Vessel seal system, axillary lymph nodes dissection, and randomized controlled trial for breast cancer.

Introduction

In 2020, it is expected that there will be 2.3 million new instances of breast cancer in women worldwide, accounting for 11.7% of the all the cancer deaths. With 685,000 fatalities annually, it ranks as the sixth greatest cause of cancer morbidity globally. Breast cancer is the most common cancer in women, accounting for one in four new cases and one in six deaths worldwide. It is also the most common cancer worldwide in terms of incidence (in 159 of 185 nations) and fatality (in 110 countries). According to a study^[1].

Similarly, in Egypt, breast cancer is the leading cancer among females, accounting for 38.8 percent of all cases in that demographic. ^[2].

Over the last several decades, there have been significant shifts in the oncological strategy taken toward treating breast cancer. Early detection of breast cancer thanks to improved screening programs ^[3], paves the way for less invasive surgery for malignancy stages I and II in conjunction with sentinel lymph-node dissection (SLNB) in the event of clinical and imaging negative of axillary lymph nodes. (ALN). ^[4]

For the treatment of smaller local advanced breast with positive lymphatic system, as determined by core needle cytology (Ktb) or a core-needle histology, or in special situations of stage IV tumors, axillary lymph node laparotomy (ALND) is still known as the gold

standard technique in conjunction with radical breast reduction either quadrantectomy.^[5]

Axillary surgery in individuals with operable breast cancer has two major goals: to stage the cancer by SLNB as well as to treat any axillary malignancy by axillary clearing or axillary dissection. Significant treatment choices for breast cancer patients are dependent on whether or not the disease has spread to the axillary lymph nodes. Predicting survival in patients who have breast cancer is the number and extent of lymph node involvement. It has been found.^[6]

There in middle of the 1890s, doctors W. Stewart Halsted or Meyer used the term "radical mastectomy" to describe the procedure (Halsted, 1894), To do this operation, the breast, pectoral muscle, and axillary tissue are all removed in one fell swoop. In his 1907 publication (Halsted, 1907) using this method, Halsted reported the 3-year radiotherapy and chemotherapy recurrence and improved survival as 6% and 40%, respectively (compared to the higher than 50% and about 20% previously recorded, respectively). For over a decade, Halsted radical mastectomies were used to treat breast cancer, due to advances in health outcomes and local recurrence.^[7]

Modified radical mastectomies developed in the 1940s despite the fact that radical mastectomy gives superior locoregional control. Surgery was performed to save the long thoracic spine thoracodorsal nerve in order to protect the subscapular muscle (Patey and Dyson, 1948). Breast conserving surgery (BCS) involves removing just the cancerous tumor(s) and some of the healthy tissue around it (negative margins). The goals of BCS are total tumor removal, decreased risk of local recurrence, and aesthetic success.^[8] Seromas, lymphedema, hematomas, prolonged axillary drainage, delayed wound healing or necrosis, functional disability of both the shoulder and upper limb, and intraoperative and post-operative bleeding are the most common complications of traditional modified radical breast reduction with ipsilateral dissection using meat cleaver, suture ligation, and electrocautery.^[9]

The incidence of postoperative seroma development, a collection containing fluid there in axillary dead space, is reported in the literature to fall anywhere from 3 to 85%.^[10]

New devices commonly used in surgical treatment can reduce cellular damage and improve vessel sealing but instead hemostasis, thereby lowering the risk of seroma formation and speeding up the healing process after surgery. This, in turn, shortens the length of time needed for surgery and the recovery period, and speeds up the start of any necessary adjuvant therapy. Because of its user-friendliness and its ability to effectively stop bleeding during surgery, thermal ablation (EC) is a useful tool for a procedure such as ALND.^[11]

Hemostasis is achieved using the LigaSure™ (LS) (Covidien, CO, USA) electro-thermal bipolar vessel-sealing device by utilizing both pressure and electro-thermal energy. Thyroidal, urological, gynecological, and colorectal operations are all cited in the literature as possible uses for this tool because to its ability to cut and ligate blood vessels up to seven millimeters.^[12]

Powered instruments, modern tools that have transformed the precision, accuracy, and delicacy of modern surgery, have rewritten the rules of the field. Despite their widespread usage, many of the individuals who use these technologies on a daily basis know very little about how they work. Having a firm grasp of the laws regulating the conduct of electrical pulses and a few basic concepts might serve as useful guides while working with such technologies. In a 2015 study.^[13]

