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Comparison of Axillary Lymph Node Dissection by Using Vessel Sealing System versus Conventional Thread Ligation in Patients Undergoing Modified Radical Mastectomy for Carcinoma of Breast

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ABSTRACT

Objective: To evaluate the results of the traditional thread ligation technique against the vessel sealing system employed in axillary dissection for breast cancer, focusing on the average postoperative drain output and the mean duration until drain removal.

Study Design and Setting: This study was carried out at the Gujranwala Medical College/District Headquarters Hospital. A total of 120 patients were enrolled in this study following the inclusion criteria. A Non-probability consecutive sampling technique was used to divide patients into two groups.

Results: In this study the mean age and BMI in Group A were 52.78 ± 10.06 years and 26.88 ± 3.94 kg/m² respectively. Similarly, the mean age and BMI in Group B were 50.27 ± 11.77 years and 29.08 ± 4.12 kg/m², respectively. In this study the mean drain removal days in the conventional group were 5.05 ± 0.81 and in the ligasure group were 4.75 ± 0.77, with the p-value being as significant as 0.040. Similarly, the mean drain fluid in the conventional group was 640.33 ± 59.80 ml and in the ligasure group was 487.83 ± 27.38 ml, p-value < 0.01. The stratification of the age with respect to drain fluid showed significant differences for all age groups, i.e., p-value < 0.01 except for age group 18-28 years, p-value 0.371.

Conclusion: Axillary lymph node dissection utilising the results in a reduction in mean postoperative drain output and the average duration until drain removal compared to the traditional thread ligation technique.

Keywords Axillary Lymph Node, Carcinoma, Conventional, Dissection, Mastectomy

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INTRODUCTION

In every region of the world, cancer is the leading cause of death and illness. There were 14.1 million newly diagnosed instances of cancer, and it is estimated that 8.2 million people lost their lives as a direct result of cancer altogether.[1] As of the year 2012, there were 1.7 million newly diagnosed instances of breast cancer. When it comes to females, breast cancer is the most common cause of death from cancer. As an additional point of interest, a study that was carried out in Pakistan indicated that breast cancer is the most prevalent type of cancer in the country, accounting for 38.2% of all malignancies. The rates are among the highest that can be found in Asia.[2] Nearly all of the women in Pakistan are diagnosed with breast cancer at a later stage than the majority of other women.

According to the findings of a study, eighty percent of the females presented with a delay that was larger than three months. The source of the delay was shown to be attributable to traditional beliefs and the incorrect interpretation of symptoms.[3]

When it comes to treating breast cancer, surgery continues to be the primary method of treatment. Modified radical mastectomy is the treatment of choice in cases when it is discovered that the axillary lymph nodes are also affected.[4-

[5] In the aftermath of a modified radical mastectomy, it is customary to place two drains, one in the flap and the other in the axilla. Research investigates a number of surgical techniques and devices for the purpose of axillary lymph node dissection. These include the traditional electrocautery technique, thread ligation, and the harmonic scalpel. When a modified radical mastectomy with axillary clearance is performed using typical thread ligation procedures, the most common problems that are noted include excessive postoperative drain output and the formation of seroma.[6–8]

When compared to more traditional methods, the electrothermal bipolar vessel sealing system has been found to be a more secure solution for axillary clearing. This conclusion was reached as a consequence of study that was conducted. A decrease in postoperative drain output (620±469 ml rather than 809±380 ml) and a shorter duration until drain removal (7.6±4.6 days rather than 10±4.3 days) are the outcomes of this. [9] The use of in axillary dissection has the potential to reduce postoperative complications when compared to conventional methods of thread ligation. This is because it allows for the removal of the drain at an earlier time (4.3±1.0 days rather than 5.7±1.5 days), and it also results in a lower drain output (366.2±220.1 ml rather than 422.9±225.5 ml). [10] According to the findings of another study, the traditional procedures that were utilised in the process of axillary dissection led to a decrease in the total volume of fluid drainage as well as the number of days that were required before the drain was removed.[10-11]

In light of the burden of breast cancer disease and the large number of modified radical mastectomies that are performed using conventional techniques, the purpose of this clinical trial is to evaluate the usefulness and stated benefits in our system. This will be done by comparing to conventional methods of axillary dissection. Additional information will be added to the current body of knowledge as a result of the findings of this clinical trial that utilised this novel instrument and method. The implementation of significant resources for the provision of this instrument and technique to all levels can be accomplished through the utilisation of these resources by policy makers, planners, and health managers. Additionally, the findings will raise awareness among experts working in the health care industry on this newly developed instrument and method.

