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A Prospective Randomized Study to Compare Postoperative Drainage After Mastectomy Using Electrosurgical Bipolar Systems and Conventional Electro-Cautery

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ABSTRACT

Purpose: Advanced energy devices, including electrosurgical bipolar systems or ultrasonic shears, are widely used in various surgeries. An electrosurgical bipolar device allows surgeons to grasp and dissect tissues, as well as simultaneously ligate and cut vessels and lymphatics during surgery. This study aimed to evaluate the effects of advanced bipolar energy devices on the reduction in seroma formation during mastectomy, axillary staging, and/or reconstruction.
Methods: This prospective randomized clinical trial with a 1:1 ratio compared the use of an electrosurgical bipolar device, LigaSure™ (LGS), against conventional cut-and-ligate techniques in mastectomy with axillary procedures for patients with breast cancer. A total of 82 patients with breast cancer who underwent definitive surgery were enrolled in this study. The primary endpoint was the total drainage volume after surgery.
Results: The clinicopathological characteristics of the two groups were not significantly different. The total postoperative drainage volume was significantly lower in the LGS group than in the control group (756.26 mL vs. 1,167.74 mL, $p = 0.009$). The actual postoperative drainage volume and duration also decreased significantly in the LGS group compared with those in the control group (all $p < 0.05$). The rate of postoperative complications was lower in the LGS group than in the control group (9.8% vs. 27.5%, $p = 0.05$).
Conclusion: Electrosurgical bipolar devices showed better performance in terms of decreasing postoperative drainage during mastectomy and axillary staging and/or reconstruction.

Keywords: Breast Neoplasms; Postoperative Complications; Seroma; Surgical Procedures, Operative

INTRODUCTION

Lymphorrhea and seroma formation are the most common complications of mastectomy in breast cancer [1-3]. Seroma formation increases the length of hospital stay, follow-

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up duration, and postoperative discomfort [2,4]. Furthermore, repeated aspiration of seromas increases the risk of readmission due to wound infection. Seroma formation after mastectomy occurs in 11%–85% of cases [2-4]. According to previous studies, known risk factors include old age (> 60 years), high body mass index (BMI), tumor size, use of preoperative chemotherapy, extent of surgery, and number of retrieved lymph nodes [2,3,5-7]. Meticulous hemostasis and lymphatic ligation techniques are necessary to reduce postoperative complications such as seroma formation [2,3,7,8].

Procedures that utilize new advanced energy devices, such as electrosurgical bipolar systems, have been introduced in clinical practice [2,7-9]. Electrosurgical bipolar devices use the body's own collagen and elastin to create a permanent fusion zone through a pressure-energy combination [2,4,10]. Previous studies have suggested that the use of these devices during surgery leads to a significant decrease in seroma formation; however, their advantages have not been well established in cases of mastectomy for breast cancer [2,4,5,7]. Several studies have also shown that these advanced energy devices can reduce operative time and postoperative management costs compared to the conventional clamp-and-tie technique used in non-breast surgeries [11-14].

The use of electrosurgical bipolar devices during mastectomy can provide potential benefits regarding vessel and lymphatic ligation [2,8,10]. Conventional ligation and monopolar cauterization techniques have disadvantages, including incomplete ligation and thermal injury [10,15,16]. Meanwhile, electrosurgical bipolar devices can simultaneously provide a combination of pressure and energy to minimize thermal injury and create a permanent fusion zone [2,3,10,16].

This prospective study is a superiority trial to evaluate whether the use of bipolar energy devices for mastectomy and axillary staging and/or reconstruction could provide clinical benefits in terms of reducing seroma formation compared to conventional ligation techniques.

METHODS

Study design
Figure 1 shows the scheme used in this prospective randomized clinical trial. A total of 82 patients aged > 20 years with early breast cancer who planned to undergo breast surgery and axillary staging with or without reconstruction were recruited. These patients were randomly assigned in a 1:1 ratio to undergo surgery using either an electrosurgical bipolar device, LigaSure™ Maryland Jaw type (LGS) (Medtronic [formerly Covidien], Minneapolis, USA), or conventional suture and ligation techniques. Patients who underwent partial/total mastectomy with level I and II axillary dissection and skin/nipple-sparing mastectomy, followed by immediate reconstruction, were included. Patients who underwent partial mastectomy with sentinel lymph node biopsy and those who underwent total mastectomy with sentinel lymph node biopsy without reconstruction were excluded.