Physiotherapy, external compression, and the use of pharmacological aids like hemostatic biological adhesives have all been recommended as ways to reduce seroma production; however, none of these methods have shown consistent and reliable success. The results of this study were published in 2001.^[14]

Since Axillary LN dissection for primary breast cancer may be performed without exposing blood veins directly, which might lengthen the operation and increase the risk of bleeding, the vessel seal system is a useful tool. In previous randomized tests, the vascular sealing system was shown to decrease drainage volume thus shorten postoperative hospital days when compared to traditional devices.^[15]

The present research aims to evaluate the efficacy of a bipolar vascular sealing device to

that of a more traditional way of breast surgery in order to determine which of the two is more beneficial to patients during and after the surgical procedure.

Patients and Methods

This prospective research included all women diagnosed with breast cancer between July.2021 and July.2022, when they had breast surgery at the South Egypt Cancer Institute

Information such as age at diagnosis, pathophysiology (type, grade, etc invasion), afflicted side, clinical stage, boundary status, reconstruction type, treatment failure (local, regional, or distant), and mortality during follow up phase was extracted from the database.

Two categories of patients were created, reflecting the differences in the types of Procedures performed on them. Patients who had a dissection of their axillary lymph nodes (LNs) performed during breast surgery (Group 1) were treated with a bipolar vascular sealing device. (The BVSS)

Those in Group 2 had axillary LNs dissected during a standard breast operation.

Criteria for inclusion included: • Patients diagnosed with breast cancer who were hospitalized to the Surgical Department of the South Egypt Cancer Society and who had surgery for breast cancer between the beginning of July.2021 and the beginning of July.2022.

All breast cancer patients who needed an armpit incision (axillary dissection).

Women only, Must be at least 15 years old and no older than 80, Those with breast cancer that has been verified by pathology, Modified radical mastectomy (also known as BCS) patient Sentinel node biopsy verified clinical N0 (no sensitive axillary nodes).

Patients who do not meet the following criteria will not be included in this study: Age 15 or select settings 80, male gender, With a history of both metastatic breast cancer and axillary surgery, you can be sure that these conditions apply Individuals selected for a sentinel node examination alone Existence of a second malignancy at the same time Axilla radiation or surgical history, Those who are taking anticoagulants or have a bleeding diathesis (e.g.

aspirin, warfarin) Individuals who have signed an informed consent form.

The Ethics Committee of the South Egyptian Cancer Institute has given its approval to the project., the research's potential applications pose no danger to the study subject acceptable standards of clinical research ethics were adhered to Privacy was guaranteed.

Statistical analysis:

The analysis of the data was carried out using the IBM SPSS 26.0 statistical package software (IBM; Armonk, New York, USA). Normality of the data was tested using the Shapiro-Wilk tests. Data were expressed as mean, and standard deviation for quantitative measures, in addition to both number and percentage for categorized data. Independent sample t test used for comparison between two independent groups in parametric data. The Chi square test or Fisher's exact test were used to compare categorical variables. A p-value less than 0.05 was considered significant.

Age, body mass index, surgery (breast conserving vs. modified radical mastectomy), and surgeon expertise were all taken into account when deciding which group each patient would be placed in (less or more 7 years). Before performing the surgeries, the randomization program notified the examining surgeons of their treatment assignments. Neither the patients nor the nurses who recorded the daily draining volumes knew which group they belonged to. Using the LigaSure Small jaw, 45 patients in the BVSS group received ALND, whereas 45 patients in the CONV group had mono- or bipolar electrocautery. All patients' preoperative information was collected, including breast cancer stage, age, and body mass index. Each patient had an en-bloc level I and II lymph node dissection during their axillary lymphadenectomy. An expert breast surgical team, including both seasoned physicians and surgical residents, carried out the treatment. All surgical and postoperative care was overseen by the leading surgeons. The LigaSure Small Jaw was used to seal the lymph drainage vessels during surgery for patients in the BVSS group, and as little dissection as possible was performed using a monopolar electrocautery device or a scalpel. Patients in the CONV group had operations with the use of a scalpel or scissors, as well as monopolar or bipolar electrocautery, or suture

ligation, to close the vessels. Before a suction device was placed in the axilla, the bleeding was stopped manually. Following the procedure, a tight suction drain was inserted into the axilla. An anterior chest closed suction drip was also inserted in the case of a complete mastectomy.