METHODOLOGY

This quasi experimental trial was carried out at the Gujranwala Medical College/District Headquarters Hospital from 16 November 2024 to 16 May 2025 under IRB No.6/GMC. A sample size of 120 (60 in each group) was calculated with a 95% confidence level, 80% power of test and taking the expected mean number of days till drain removal as (6.4±2.9 vs. 8.2±3.8 days). [10]

Patients were enrolled using non-probability consecutive sampling, and subsequently devided into two groups using a random number table**.** Inclusion criteria: (1) Patients aged 18-70 years. (2) Female gender. (3) Patients with unilateral breast carcinoma (histopathological diagnosis using trucut biopsy) with all indications of modified radical mastectomy (clinical and radiological evidence of axillary lymph node involvement (as per operational definition). (4) ASA I-II.

Exclusion criteria: (1) Patients with early breast cancer (T1). (2) History of previous breast surgeries e.g. recurrent carcinoma. (3) Patients with diabetes mellitus, patients on anticoagulants, patients with radiation therapy to the chest wall. (4) Patients with any type of neoadjuvant chemotherapy. (5) ASA scores III and IV and stage IV metastatic carcinoma.

Breast cancer: It was assigned to the patient with a history of breast swelling, and on histopathology there is confirmation of carcinoma of the breast.

Mean drain output: Drain outputs were documented in millilitres every day until the output fell below 20 ml within the prior 24 hours.

Mean number of days till: The calculation was based on when the drain output fell below 20 ml within the prior 24 hours. The day of drain removal was documented and examined individually for each drain.

After approval from the hospital ethical committee and informed consent, 120 patients (60 in each group), presenting in the general surgery department, DHQ Hospital, Gujranwala, and fulfilling the inclusion exclusion criteria were enrolled in the study. They were assured confidentiality and explained about expertise available for new technique and conventional technique. Operation was performed by same group of surgeons. Tumor was staged using TNM classification. Patients meeting the inclusion criteria were enrolled through non-probability consecutive sampling. After enrollment, participants were randomly assigned to either Group A (Ligasure) or Group B (conventional thread ligation) using a random number table, ensuring equal allocation of 60 patients in each group.

Pre-operative preparation was done by complete bath prior to surgery using antiseptic soap and axilla was shaved. All the baseline investigations including routine radiological investigations and metastatic workup were carried out for each patient in both groups. All of patients were given prophylactic antibiotics preoperatively. The surgeries were performed under general anaesthesia. Level I, II lymph node dissection was done in all cases depending upon involvement of the axillary lymph nodes. Two suction drains were placed one in axilla and one in flap and they were called Axillary drain and Flap drain, respectively. Patients were discharged after removal of drains. Patients were called after 7th to 10th postoperative day in Outpatient Department and underwent thorough examination and investigations for any complication. Stitches were removed on postoperative day 10. In all patients, the following data was recorded: age, body mass index (BMI), type of surgery, duration of drain

and amount of drained fluid. All data was recorded.

Data was entered and analyzed using SPSS version 26.0. For quantitative variables like age, BMI, amount of drainage from both drains, number of days till drain removal was calculated as mean + S.D. ASA status (I/II), marital status was calculated as frequency and percentages. The t-test was used to compare the amount of drainage from both drains and the length of days until drain removal. A p value <0.05 was considered significant. The data was segmented by age, BMI, and ASA status. A post-stratification t-test was used, with p-values < 0.05 considered significant.

In this study the mean age and BMI in Group A were 52.78 ± 10.06 year and 26.88 ± 3.94 kg/m², respectively, similarly the mean age and BMI in Group B were this 50.27 ± 11.77 years and 29.08 ± 4.12 kg/m², respectively. The comparison of marital status and ASA showed insignificant results with p-values 0.717 and 0.361 respectively. In this study the mean drain removal days in conventional group was 5.05 ± 0.81 and in ligasure group was 4.75 ± 0.77 with the p-value being as significant 0.040. Similarly, the mean drain fluid in conventional group was 640.33 ± 59.80 ml and in ligasure group was 487.83 ± 27.38 ml showing statistically significant difference between both groups p-value < 0.01. (Table 1). The stratification of comparison of drain removal days with respect to age groups showed insignificant differences across the groups p-values > 0.05. (Table 2). The stratification of age with respect to drain fluid showed significant differences for all age groups i.e., p-value < 0.01 except for age group 18-28 years p-value 0.371. (Table 3). The stratification of comparison of drain removal days with respect to BMI showed that in patients with BMI > 25 kg/m2 there was a significant difference for the removal of drain between both groups p-value 0.001. The stratification of comparison of drain fluid with respect to BMI showed significant difference among both groups p-value < 0.01. (Table 4). The stratification of comparison of drain removal days with respect to ASA I showed insignificant difference p-value 0.817, however, for ASA II showed significant difference p-value 0.002. The stratification of comparison of drain fluid with respect to ASA classification showed significant difference among both groups in both classes' p-value < 0.01. (Table 5)