A sealed randomization envelope was opened immediately before the operation. The study personnel were unaware of the assignments of the study groups until the intraoperative randomization was conducted. In the study group, the surgeon used an electrosurgical bipolar device as much as possible during tissue dissection and vessel ligation (**Supplementary Video 1**). The surgeon did not use an electrosurgical bipolar device for
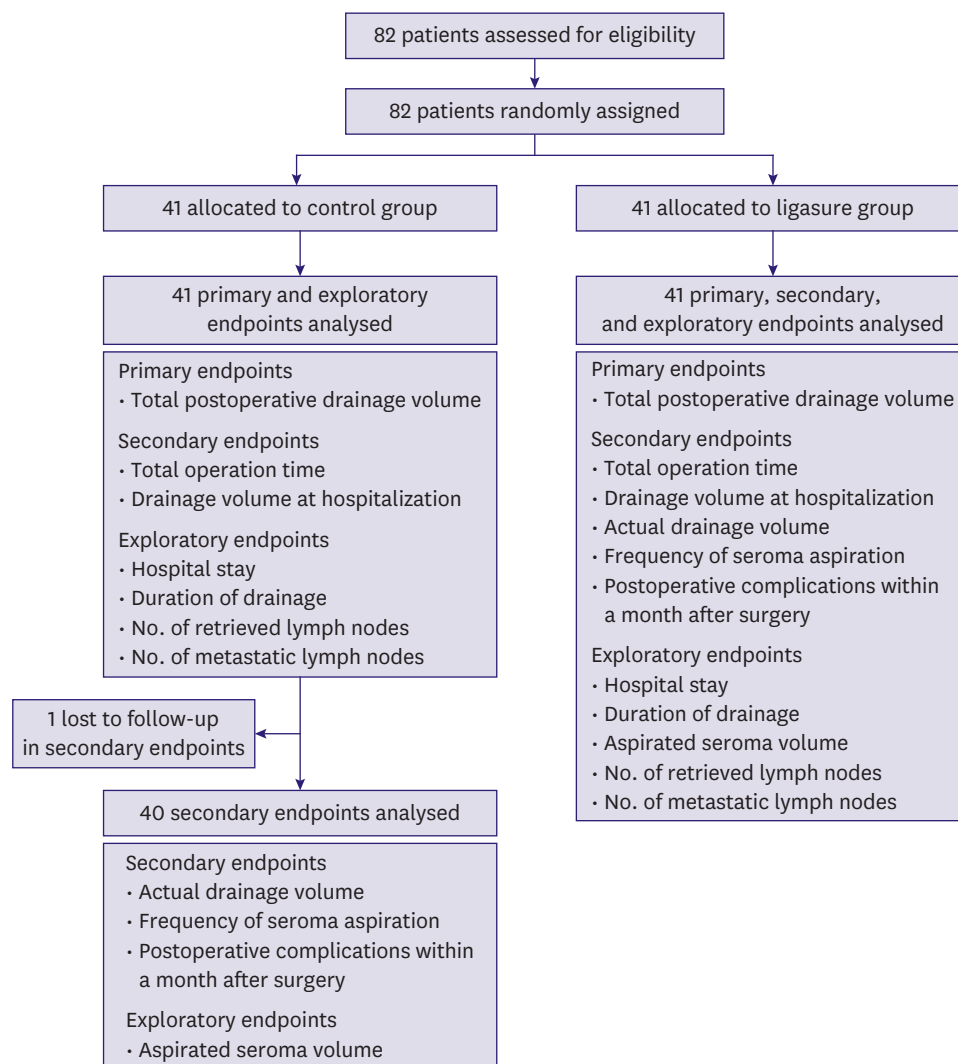
Figure 1. Study diagram according to the CONSORT statement.

the patients in the control group and only used conventional electrocauterization, tie, and ligation techniques during tissue dissection and vessel ligation.

