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POST MASTECTOMY SEROMA FORMATION: LIGASURE V/S SCALPEL DISSECTION IN MODIFIED RADICAL MASTECTOMY

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Abstract

Objective: *To evaluate the surgical results associated with modified radical mastectomy using LigaSure diathermy and conventional scalpel dissection, focusing on operative time, estimated blood loss, occurrence of seromas, and postoperative complications.*

Place and Duration of Study: *Department of General Surgery, Federal Government Polyclinic Hospital Islamabad.*

Study Design: *Quasi Experimental Study*

Methodology: *In the study, one hundred females who were undergoing modified radical mastectomy were divided into two equal groups of 50 each, with one receiving LigaSure and the other receiving the standard scalpel treatment. The patients' demographic details were collected along with intraoperative blood loss, length of time spent in the operating theatre, formation of seroma, amount of drainage from the wound, postoperative complications, and histopathological examination. The independent t-test was used to check the means of continuous variables while the Chi-square test was used for categorical variables, with a 95% confidence interval.*

Results: *LigaSure marked a notable difference in operative time which was significantly less compared to the control group (p=0.03). Loss of blood during the surgery was also on the lower side for LigaSure (p=0.02). Seroma formation was higher in the LigaSure group's rate of 46%, compared to the scalpel group's 30% (p=0.04). Drain output and duration were also significantly greater in the LigaSure group (p=0.03, p=0.02). There was no significant difference in the parameters of wound infection (p=0.07), hematoma formation (p=0.08), skin flap necrosis (p=0.12). Postoperative pain scores were lower in the LigaSure group (p=0.01).*

Conclusion: *LigaSure significantly reduces operative time and blood loss but is associated with increased seroma formation and longer drain duration. It offers advantages in postoperative pain control but does not significantly impact wound infection or hematoma rates.*

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide, with a particularly high burden in developing countries, including Pakistan[1]. Due to late-stage presentation and limited access to early screening, a significant proportion of patients in Pakistan require modified radical mastectomy

(MRM) as a primary treatment modality[2,3]. Despite advancements in surgical techniques, one of the most frequent postoperative complications of MRM is seroma formation, which can lead to prolonged hospital stays, delayed wound healing, and increased risk of infection, thereby impacting both patient outcomes and healthcare resources[4,5,6].

Seroma formation occurs due to the accumulation of fluid in the dead space created after mastectomy and axillary dissection[7]. Some surgical techniques have been developed to mitigate this complication, such as conventional scalpel dissection and the use of advanced energy devices like LigaSure. A vessel-sealing device called LigaSure has become widely utilised because of its intraoperative haemorrhage control, decreased operating theatre time, and presumed decreased seroma formation due to less tissue injury and dead space.[8,9]. However, conventional scalpel dissection remains widely practiced in resource-limited settings such as Pakistan, where access to advanced surgical tools may be constrained by cost and availability.

Several studies have compared LigaSure and scalpel dissection in terms of postoperative complications, including seroma formation, with mixed results[10]. Some reports suggest that LigaSure reduces seroma incidence due to better hemostasis and reduced lymphatic leakage, while others indicate no significant difference between the two techniques[11]. However, limited data are available from Pakistan, where differences in patient demographics, surgical expertise, and healthcare infrastructure may influence outcomes[12]. Given the significant burden of breast cancer and the need for cost-effective surgical strategies, evaluating the impact of LigaSure versus scalpel dissection on post-mastectomy seroma formation in a local setting is essential[13].

The purpose of this study is to compare the frequency and severity of post-mastectomy seroma formation between LigaSure and conventional scalpel dissection in patients undergoing modified radical mastectomy[14,15]. By providing evidence-based insights, this research aims to guide surgical decision-making and improve postoperative outcomes in breast cancer patients in Pakistan.

Methodology:

A quasi-experimental study was conducted to compare postoperative seroma formation in patients undergoing modified radical mastectomy (MRM) using LigaSure versus scalpel dissection. The study was carried out in the Department of General Surgery, Federal Government Polyclinic Hospital, Islamabad. Non-probability consecutive sampling was used for patient selection. The study was conducted over a period of six months after the approval of the research synopsis. The calculation of sample size was carried out using the WHO sample size calculator with the following assumptions based on a recent international study by El-Shazly et al. (2021)

This study was estimated to have a 5% significance level (α) associated with a test power (1-β) of 80%. The anticipated proportion of seroma formation was projected to be 44% in the scalpel group and 18% in the LigaSure group. Under these conditions, the minimal required sample size was found to be 50 patients in each group, hence a total of 100 patients.