All patients had breast surgery before undergoing axillary dissection, and the total surgical time included both procedures. All patients were given the same postoperative dressing, which was non-compressive. There was no planned restriction on the use of one's arms. When the output from the axillary outlet was below 30 mL per day for more than 72 hours, it was withdrawn as per protocol. During their time in the hospital, the nurses took daily measurements of the total drainage volume without knowing the specifics of the measuring instruments. After being released from the hospital, patients were monitored for at least 30 days at an outpatient clinic, where they were seen once every one to two weeks.

The major objective was to evaluate the difference in time required for drain removal between the two surgical methods, the total amount of fluid collected as in axillary drain, the duration of surgery, and the prevalence of seroma, the number of problems experienced after surgery and the amount of blood lost during surgery were used as indicators of the experimental method's safety

Results

The study was prospective one included 90 patient who underwent breast surgery for breast primary cancer at surgical department of South Egypt Cancer Institute in the time from July 2021 to July 2022.

Patients allocated into 2 groups: Group I: (n. 45) patients who underwent breast surgeries using conventional method in axillary LNs dissection. Group II: (n. 45) patients who underwent breast surgeries using bipolar vessel sealing system in axillary LNs dissection.

The analysis of the data was carried out using the IBM SPSS 26.0 statistical package software (IBM; Armonk, New York, USA). Normality of the data was tested using the Shapiro-Wilk tests. Data were expressed as mean, and standard deviation for quantitative measures, in addition

to both number and percentage for categorized data. Independent sample t test used for comparison between two independent groups in parametric data. The Chi square test or Fisher's exact test were used to compare categorical variables. A p-value less than 0.05 was considered significant.

Background characteristics of the patients During the study period, 90 patients underwent axillary lymph node dissection for primary breast cancer. patients were enrolled and randomized, with 45 in the CONV group and 45 in the BVSS group. No patient was excluded after randomization, and no one was lost to follow up. Finally, a total of 45 patients in the BVSS group, and 45 patients in the CONV group were analyzed on an intention-to-treat basis.

Clinical variables: Age: This study Shows no statistically significant difference between the Two groups regarding to patients age, in group-I, mean age was 54.2 ± 8.3 years and 55.7 ± 12.1 years in group-II. **BMI:** There was no statistically significant difference between the Two groups regarding to patients' BMI, in group-I, mean BMI was 25.6 ± 5.3 and 24.9 ± 3.9 in group-II.

Medical History and comorbidities: There were no statistically significant difference between the Two groups regarding to patients' comorbidities. **HTN:** percentage of hypertensive patients was 31.1% in group-I, and 24.4% in group-II. **DM:** percentage of hypertensive patients was 17.8% in group-I, and 31.1% in group-II. **Smoking:** there were no smokers in group-I versus 3 smokers in group-II.

Intraoperative data: Type of surgery: There was no significant statistical difference in Type of surgery, in Group I, 28 of patients underwent MRM and 17 patients underwent BCS. While in Group II, 30 of patients underwent MRM and 15 patients underwent BCS. Table 2.

Total operating time: There was a significant statistical difference in Total operating time between the two groups. in group-I, Total operating time was 126.9 ± 12.4 minutes and 119.8 ± 12.9 minutes in group-II (P-value: 0.009). Table 3. **Axillary dissection time:** There was a significant statistical difference in Axillary dissection time between the two groups. in

group-I, Axillary dissection time was 37.3 ± 5.5 minutes and 28.8 ± 4.4 minutes in group-II (P-value: <0.001). Table 3. Blood loss: In group-I, mean Blood loss was 215.6 ± 50.9 ml and 147.8 ± 33.6 ml in group-II with a P-value <0.001 , which is statistically significant. Table 4.

Post-operative data: Total drain volume: In group-I, mean drain volume was 851.1 ± 96.2 ml and 370 ± 152 ml in group-II with a p-value <0.001 , which is statistically significant. Table 4. Post-operative bleeding: In group-I, post-operative bleeding occurred in 2 patient and in one patient in group-II, with no statistical difference. Table 5.