Sample size calculation

In the institutional survey, the average drainage volume after mastectomy was 800 mL (standard deviation = 500 mL). Because this was similar to the average drainage volume reported in a previous study [2], we defined 800 mL as the control for drainage measurements. A sample size of 41 subjects per study arm was planned to provide 85% power to detect a 40% reduction in total volume, according to the results of a previous randomized controlled trial [3]. The sample size was calculated using G*Power 3.1.9.2 [17].

Clinicopathological characteristics

Patient characteristics such as age, BMI, menopausal status, comorbidities, operation type, and treatment methods were reviewed. Preoperative imaging evaluations, including mammography, ultrasonography, and magnetic resonance imaging, were performed. The initial reports of preoperative imaging studies were reviewed and correlated with the final pathology.

The final pathological records were reviewed to analyze histopathological variables, including tumor size, nodal status, grade, and estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor (HER) 2/neu expression. Hormone receptors and HER2/neu were evaluated based on formalin-fixed, paraffin-embedded whole sections of surgically resected breast specimens using immunohistochemistry (IHC). The cutoff value for ER and PR positivity was > 1% for IHC staining. HER2/neu 3+ positivity on IHC was defined as HER2/neu overexpression. When HER2/neu 2+ was observed by IHC, fluorescence in situ hybridization or silver in situ hybridization was performed to analyze HER2/neu overexpression.

Endpoints
The primary endpoint of the study was the total postoperative drainage volume. Secondary endpoints were total operation time, actual drainage volume, drainage volume in the hospital, frequency of seroma aspiration, and postoperative complication rates within 1 month after surgery. The exploratory endpoints were hospital stay, duration of drainage, aspirated seroma volume, and the number of retrieved and metastatic lymph nodes. Nurses routinely checked the daily drainage volume during the in-hospital stay. The patients were educated on how to check for drainage once discharged daily. If the daily drainage volume decreased to < 50 cc, the drains were removed by surgeons during the next visit to the outpatient clinic, as is the usual practice. Postoperative complications were evaluated on postoperative day 30. For patients who did not undergo follow-up within 30 postoperative days after drain removal, endpoints, such as total postoperative drainage volume, duration of drainage, total operation time, drainage volume at hospitalization, and hospital stay, were included in the analysis. However, secondary endpoints, including actual drainage volume, aspirated seroma volume, and postoperative complications within a month after surgery, were not included (**Figure 1**).

The total drainage volume was defined as the sum of the daily drainage volume (SDDV) before the removal of the drains or at time points when the daily drainage volume was < 50 cc. The actual drainage volume was defined as the sum of the SDDV before drain removal and the aspirated seroma volume after drain removal. Seroma aspiration was stopped when the aspirated volume was found to be < 10 mL/day. Postoperative complications included lymphorrhea, seroma formation, wound infection, and wound dehiscence, as defined in a previous study [3].

Statistical analysis
Categorical variables were analyzed using the chi-square test or Fisher's exact test, as indicated. Continuous variables were analyzed using Student's *t*-test. Kaplan–Meier and log-rank analyses were used to analyze the drainage removal time. The Cox proportional hazard model was used to determine the factors associated with drainage removal time. We defined drain removal as both the procedure and time of removal after surgery, as time periods in the Kaplan–Meier and log-rank tests.

P-values < 0.05 were considered significant; all tests were two-sided. Statistical analyses were performed using commercially available statistical software SPSS Statistics 25 (IBM Corp., Armonk, USA) and R (version 3.0.0; R Foundation for Statistical Computing, Vienna, Austria).

Ethics

All procedures performed in this study involving human participants were following the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its subsequent amendments or comparable ethical standards. Informed consent was obtained from all participants.