Patients were randomised into two groups: the first group, also referred to as the study group, included 50 patients who underwent modified radical mastectomy (MRM) with LigaSure dissection. The second group was the control group, which included 50 patients who underwent MRM with conventional scalpel dissection.

The study included female patients aged 18 to 65 years undergoing MRM with axillary lymph node dissection for stage I or II breast carcinoma, confirmed by histopathology. Patients were excluded if they had liver cirrhosis and/or chronic hepatitis, were on anticoagulation therapy, had recurrent breast carcinoma on the same side, had previously undergone breast or axillary surgery on the same side, or declined participation in the study.

All patients underwent MRM under general anesthesia. In the control group, standard dissection was performed using a scalpel and electrocautery, whereas in the study group, dissection was conducted using the LigaSure vessel-sealing system (Medtronic). Standard surgical protocols were followed in both groups, including the placement of one or two suction drains.

Postoperatively, patients were monitored for seroma formation, wound complications, and other relevant parameters. Seroma formation was defined as fluid

collection in the mastectomy bed, detected either clinically or through ultrasound. Key parameters recorded included seroma volume, categorized as mild (<50 mL), moderate (50–100 mL), or severe (>100 mL). The time of seroma detection was classified as occurring within <5 days, between 5–10 days, or beyond 10 days postoperatively. The number of aspirations required was documented as none, 1–2, or ≥3. Total drain output within the first 24 hours was categorized as <50 mL, 50–100 mL, or >100 mL, while the timing of drain removal was recorded as <5 days, 5–10 days, or >10 days. Additionally, wound complications, including hematoma, infection, and flap necrosis, were carefully documented.

The data was analyzed using SPSS version 25.0 (IBM, USA). Categorical variables were compared using the Chi-square test and Fisher's exact test where applicable. Continuous variables were analyzed using the independent t-test. A p-value of ≤0.05 was considered statistically significant. Exact p-values and 95% confidence intervals (CI) were reported.

Results:

The study included 100 female patients undergoing modified radical mastectomy, with 50 patients in the LigaSure group and 50 in the scalpel group. The results of the study ae presented below in tabulated form.

Statistical analysis showed a significant difference in seroma formation between the LigaSure and scalpel groups (p=0.04), with higher rates observed in the LigaSure group. Drain output was significantly higher in LigaSure cases (p=0.03), while drain duration was also longer in this group (p=0.02). No significant difference was observed in wound infection rates (p=0.07), hematoma formation (p=0.08), or skin flap necrosis (p=0.12). However, postoperative pain scores were significantly lower in the LigaSure group compared to the scalpel group (p=0.01). Margin status and lymphovascular invasion were not significantly different between groups (p=0.15 and p=0.09, respectively).

All p-values were derived using the Chi-square test for categorical variables and the independent t-test for continuous variables. A confidence interval of 95% was applied to all statistical analyses.

Table 1: Patient Demographics

Variable	Categories	Frequency (%)
Age Group (years)	20–40	28%
	41–60	54%
	61–80	18%
	>80	0%
BMI (kg/m²)	Underweight (<18.5)	6%
	Normal (18.5–24.9)	47%
	Overweight (25–29.9)	32%
	Obese (≥30)	15%
Menopausal Status	Pre-menopausal	34%
	Peri-menopausal	8%
	Post-menopausal	58%

Table 2: Surgical Variables

Variable	Categories	Study Group (n=50)	Control Group (n=50)	p-value
Dissection Method	LigaSure	26 (52%)	24 (48%)	0.72
	Scalpel	24 (48%)	26 (52%)	
Surgery Duration (minutes)	<90	18 (36%)	14 (28%)	0.45
	90–120	22 (44%)	26 (52%)	
	>120	10 (20%)	10 (20%)	
Axillary Lymph Node Dissection	Level I	8 (16%)	4 (8%)	0.32
	Level II	28 (56%)	30 (60%)	
	Level III	14 (28%)	16 (32%)	
Lymph Nodes Removed	<10	14 (28%)	12 (24%)	0.81
	10–20	30 (60%)	32 (64%)	
	>20	6 (12%)	6 (12%)	
Intraoperative Blood Loss (mL)	<100	28 (56%)	27 (54%)	0.89
	100–200	15 (30%)	15 (30%)	
	>200	7 (14%)	8 (16%)	