Hematoma: In group-I, post-operative hematoma occurred in 2 patient and in one patient in group-II, with no statistical difference. Table 5. Seroma: There was no significant statistical difference in post-operative seroma, in group-I, seroma occurred in 7 patients (15%) and in 5 patients (11.1%) in group-II. Table 5. Wound infection: 2 patients for each group have post-operative wound infection. Table 5. **Flap necrosis:** In group-I, flap necrosis occurred in 2

patients and none patient in group-II, with no statistical difference. Table 5. Skin burn: In group-I, flap necrosis occurred in 6 patients and 3 patients in group-II, with no statistical difference. Table 5. Days until drain removal: There was a significant statistical difference in the number of days until drain removal between the two groups. conventional group, 10.6 ± 1.9 days till drain removal Versus 6.2 ± 0.8 days in group-II (P-value: 0.001). Table 6. Post-operative stay: There was a significant statistical difference in the number of days until patient's hospital discharge between the two groups. in group-I, 1.5 ± 0.7 days till drain removal Versus 1.2 ± 0.5 days in group-II (P-value: 0.024). Table 6. Tumor Size: In group-I, 20(44.4%) patients had tumor size <2 cm, while 25(55.6%) had tumor size ≥ 2 cm. In group-B, 18(40%) patients had tumor size <2 cm, while 27(60%) had tumor size ≥ 2 cm. Table 7. Total number of removed LN: In group-I, Total number of removed LN was 14.9 ± 3.4 and 15.6 ± 4 in group-II, with no statistical difference. Table 8. Positive lymph nodes: no statistical difference in number of post-operative positive lymph node in both groups.

Table 1: Demographic data of Conventional group and BVSS group:

		Group I	Group II	P value
		N=45	N=45	
Age	Range	(44-75)	(35-84)	0.486
	Mean \pm SD	54.2 ± 8.3	55.7 ± 12.1	
BMI	Range	(18-35)	(18-33)	0.512
	Mean \pm SD	25.6 ± 5.3	24.9 ± 3.9	
HTN	No	31(68.9%)	34(75.6%)	0.480
	Yes	14(31.1%)	11(24.4%)	
DM	No	37(82.2%)	31(68.9%)	0.141
	Yes	8(17.8%)	14(31.1%)	
Smoking	No	45(100%)	42(93.3%)	0.078
	Yes	0(0%)	3(6.7%)	

Table 2: Type of Surgery comparison between Conventional group and BVSS group:

		Group I	Group II	P value
		N=45	N=45	
Type of surgery	BCSS	17(37.7%)	15(33.3%)	0.777
	MRM	28(62.2%)	30(66.6%)	

Table 3: Operative time of Conventional group and BVSS group:

		Group I	Group II	P value
		N=45	N=45	
Total operating time	<i>Range</i> <i>Mean ± SD</i>	(110-140) 126.9±12.4	(100-150) 119.8±12.9	0.009*
Axillary dissection time	<i>Range</i> <i>Mean ± SD</i>	(30-45) 37.3±5.5	(20-40) 28.8±4.4	<0.001*

Table 4: Drain volume data and blood loss of Conventional group and BVSS group:

		Group I	Group II	P value
		N=45	N=45	
Total drain volume	<i>Range</i> <i>Mean ± SD</i>	(600-1050) 851.1±96.2	(250-800) 370±152	<0.001*
Blood loss	<i>Range</i> <i>Mean ± SD</i>	(150-350) 215.6±50.9	(100-200) 147.8±33.6	<0.001*

Table 5: Post-operative complications of Conventional group and BVSS group:

		Group I	Group II	P value
		N=45	N=45	
Post operative bleeding	<i>No</i> <i>Yes</i>	43(95.6%) 2(4.4%)	44(97.8%) 1(2.2%)	0.557
Hematoma	<i>No</i> <i>Yes</i>	43(95.6%) 2(4.4%)	44(97.8%) 1(2.2%)	0.557
Seroma	<i>No</i> <i>Yes</i>	38(84.4%) 7(15.6%)	40(88.9%) 5(11.1%)	0.535
Wound infection	<i>No</i> <i>Yes</i>	43(95.6%) 2(4.4%)	43(95.6%) 2(4.4%)	1
Flap necrosis	<i>No</i> <i>Yes</i>	43(95.6%) 2(4.4%)	45(100%) 0(0%)	0.153
Skin burns	<i>No</i> <i>Yes</i>	39(86.7%) 6(13.3%)	42(93.3%) 3(6.7%)	0.292

Table 6: Days until drain removal and post operative stay of Conventional group and BVSS group:

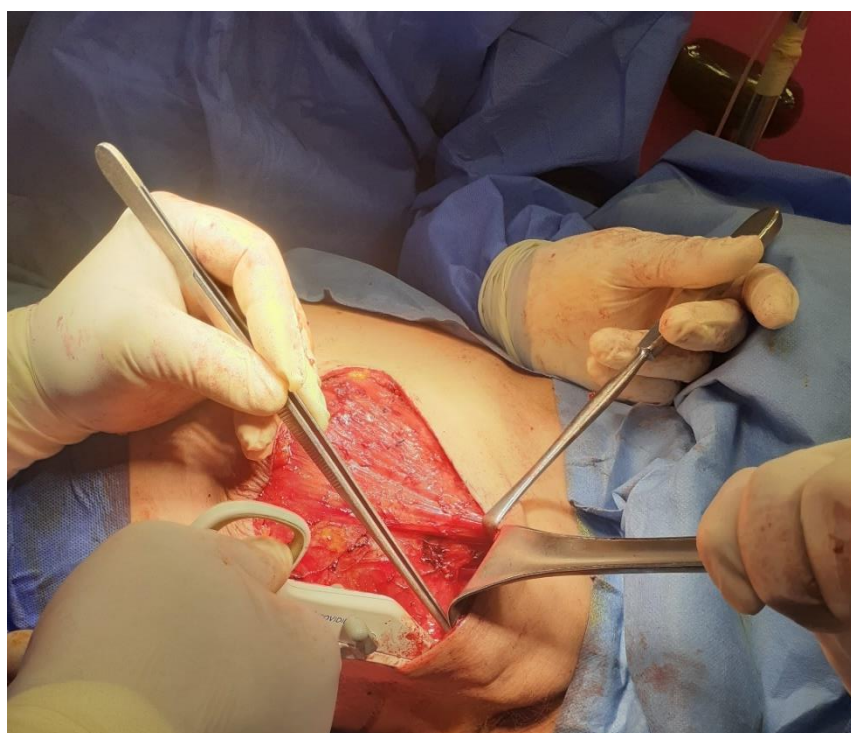
		Group I	Group II	P value
		N=45	N=45	
Days until drain removal	<i>Range</i> <i>Mean ± SD</i>	(9-14) 10.6 ± 1.9	(6-10) 6.2 ± 0.8	0.001*
Post operative stay	<i>1 day</i> <i>2 days</i> <i>3 days</i>	25(55.6%) 16(35.6%) 4(8.9%)	36(80%) 7(15.6%) 2(4.4%)	0.046*
	<i>Range</i> <i>Mean ± SD</i>	(1-3) 1.5±0.7.	(1-3) 1.2±0.5	

Table 7: Comparison of tumour size distribution between groups:

		Group I	Group II	P value
		N=45	N=45	
Tumour size	<2	20(44.4%)	18(40%)	<i>0.670</i>
	≥2	25(55.6%)	27(60%)	
	<i>Median</i> <i>IQR</i>	2 (1.5-2.5)	2 (1.5-3)	<i>0.139</i>

Table 8: Comparison of Total number and positive LNs distribution between groups:

		Group I	Group II	P value
		N=45	N=45	
Total number of removed LN	<i>Range</i>	(10-22)	(12-23)	<i>0.398</i>
	<i>Mean ± SD</i>	14.9±3.4	15.6±4	
Positive lymph nodes	<i>Median</i>	2	2	<i>0.655</i>
	<i>IQR</i>	(0-5)	(0-5)	