Written informed consent was obtained from all patients before randomization. This study was approved by the Institutional Review Board of Severance Hospital, Yonsei University Health System (1-2017-0002). The clinicaltrials.gov identifier and study title are NCT03166384 and "A Prospective Randomized Study Comparing Surgery Using Electrosurgical Bipolar Sealing Devices and Surgery Using Conventional Electro-cautery (ELBCE)," respectively.

RESULTS

The clinicopathological characteristics of the patients are described in **Table 1**. The mean age of the patients was 50.15 ± 13.90 years in the LGS group and 52.46 ± 12.95 years in the control group. The clinicopathological characteristics of the patients were not significantly different between the two groups (**Table 1**). Node-positive disease was observed in >50% of the study population (53.7% in the control group and 61.0% in the LGS group, $p = 0.50$). The types of reconstruction were not significantly different between the two groups (13 tissue expanders and one direct-to-implant in the control group vs. nine tissue expanders and one direct-to-implant in the LGS group, $p = 0.61$).

The primary, secondary, and exploratory endpoints of this study are listed in **Table 2**. The total operative time was not significantly different between the two groups. The mean operation time was 120.59 ± 43.17 minutes in the LGS group and 106.71 ± 32.66 minutes in the control group ($p = 0.11$). There were no significant differences in the length of hospital stay between the two groups ($p = 0.93$). The total postoperative drainage volume was significantly smaller in the LGS group than in the control group, with a mean difference of 411.48 cc (the mean total postoperative drainage volume in the LGS group was 756.26 cc vs. 1,167.74 cc in the control group, $p = 0.009$). Furthermore, the actual postoperative drainage volume was significantly smaller in the LGS group than in the control group ($p = 0.009$). Five patients in each group underwent seroma aspiration. Almost all patients underwent seroma aspiration less than six times. Only one patient in the control group underwent seroma aspiration 15 times (**Table 2**).

The mean aspirated seroma volume after drainage removal was 13.29 ± 58.88 cc in the LGS group and 35.58 ± 139.81 cc in the control group; however, the difference was not statistically significant ($p = 0.36$). The number of retrieved and metastatic lymph nodes was not statistically different between the two groups (all $p > 0.05$). The forest plot of clinical outcomes, including actual and total drainage volumes and duration of drainage, showed significantly favorable results in the LGS group compared to the control group (**Figure 2**).

The mean duration of drainage was significantly shorter in the LGS group than in the control group (13.85 ± 4.45 days for the LGS group vs. 17.05 ± 5.96 days for the control group, $p = 0.007$, Student's t-test). **Figure 3** illustrates the curves of the duration of drainage between the two groups using the Kaplan–Meier method. A log-rank test showed that the drains were removed significantly earlier in the LGS group than in the control group ($p = 0.007$).

Table 1. Clinicopathologic characteristics of the study population

Variables	Control (n = 41)	Ligasure (n = 41)	*p*-value*
Age (yr)	52.46 ± 12.95	50.15 ± 13.90	0.44†
BMI (kg/m²)	23.44 ± 3.84	23.59 ± 4.03	0.86†
Menopause			0.17
Pre-menopause	22 (53.7)	28 (68.3)	
Post-menopause	19 (46.3)	13 (31.7)	
Comorbidity			0.82
Yes	15 (36.6)	13 (31.7)	
No	26 (63.4)	28 (68.3)	
Laterality			0.66
Left	23 (56.1)	20 (48.8)	
Right	18 (43.9)	21 (51.2)	
Operation			0.41
PM+ALND	18 (43.9)	17 (41.5)	
MRM	9 (22.0)	14 (34.1)	
TM+Reconstruction	14 (34.1)	10 (24.4)	
Reconstruction			0.61
No	27 (65.9)	31 (75.6)	
Tissue expander	13 (31.7)	9 (22.0)	
Direct-to-implant	1 (2.4)	1 (2.4)	
T			0.48
≤ T1	26 (63.4)	29 (70.7)	
> T1	15 (36.6)	12 (29.3)	
N			0.50
N0	19 (46.3)	16 (39.0)	
N1–N3	22 (53.7)	25 (61.0)	
M			> 0.99
M0	41 (50.6)	40 (49.4)	
M1	0 (0.0)	1 (2.4)	
TNM stage			0.43
0	3 (7.3)	2 (4.9)	
I	13 (31.7)	14 (34.1)	
II	19 (46.3)	13 (31.7)	
III	6 (14.6)	11 (26.8)	
IV	0 (0.0)	1 (2.4)	
Histologic grade			0.94
Grade I	9 (22.0)	10 (24.4)	
Grade II	24 (58.5)	23 (56.1)	
Grade III	8 (19.5)	7 (17.1)	
Unknown	0 (0.0)	1 (2.4)	
ER			0.79
Positive	32 (78.0)	33 (80.5)	
Negative	9 (22.0)	8 (19.5)	
PR			0.82
Positive	24 (58.5)	25 (61.0)	
Negative	17 (41.5)	16 (39.0)	
HER2			0.78
Positive	8 (19.5)	7 (17.1)	
Negative	33 (80.5)	34 (82.9)	
Radiotherapy‡			0.30
Yes	26 (65.0)	31 (75.6)	
No	14 (35.0)	10 (24.4)	
Chemotherapy‡			0.25
Yes	9 (22.5)	14 (34.1)	
No	31 (77.5)	27 (65.9)	
Target therapy‡			0.34
Yes	8 (20.0)	5 (12.2)	
No	32 (80.0)	36 (87.8)	