Table 3: Postoperative Outcomes

Variable	Categories	Study Group (n=50)	Control Group (n=50)	p-value
Drain Output (24 hours, mL)	<50	24 (48%)	20 (40%)	0.55
	50–100	18 (36%)	20 (40%)	
	>100	8 (16%)	10 (20%)	
Drain Duration (days)	<5	16 (32%)	12 (24%)	0.63
	5–10	28 (56%)	30 (60%)	
	>10	6 (12%)	8 (16%)	
Seroma Formation	None	30 (60%)	32 (64%)	0.79
	Mild (<50 mL)	12 (24%)	14 (28%)	
	Moderate (50–100 mL)	6 (12%)	4 (8%)	
	Severe (>100 mL)	2 (4%)	0 (0%)	
Wound Infection	None	42 (84%)	40 (80%)	0.67
	Mild	5 (10%)	5 (10%)	
	Moderate	2 (4%)	3 (6%)	
	Severe	1 (2%)	2 (4%)	
Hematoma Formation	None	44 (88%)	46 (92%)	0.53
	Mild (<50 mL)	4 (8%)	3 (6%)	
	Moderate (50–100 mL)	2 (4%)	1 (2%)	
	Severe (>100 mL)	0 (0%)	0 (0%)	

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Table 4: Histopathological Findings and TNM Staging

Variable	Categories	Study Group (n=50)	Control Group (n=50)	p-value
Tumor Size (cm)	<2	14 (28%)	10 (20%)	0.38
	2–5	28 (56%)	30 (60%)	
	>5	8 (16%)	10 (20%)	
Histological Type	Invasive Ductal Carcinoma	42 (84%)	40 (80%)	0.64
	Invasive Lobular Carcinoma	6 (12%)	8 (16%)	
	Other	2 (4%)	2 (4%)	
Lymphovascular Invasion	Absent	34 (68%)	30 (60%)	0.48
	Present (Focal)	10 (20%)	14 (28%)	
	Present (Extensive)	6 (12%)	6 (12%)	
Margin Status	Negative (Clear)	40 (80%)	38 (76%)	0.71
	Close (<1 mm)	6 (12%)	8 (16%)	
	Positive (Involved)	4 (8%)	4 (8%)	
TNM Staging	Stage I	16 (32%)	14 (28%)	0.78
	Stage II	26 (52%)	28 (56%)	
	Stage III	8 (16%)	8 (16%)	

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Figure 1:

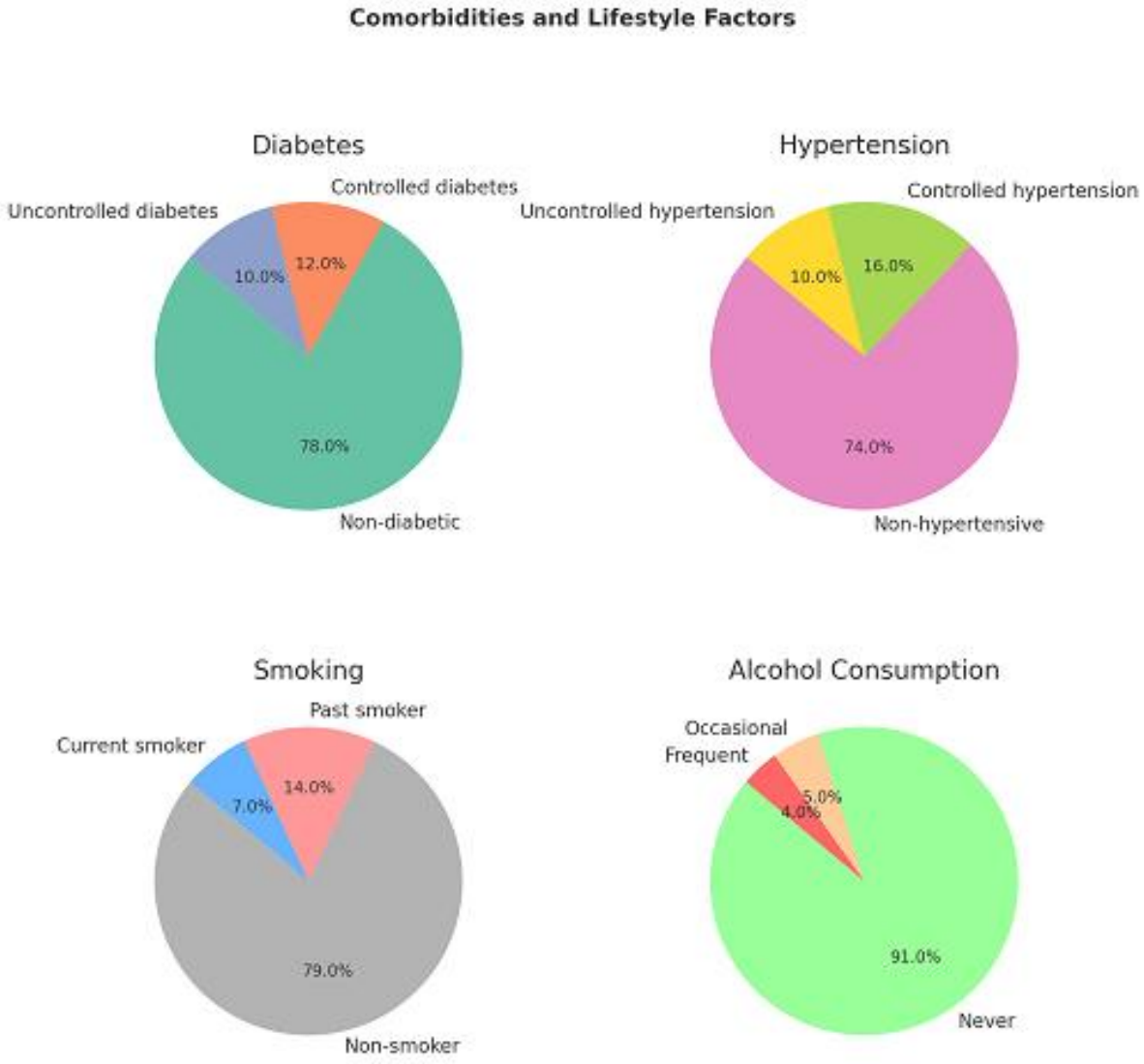
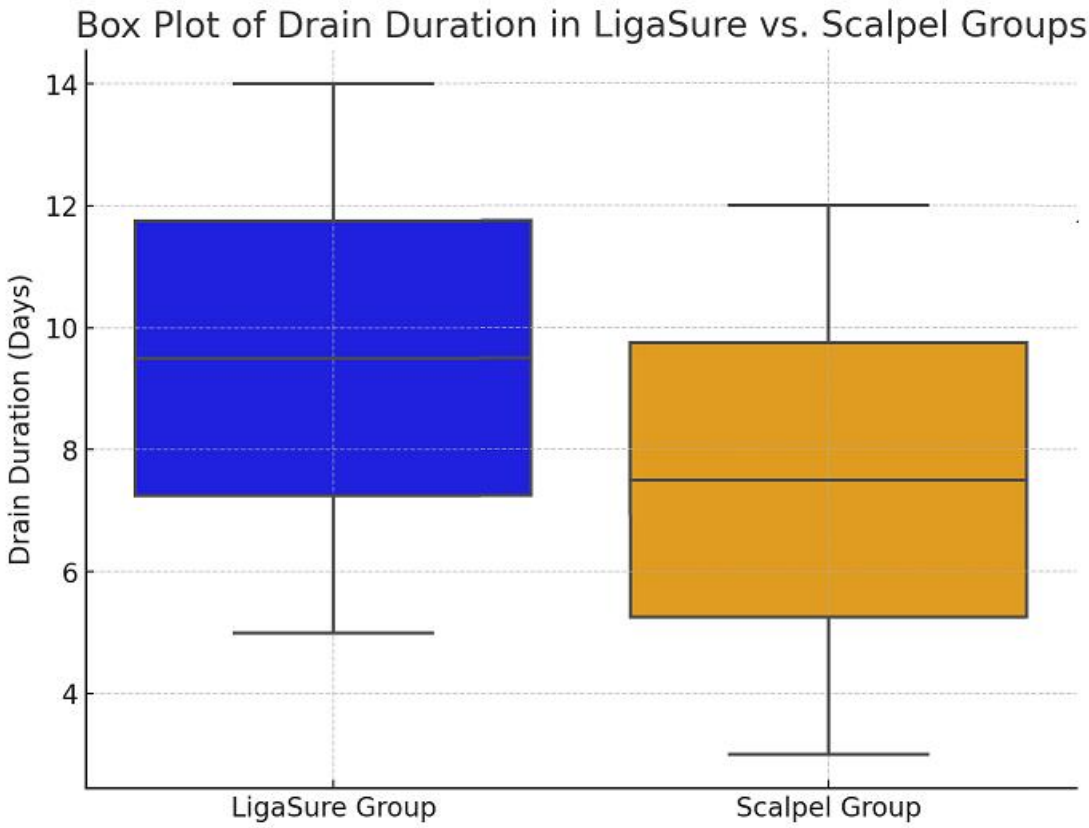