**Figure 1: A case underwent MRM showing exposure of pectoralis major muscle**

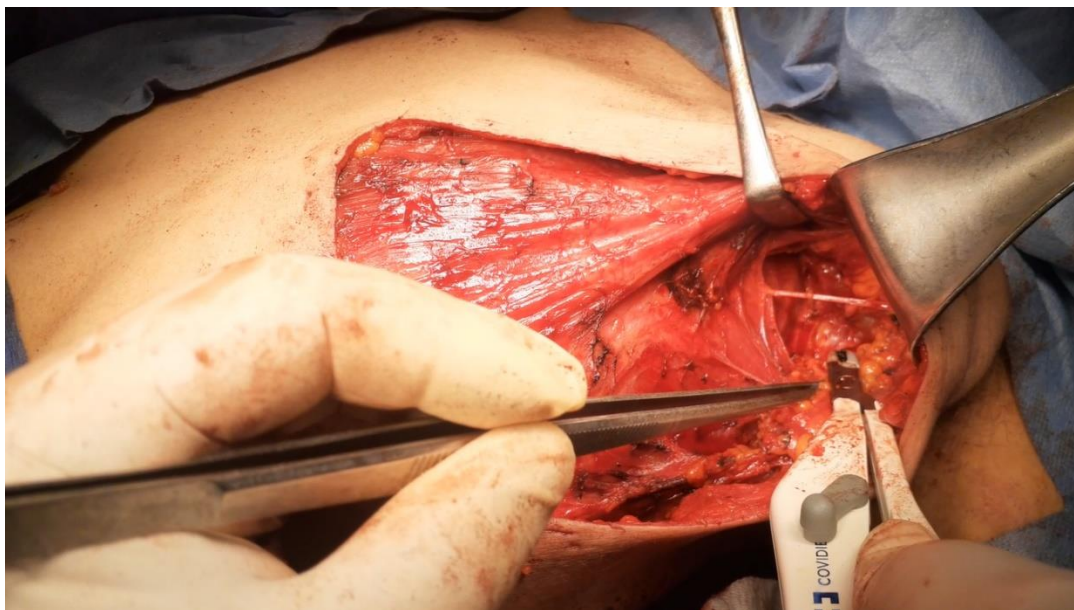


Figure 2: A case of underwent MRM with ALND via Ligasure.

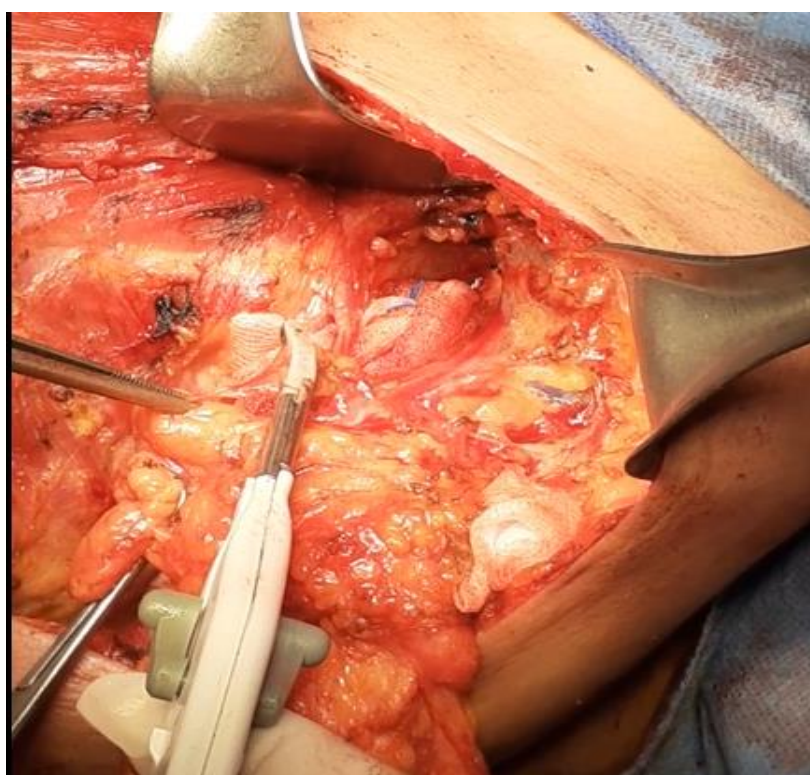


Figure 3: showing gauze for hemostasis and non-toothed forceps for traction.

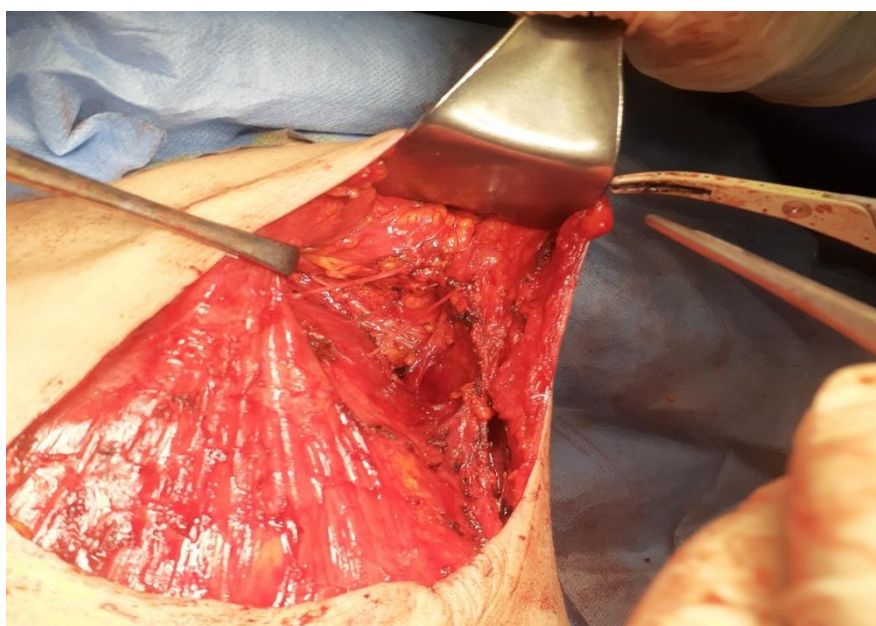


Figure 4: exposure of intercostobrachial nerve.