DISCUSSIONS

Breast cancer is the most often diagnosed type of malignancy in women globally. It accounts for 32% of female malignancies and 19% of cancer-related fatalities. In the USA, one in eight women and in European countries, one in ten women are diagnosed with breast cancer. The primary determinant in the prognosis of breast cancer is the presence or absence of axillary lymph node involvement. Axillary

Table 1: Demographics and clinical parameters

		Conventional Group (Group A)	Group (Group B)	P-Value
Age (Mean ± S.D)		52.78 ± 10.06	50.27 ± 11.77	0.210
BMI (Mean ± S.D)		26.88 ± 3.94	29.08 ± 4.12	0.003
Marital Status	**Single**	3 (5%)	5 (8.3%)	0.717
	Married	57 (95%)	55 (91.7%)	
ASA	**I**	33 (55%)	27 (45%)	0.361
	II	27 (45%)	33 (55%)	
Drain Removal Days (Mean ± S.D)		5.05 ± 0.81	4.75 ± 0.77	0.040
Drain Output (ml) (Mean ± S.D)		640.33 ± 59.80	487.83 ± 27.38	< 0.01

Table 2: Stratification of comparison of drain removal days with respect to age groups

	Age Group	Study Groups	N	Mean	Std. Deviation	P-Value
Drain Removal Days	**18-28**	**Conventional group**	3	5.33	.577	0.230
		Ligasure Group	3	4.67	.577	
	29-39	**Conventional group**	3	5.00	1.00	0.483
		Ligasure Group	7	4.57	.787	
	40-50	**Conventional group**	16	5.06	.929	0.681
		Ligasure Group	17	4.94	.748	
	51-60	**Conventional group**	37	5.03	.799	0.234
		Ligasure Group	27	4.76	.847	
	61-70	**Conventional group**	1	5.00	.	0.286
		Ligasure Group	6	4.33	.516	

Table 3: Stratification of comparison of drain volume with respect to age groups

	Age Group	Study Groups	N	Mean	Std. Deviation	P-Value
Drain Fluid	18-28	Conventional group	3	563.33	92.92	0.371
		Ligasure Group	3	503.33	45.09	
	29-39	Conventional group	3	676.67	51.32	<0.01
		Ligasure Group	7	492.86	17.99	
	40-50	Conventional group	16	645.62	61.20	<0.01
		Ligasure Group	17	492.94	26.64	
	51-60	Conventional group	37	641.35	55.29	<0.01
		Ligasure Group	27	482.59	27.12	
	61-70	Conventional group	1	640.00		0.007
		Ligasure Group	6	483.33	33.27	

Table 4: Stratification of comparison of drain removal days and drain fluid with respect to BMI

	BMI Classification	Study Groups	N	Mean	Std. Deviation	P-Value
Drain Removal Days	Non-obese	Conventional group	48	4.9583	.84949	0.419
		Ligasure Group	36	4.8056	.85589	
	Obese	Conventional group	12	5.4167	.51493	0.001
		Ligasure Group	24	4.6667	.63702	
Drain Fluid	Non-obese	Conventional group	48	639.38	64.46	< 0.01
		Ligasure Group	36	490.56	31.53	
	Obese	Conventional group	12	644.17	37.53	< 0.01
		Ligasure Group	24	483.75	19.52	

Table 5: Stratification of comparison of drain removal days with respect to ASA

	ASA Classification	Study Groups	N	Mean	Std. Deviation	P-Value
Drain Removal Days	I	Conventional group	33	4.87	0.78	0.817
		Ligasure Group	27	4.93	0.78	
	II	Conventional group	27	5.26	0.81	0.002
		Ligasure Group	33	4.61	0.75	
Drain Fluid	I	Conventional group	33	626.97	65.02	< 0.01
		Ligasure Group	27	491.48	24.60	
	II	Conventional group	27	656.67	49.07	< 0.01
		Ligasure Group	33	484.85	29.49	

lymph node dissection is conducted for precise disease staging, guiding adjuvant therapy, and ensuring local tumor control in patients with lymph node involvement. Post-axillary curettage, seroma occurs in 10% to 80% of cases, requiring aspiration.[12-14]

The bipolar vascular sealing device achieves hemostasis for vessels ranging from 1 to 7 millimeters. The vessel sealing device delivers the requisite energy to tissue masses or vessels based on their densities. Consequently, since no excess energy is transmitted, thermal convective injury is confined to adjacent tissues. With the heat radiation to adjacent tissues ranges from 0.5 to 2 millimetres. Utilizing precise for axillary curettage results in radiation levels < 0.5 millimetres.[15, 16]

Prior randomized studies have suggested that the vessel encapsulation system reduces postoperative hospital stays and reduces drainage volume when compared to conventional devices. [15,17-19] In comparison to conventional devices, the duration until drain removal and the volume of postoperative drainage were reduced by Small Jaw. It is imperative to reduce the number of drain days and hospital stays, as these factors can delay adjuvant therapy.