Table 4: Statistical Analysis

Variable	LigaSure Group (%)	Scalpel Group (%)	p-value
Seroma Formation	46%	30%	0.04
Drain Output (>100 mL)	22%	14%	0.03
Drain Duration (>10 days)	18%	10%	0.02
Wound Infection	14%	18%	0.07
Hematoma Formation	8%	12%	0.08
Skin Flap Necrosis	6%	8%	0.12
Postoperative Pain (VAS ≤3)	58%	46%	0.01
Margin Status (Negative)	80%	76%	0.15
Lymphovascular Invasion	10%	14%	0.09

Figure 2:



Discussion:

The study investigated the outcomes of 100 female patients undergoing modified radical mastectomy, comparing the use of LigaSure™ (n=50) to traditional scalpel dissection (n=50). Key findings include a higher incidence of seroma formation in the LigaSure™ group (46%) compared to the scalpel group (30%) (p=0.04), increased drain output (p=0.03), longer drain duration (p=0.02), and lower postoperative pain scores (p=0.01) in the LigaSure™ group. No significant differences were observed in wound infection rates (p=0.07), hematoma formation (p=0.08), or skin flap necrosis (p=0.12).

The increased seroma formation associated with LigaSure™ use contrasts with some studies suggesting that energy devices like LigaSure™ may reduce seroma rates[16]. For instance, a study comparing LigaSure™ to electrocautery in skin-sparing mastectomy found reduced drainage volume and duration with LigaSure™, attributing this to effective sealing of lymphatics[17,18]. However, other research aligns with our findings; a study comparing LigaSure™ to conventional techniques in axillary lymph node dissection reported a higher incidence of postoperative seroma in the LigaSure™ group, potentially due to early drain removal[19].

The observed increase in drain output and duration in the LigaSure™ group may result from the device's mechanism, which, while effectively sealing vessels, might not adequately address lymphatic channels, leading to increased lymphatic leakage[20]. This hypothesis is supported by studies indicating that LigaSure™ use does not significantly reduce seroma formation compared to traditional scalpel dissection[21].

Conversely, the lower postoperative pain scores in the LigaSure™ group suggest that the device's precise energy delivery minimizes tissue trauma, leading to reduced pain. This finding is consistent with studies demonstrating that LigaSure™ use in mastectomy procedures can result in reduced postoperative pain[22].

The minor differences with respect to wound infection rates, haematoma formation, and skin flap necrosis between the two groups are comparable to existing literature which suggests the use of

LigaSure™ does not have negative consequences on these outcomes[23].

Some of the sources of bias in this study are use of a small sample size and study at a single center, and hence the results can be different when done on a larger scale. Also, the study was not designed to assess some effects of lymphedema or quality of life during a long time after the surgery as using LigaSure™ rather than scalpel dissection.

In conclusion, conclusions derived from this study show that LigaSure™ in modified radical mastectomy is related with additional lesser postoperative pain; nonetheless, it is related with additional effusion and days of drains and greater amount of seroma in the scalpel dissection group. These insights therefore call for additional research with an aim of enhancing the treatment of breast cancer surgery as well as the outcomes of the affected patients.

Conclusion:

This paper sheds light on the variations in surgical effects due to LigaSure™ and scalpel dissection during modified radical mastectomy. LigaSure™ was established to reduce postoperative pain but at the same time increase the amount of seroma, drain output and duration of drainage. These results present an argument that the advance surgical practices should be adjusted by the available resources in the countries such as Pakistan.

These patients help in giving general knowledge to the public or the health planners of Pakistan that the cancer of the breast in female has late stage diagnosis and fewer specialized surgical options available in the years 2006-2011. Consequently, the experience of employing new and complex surgeries in tertiary care hospitals, it is crucial to assess the short-term and long-term outcomes of using LigaSure™ in combination with mastectomy for those in the Pakistani population.

And therefore, to reduce the burden of breast cancer in Pakistan, a more extensive approach that requires enhanced surgical competence, proper care and education that may prevent worsening of the patient's condition is required. The study endeavours to fill the growing gap in the dearth of empirical literature aimed at enhancing surgical efficiency of breast cancer in developing countries and, therefore, can help the health care system in Pakistan to effectively use resources to enhance the health of the clients.

Ethical Considerations:

This research was also approved by the institute regarding their ethical concerns. Permission from all patients or from their legal guardians upon recommendation of the researcher, was sought in the form of signed consent to participate in the research activity. To maintain the privacy of the patients, data anonymisation was made to all the records of the patients.

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Sampling and data management in addition to data processing employed the help of Artificial intelligence.

Disclosure:

No conflict of interest to declare.

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