Discussion

Breast cancer is the most frequently encountered kind of tumor spotted in women worldwide. It is responsible for 32% of female cancers and 19% of deaths related to cancer. One of the most important parameters in the prognosis of breast cancer is whether there is axillary lymph node involvement or not. Axillary lymph node dissection is performed for accurate staging of the disease, directing adjuvant therapies, and providing local tumor control in patients with lymph node involvement. ^[11]

Conventional modified radical mastectomy with axillary dissection using scalpel, clamp-and-tie techniques, and electrocautery is frequently associated with complications such as seroma and lymphedema. Other less common complications include hematoma, prolonged axillary drainage, wound infection or necrosis, and intraoperative and postoperative bleeding. ^[16]

Following axillary dissection, seroma is seen between 10% and 80%, and it necessitates aspiration ^[17]

Energy dependent thermal coagulation instruments have first been used by Bovie and Cushing in 1928. In recent systems high

frequency oscillating currents are being used for coagulation. There are two fundamental electrocautery systems such as monopolar or bipolar with regard to style of distributing sufficient energy to provide hemostasis. ^[18]

LigaSure bipolar vessel sealing system provides hemostasis of vessels between 1 and 7 millimeters. LigaSure vessel sealing system transfers the appropriate amount of energy in tissue lumps or vessels according to their densities. Thus, as no exceeding energy is transferred, thermal convectional damage is limited to neighboring tissues. With Ligasure, thermal radiation to nearby tissues is between 0.5 and 2 millimeters. ^[19]

Previous randomized studies comparing the vessel sealing system with conventional devices have reported that vessel sealing system seems to reduce the drainage volume and shorten the postoperative hospital days. ^[20]

In addition, a number of questions regarding factors related to postsurgical seroma and the efficacy of interventions with the aim of reducing seroma formation remain unanswered. In multivariate logistic regression analyses,

surgical procedure (modified radical mastectomy), total amount of drainage, size of the tumor, and neoadjuvant chemotherapy have been associated with postoperative seroma formation. It appears that immediate reconstruction may reduce the incidence of postoperative seromas, presumably by filling the dead space in the chest wall. [21]

Our study shows that the use of the LigaSure Small Jaw reduced the days until drain removal and postoperative drainage volume when comparing to the conventional devices. It is extremely important to shorten drain days and hospital stay, because delays in these factors can lead to delays in adjuvant therapy.

An advantage of using the vessel sealing system is that this procedure does not require direct exposure of blood vessels, which can increase operative time and cause unnecessary bleeding. Previous randomized studies comparing the vessel sealing system with conventional devices have reported that vessel sealing system seems to reduce the drainage volume and shorten the postoperative hospital days.

The vessel sealing system used in these studies was the LigaSure Precise, not the newest device, the LigaSure Small Jaw.

The LigaSure Small Jaw is a manual device, 18.8 cm long. It is designed to be used in confined surgical spaces where access and visibility are limited. This instrument, designed for open surgery, offers the ability to selectively cut or grasp tissue and permanently seal vessels with a diameter of up to and including 7 mm, lymphatic vessels, and tissue bundles without using sutures, staples, or clips. Although some studies comparing the LigaSure Small Jaw with conventional suture ligation in thyroidectomy [22] and hepatic resection [23] showed intraoperative blood loss to be statistically significantly less for the LigaSure Small Jaw.

In this study, the vessel sealing system seems to be more effective for patients as drainage volume and days were reduced, seroma formation could not be completely avoided. The optimal way to prevent and treat seromas remains inconclusive. Other postoperative complications, including hematoma, wound infection, skin necrosis were also lower in the LigaSure group. There was a statistically

significant difference was seen in intraoperative blood loss on use of the vessel sealing system compared to use of conventional devices.