Table 1. (Continued) Clinicopathologic characteristics of the study population

Variables	Control (n = 41)	Ligasure (n = 41)	p-value*
Hormone therapy‡			0.40
Yes	29 (72.5)	33 (80.5)	
No	11 (27.5)	8 (19.5)	
Recurrence‡			-
Yes	0 (0)	0 (0)	
No	40 (100)	41 (100)	

Values are represented as mean ± standard deviation or number (%).
BMI = body mass index; PM = partial mastectomy; ALND = axillary lymph node dissection; MRM = modified radical mastectomy; TM = total mastectomy; ER = estrogen receptor; PR = progesterone receptor; HER = human epidermal growth factor receptor.
*Chi-square test or Fisher's exact test, except †Student's t-test; ‡One patient in the control group who was not followed up after drain removal within postoperative 30 days was not included (n = 40).

Table 2. Clinical results of the Ligasure and control groups

Variables	Control (n = 41)	Ligasure (n = 41)	p-value*
Total operation time (min)	106.71 ± 32.66	120.59 ± 43.17	0.11
Hospital stay (day)	5.37 ± 3.86	5.29 ± 4.03	0.93
Duration of drainage (day)	17.05 ± 5.96	13.85 ± 4.45	0.01
Total postoperative drainage volume (mL)	1,167.74 ± 834.95	756.26 ± 499.89	0.01
Actual postoperative drainage volume (mL)‡	1,362.85 ± 966.29	897.73 ± 531.77	0.01
Drainage volume at hospitalization (mL)	535.87 ± 502.16	481.58 ± 450.72	0.61
Total aspiration volume (mL)‡	35.58 ± 139.81	13.29 ± 58.88	0.36
Seroma aspiration frequency‡			> 0.99†
0	35 (87.5)	36 (87.8)	
1–5	4 (10.0)	5 (12.2)	
> 5	1 (2.5)	0 (0)	
Retrieved lymph nodes	12 (2–31)	13 (3–27)	0.45†
Metastatic lymph nodes	1 (0–23)	2 (0–24)	0.54†
Complications‡			0.05†
Yes	11 (27.5)	4 (9.8)	
No	29 (72.5)	37 (90.2)	

Values are represented as mean ± standard deviation or number (%).
*Student's t-test, except for †Fisher's exact test; ‡One patient in the control group who did not attend follow-up after drain removal within 30 postoperative days was not included (n = 40).