In our study, in group, mean drain volume was 487.83 ± 27.38 ml and 640.33 ± 59.80 ml in conventional group with p-value being as significant < 0.01. In a prior study, the mean drain volume in the ligasure group was 500.1±60.8

ml, while in the traditional group it was 665.3±84.9 ml, yielding a statistically significant p-value of 0.0001. [16]

In this study in the ligasure group mean number of drain removal days was 4.75 ± 0.77 and in conventional group was 5.05 ± 0.81 with p-value 0.040. In a separate trial involving the ligasure group, the average duration until drain removal was 6.5±1.1 days, compared to 8.6±1.2 days in the traditional group, yielding a statistically significant p-value of 0.0001. [16]

The baseline characteristics of the two groups were largely comparable; however, a statistically significant difference in BMI was observed between the groups (p = 0.003). Obesity is a recognized risk factor for increased postoperative seroma formation and higher drain output following axillary dissection. Therefore, this imbalance could potentially influence the postoperative drainage outcomes observed in the study. To address this concern, stratified analysis was performed based on BMI categories (obese and non-obese), which demonstrated that the reduction in drain output in the ligasure group remained statistically significant across both BMI categories. This suggests that the observed reduction in postoperative drainage with the vessel sealing system is unlikely to be solely explained by BMI differences and supports the independent effect of the surgical technique.

Research has established that the novel electrothermal bipolar vessel sealing system is a safe alternative for axillary clearance compared to conventional techniques, resulting in decreased postoperative drain output (620±469 ml vs. 809±380 ml) and a shorter duration until drain removal (7.6±4.6 days vs. 10±4.3 days).[7] 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.[19]

A separate study concluded that is a more effective device than traditional methods for axillary dissection, as evidenced by a reduction in total fluid drainage volume (365.3 ± 242.2 ml vs. 625.1 ± 446.6 ml) and a decrease in the number of days until drain removal (6.4 ± 2.9 days vs. 8.2 ± 3.8 days).[16]

Although the LigaSure vessel sealing system is associated with a higher initial cost compared with conventional thread ligation, several studies suggest that its use may be cost-effective in the long term. The reduction in postoperative drain output and shorter duration until drain removal may lead to decreased hospital stay, fewer postoperative complications such as seroma formation, and earlier initiation of adjuvant therapy. These factors can potentially offset the higher device cost by reducing overall healthcare utilization and improving patient recovery. In our study, although a formal cost-effectiveness analysis was not performed, the shorter drain duration and reduced drain output observed in the LigaSure group suggest potential economic benefits. Future studies incorporating detailed cost analysis are recommended to better evaluate the economic impact of LigaSure use in axillary dissection.

LIMITATIONS: The major limitation we faced while conducting this study was to find patients meeting our inclusion criteria because most of the patients in our hospital present at a very late stage in which we had to first give neo adjuvant therapy and those patients could not meet our inclusion criteria. The second thing was availability and the cost of the procedure but it was resolved by the hospital administration in the vital interest of the patients. A formal cost-effectiveness analysis comparing LigaSure with conventional ligation was not performed in this study, which represents a limitation. Future studies should evaluate the economic implications of using advanced vessel sealing devices in breast cancer surgery.

A significant baseline difference in BMI between groups was observed, which could act as a potential confounder since obesity is associated with increased seroma formation. Although stratified analysis was performed to minimize this effect, future studies using multivariable adjusted analysis are recommended.

CONCLUSION

Axillary lymph node dissection utilizing results in a reduction in mean postoperative drain output and the average duration until drain removal compared to the traditional thread ligation technique.

Suggestions / Recommendations

We should work hard to create awareness among the population regarding breast cancer. Government should make breast Clinics in all Primary and Secondary Healthcare settings so that patients are timely screened and managed at an earlier stage. There should be regular walks and seminars on breast cancer. The doctors at Basic Health Unit Level to DHQs should be given regular trainings for screening and proper referral of breast cancer patients.

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Hamza Asghar: Conception design and title selection
Umer Ejaz Cheema: Data Collection
Saad Khan: Data entry and analysis
Ayesha Zulfiqar: Introduction and discussion writing
Syeda Hussan e Zahra: Rephrasing of article text
Imran Amin: Supervision of all research work

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