Our Study is a randomized controlled study with a well-planned consistent protocol of peri-operative care, data management, and statistical analysis. Patients were strictly followed up until the end of the study. Although randomized controlled studies are usually the highest level of evidence for judging the efficacy of therapeutic interventions, a limitation of this study is that it is not possible to blind the operating surgeon on the result of randomization which could influence the outcome of the study. Another limitation is the low patient population in this study. This study was conducted in a single institution and was therefore not adequately powered to assess the benefit of treatment in different subgroups.

There was no significant statistical difference in Type of surgery, in Group I, 28 of patients underwent MRM and 17 patients underwent BCS. While in Group II, 30 of patients underwent MRM and 15 patients underwent BCS.

Total operating time was calculated from skin incision till skin closure. There was a significant statistical difference in Total operating time between the two groups. in group-I, Total operating time was 126.9 ± 12.4 minutes and 119.8 ± 12.9 minutes in group-II. Although Axillary dissection time was reduced by 28.8 ± 4.4 minutes in ligasure group versus 37.3 ± 5.5 minutes for two groups. in conventional group.

In conventional group, mean Blood loss was 215.6 ± 50.9 ml and 147.8 ± 33.6 ml in ligasure group, no intra operative blood transfusion was needed for any patient.

In this study, in conventional group, mean drain volume was 851.1 ± 96.2 ml and 370 ± 152 ml in ligasure group with a p-value of <0.001 , which is statistically significant. In conventional group, mean number of days till drain removal was 10.6 ± 1.9 days and 6.2 ± 0.8 days in ligasure group with a p-value of 0.001 which is statistically significant.

Studies have documented that the new Ligasure electro thermal bipolar vessel sealing system is safe to use in axillary clearance as an alternative

to traditional methods and it reduces postoperative drain output (620 ± 469 ml vs. 809 ± 380 ml) and duration of drain till removal (7.6 ± 4.6 days vs. 10 ± 4.3 days).^[24]

Ligasure used in axillary dissection reduces postoperative complications and allows early drain removal (4.3 ± 1.0 days vs. 5.7 ± 1.5 days) and less drain output (366.2 ± 220.1 ml vs. 422.9 ± 225.5 ml) as compared to traditional methods of thread ligation.^[20]

In another study, it was concluded that Ligasure is more effective device compared to traditional methods in axillary dissection in terms of reducing total volume of fluid drainage (365.3 ± 242.2 vs. 625.1 ± 446.6 ml) and number of days till drain removal (6.4 ± 2.9 vs. 8.2 ± 3.8 days).^[15] Drain was removed after drainage is less than 30 ml in 24 hours for 2 days for each group.

As regard post-operative Seroma, in conventional group, seroma occurred in 7 patients (15%) 5 of them was managed conservatively and 2 needed repeated needle aspiration, in ligasure group 5 patients (11.1%) 3 of them was managed conservatively and 2 needed repeated needle aspiration.

Furthermore, no upper limb lymphedema has been observed in our patients. However, this result should be carefully evaluated because the follow-up period of our patients is short, ranging from 1 to 2 years, and the frequency of lymphedema is known to rise with an increasing interval since surgery.

flap necrosis occurred in 2 patients in conventional group and them needed debridement and suturing. Skin burn occurred in 6 patients in conventional group and 3 patients in ligasure group and all of the were managed conservatively.

Two patients for each group have post-operative wound infection and were treated by suitable antibiotics and anti-inflammatory agents.

As regard Tumour size, in group-I, 20(44.4%) patients had tumour size <2 cm, while 25(55.6%) had tumour size ≥ 2 cm. In group-B, 18(40%) patients had tumour size <2 cm, while 27(60%) had tumour size ≥ 2 cm.

Total number of removed LNs in conventional group was 14.9 ± 3.4 and 15.6 ± 4 in ligasure group, with no statistical difference.

The use of the electrothermal bipolar vessel sealing system seems to be more expensive than conventional techniques. This is probably the major disadvantage of the device. However, the potential added cost should be compared with the benefit in operative time savings and in the reduction of resources used in the operating room. The increased comfort of the surgeons associated with shortened operative time should also be emphasized. The benefits and the potential reduction of complications may render this device cost-effective.

Conclusion:

When comparing LigaSure to traditional techniques for surgical hemostasis in axillary surgery, the current research found that LigaSure dramatically shortened the operational time, days of suction drained, and duration of hospital stay without worsening postoperative complications. After leaving the hospital, both the total volume of fluid drained via the axillary drain and the frequency of seroma punctures were reduced.

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Conflict of interest: None.

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