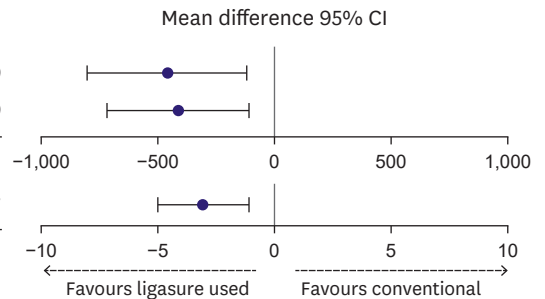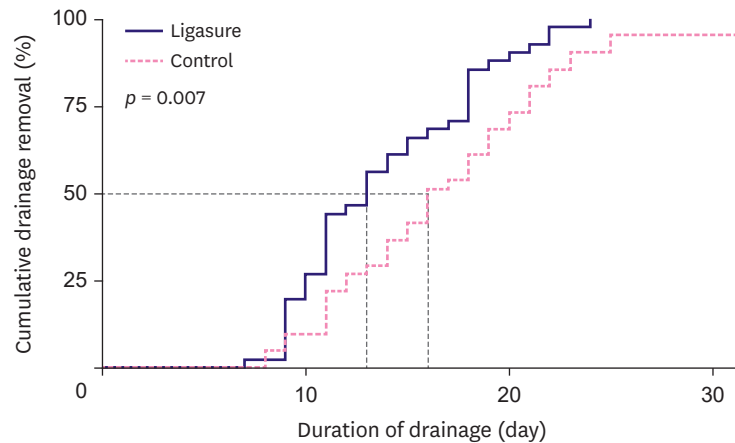| Variable	Ligasure (n = 41) mean (SD)	Conventional method (n = 41) mean (SD)	Mean difference 95% CI	p-value
Drain (cc)				
Actual drainage volume*	897.7 (531.8)	1,362.9 (966.3)	−456.2 (−799.9, −117.5)	0.009
Total drainage volume	756.3 (499.9)	1,167.7 (834.9)	−411.4 (−715, −108)	0.009
Duration of drainage (day)	13.9 (4.5)	17.1 (5.9)	−3.2 (−5.5, −0.88)	0.007

Figure 2. Forest plot of clinical outcomes between the LigaSure and control groups.
SD = standard deviation; CI = confidence interval.
*One patient in the control group who did not attend follow-up after drain removal within 30 postoperative days was excluded (n = 40).

In multivariate analyses adjusted for factors associated with drainage removal, the use of LGS was significantly associated with earlier drainage removal (**Supplementary Table 1**, p = 0.028). Furthermore, **Figure 4** shows that the use of LGS was favorable for early drainage removal with a range of 95% confidence intervals.

Figure 3. The curves of cumulative drainage removal in the LigaSure and control groups.

No. at risk						
Ligasure	41	33	16	5	0	0
Control	41	37	26	13	4	2

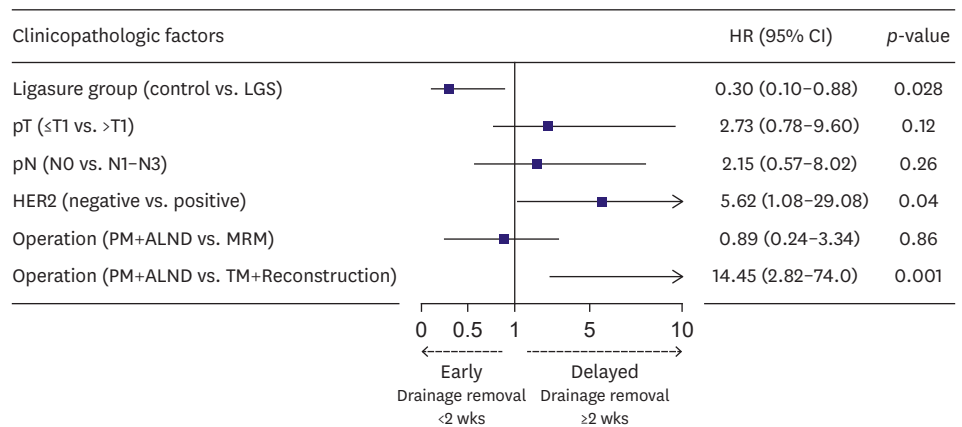| Clinicopathologic factors	HR (95% CI)	p-value
Ligasure group (control vs. LGS)	0.30 (0.10–0.88)	0.028
pT (≤T1 vs. >T1)	2.73 (0.78–9.60)	0.12
pN (N0 vs. N1–N3)	2.15 (0.57–8.02)	0.26
HER2 (negative vs. positive)	5.62 (1.08–29.08)	0.04
Operation (PM+ALND vs. MRM)	0.89 (0.24–3.34)	0.86
Operation (PM+ALND vs. TM+Reconstruction)	14.45 (2.82–74.0)	0.001

Figure 4. Forest plot of multivariate analyses for associated factors in drainage removal by logistic regression analysis.
HR = hazard ratio; CI = confidence interval; HER = human epidermal growth factor receptor; PM = partial mastectomy; ALND = axillary lymph node dissection; MRM = modified radical mastectomy; TM = total mastectomy.

DISCUSSION

In the current study, the use of LGS in breast surgery had significant advantages in reducing drainage volume and duration. Previous studies have suggested that electrosurgical bipolar devices shorten the duration of drainage after axillary lymph node dissection compared to conventional methods [2-4]. Other studies reported the benefits of electrosurgical bipolar devices for breast surgery in reducing blood loss, drainage volume, and length of hospital stay [4,10,18]. Furthermore, a recent study reported that skin-sparing mastectomy with electrosurgical bipolar devices could be performed in patients with breast cancer [10,19]. These findings are consistent with those of the present study. These advantages of LGS might be caused by adequate and permanent sealing of the lymphatics by electrothermal energy and mechanical pressure with minimal unintended injury to the surrounding tissues [3,10].

However, some studies have reported no benefit of drainage volume with the use of advanced energy devices in breast surgery [3,20,21]. The difference between current and previous studies may be due to heterogeneous designs, different techniques, or devices that may influence the amount of drained fluid [3,20,21]. However, previous studies showed statistically better surgical parameters such as shorter duration of drainage, smaller aspirated seroma volume, and shorter operation time in the LGS group. These advantages of advanced energy devices are similar to those of our study.

This study included patients who underwent a mastectomy and immediate breast reconstruction. Almost all patients who underwent immediate breast reconstruction underwent nipple-sparing mastectomy or skin-sparing mastectomy. The use of LGS during nipple-sparing mastectomy or skin-sparing mastectomy can be beneficial in reducing drainage volume and in efficient dissection of the medial area of the breast parenchyma, which is usually difficult to approach using radial or infra-mammary fold incisions. The current study did not analyze the technical ease of using LGS during nipple-spring mastectomy or skin-sparing mastectomy. A previous study reported that advanced energy devices can facilitate dissection during nipple-sparing mastectomy [10]. When performing minimally invasive breast surgery, especially in nipple/skin-sparing mastectomy, the use of advanced energy devices with long, adjustable shafts could be beneficial when approaching the whole breast and armpit and may also reduce the surgeon's workload, which is another potential advantage of using LGS in breast surgery and needs to be validated in further studies.

Effective tissue dissection and vessel ligation may shorten hospital stay and reduce postoperative complications. In this study, the use of LGS during breast surgery did not affect the operation time or length of hospital stay. However, the use of LGS in breast surgery has reduced postoperative complications compared with conventional methods. Lymphorrhea and seroma formation after drainage removal were more common and severe in the control group than in the LGS group. This suggests that the use of LGS allows effective ligation of the patient's lymphatics and reduces tissue damage that may influence lymphorrhea or seroma formation compared to conventional cut-and-ligate or monopolar electrocauterization techniques.

In conclusion, this study showed that the use of LGS in breast surgery resulted in better surgical outcomes, particularly in the reduction of the postoperative drainage volume and duration. LGS is highly recommended for breast surgery with axillary staging.

SUPPLEMENTARY MATERIALS

Supplementary Table 1
Multivariate analyses of associated factors for drainage removal by Logistic regression analysis

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Supplementary Video 1
This breast surgical video, which includes sentinel lymph node biopsy, ligation of vessels and lymphatics, and dissection of the skin flap, shows how to use LigaSure during procedures effectively.

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