Reduction of seroma by pectoralis fascia dissection using an energy device in total mastectomy for breast cancer: An observational study

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Abstract. Seroma formation is one of the unresolved complications of breast cancer surgery. The use of energy devices (EDs) can improve breast cancer surgery outcomes. Dissection of the pectoralis fascia is an important process in total mastectomy, which involves a wide area of the posterior wall of the mammary glands. The current study investigated whether using EDs for this process could lead to a reduction in seroma formation or potentially reduce other complications. In the present observational study, the use of an ED for pectoralis fascia dissection was compared with conventional electrocautery. The main outcomes were the total amount of drainage (total AD), amount of drainage per day and adverse events (AEs) after propensity score matching (PSM). in addition, a univariate analysis of AE occurrence was performed. Overall, 41 and 117 patients were included in the ED and control groups, respectively. PSM was performed for three covariates: Presence or absence of axillary dissection, preoperative chemotherapy and body mass index >25 kg/m^2. Compared with those in the control group, the total AD post-PSM in the ED group did not decrease (P=0.1778), whereas the amount of drainage per day was markedly decreased on postoperative day 8 in the ED group. In the univariate analysis, only the use of ED was associated with a reduction in AEs requiring intervention; other factors showed no significant association. The frequency of AEs requiring intervention was significantly lower in the ED group than that in the control group post-PSM (P=0.0372). Notably, seroma accounted for most AEs. The results of the present study suggested that pectoralis fascia dissection using an ED may reduce fluid drainage and the incidence of AEs. This simple modification suggests the possibility of improving surgical techniques and is expected to contribute to favorable surgical outcomes.

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Key words: total mastectomy, pectoralis fascia dissection, energy device, seroma, surgical site infection, drainage

Introduction

Recently, breast cancer incidence has increased and total mastectomy was common surgical method for breast cancer patients (1). In total mastectomy, it is generally common to place drains. Although early drain removal can reduce the length of hospital stay, a meta-analysis pointed out that the frequency of adverse events (AE) such as seroma increases due to the early removal of drains (2). The meta-analysis indicates that AE increase when the drain is removed early, in practice, each facility decides on its own criteria for removal. Particularly, removing the drain at 30-50 ml/d is a relatively common criterion in view of the benefits and disadvantages (3-7). However, it is undeniable that we aim for fewer complications and early discharge. Therefore, ensuring a reliable improvement in surgical techniques becomes one of the key factors.

Recent advancements in surgical devices have facilitated the sealing of blood vessels and reduced the burden of the surgeon. In Japan, under the health insurance system, energy devices (EDs) can be employed in axillary dissection. This is based on positive evidence on the use of devices such as the Harmonic Focus® and LigaSure Exact Dissector® (8,9). Using EDs to dissect mammary fat tissue from the pectoralis major muscle during total mastectomy may help reduce surgical complications, including seroma formation. Dissection of the

Figure 1. During a total mastectomy, the pectoralis major fascia is sealed with an energy device to separate the pectoralis major muscle and breast tissue. This process is performed in the area where the pectoralis major muscle is exposed.

pectoralis fascia in total mastectomy involves a wide area of the posterior wall of the mammary gland, which making it likely to benefit from the use of ED. In this study, we aimed to evaluate the amount of drainage and seroma incidence in patients undergoing total mastectomy with pectoralis fascia dissection using EDs.

Materials and methods

Study design. This was a single-center, observational study, with an exposure group comprising 41 consecutive patients with breast cancer who underwent total mastectomy using an ED (Harmonic Focus or LigaSure Exact) to separate breast fat tissue from the pectoralis major muscle between January 1, 2020 and December 31, 2024. It is well known that breast cancer occurs predominantly in women, while cases in men are rare. Therefore, all eligible cases in this study are female. The historical control group comprised 117 consecutive patients who underwent total mastectomy for breast cancer in Sapporo Medical University Hospital (Sapporo, Japan) between January and December 2019, and conventional electrocautery during chest wall dissection. A suction drain (5 mm SB VAC, Sumitomo Bakelite, Tokyo, Japan) was inserted in all cases. The suction drain was removed when the daily drainage volume was approximately <40 ml.

The surgical procedure for total mastectomy is described below. Electrocautery was conventionally used for skin flap dissection in both groups. In both groups, using an ED, axillary dissection was performed from the lateral chest wall to axillary levels I and II. In the exposure group, an ED was used for all pectoralis fascia dissection procedures, separating breast tissue from the pectoralis major muscle, whereas electrocautery was used in the control group (Fig. 1). Four breast specialists with >10 years of experience performed the surgeries.

The study outcomes were as follows: primary outcome, total amount until drain removal; secondary outcomes, daily drainage fluid output [postoperative days (POD) 1-10], operative time, blood loss, length of hospital stay, and frequency of AEs requiring intervention.

This study adhered to the ethical tenets of The Declaration of Helsinki and the Ethical Principles for Medical Research Involving Human Subjects. It was approved by the Clinical Trial Center of Sapporo Medical University (approval number 352-93), and registered with UMIN-CTR (UMIN000056764). The need for informed consent was waived owing to the observational nature of this study. An opt-out consent process was used, with disclosures made on the university website (https://web.sapmed.ac.jp/byoin/rinshokenkyu/koukai/).

Statistical analysis. Statistical analyses were performed using JMP17 (SAS Institute Inc., Cary, NC, USA). The unpaired Student's t-test was used to compare the total amount of drain fluid, daily drainage fluid output (postoperative days 1-10), operative time, blood loss, and length of hospital stay between the ED and control groups. The χ^2 test or Fisher's exact test was used to analyze cT stage (as a sequential variable) and the following nominal variables: cN status (negative or negative), body mass index (BMI; cutoff 25 kg/m^2), prior chemotherapy, subtype, breast surgery procedure (total mastectomy only), axillary surgery procedure [axillary lymph node dissection (ALND) vs. sentinel lymph node biopsy (SLNB)], and reconstructive surgery (presence or absence). $P<0.05$ was considered to indicate a statistically significant difference. Among these clinicopathological factors, BMI, prior chemotherapy, and axillary surgery were treated as covariates, and propensity score matching (PSM) was used to adjust for these three factors. To identify independent factors associated with AEs requiring intervention, a univariate analysis was performed.

Table I. Patient characteristics before and after PSM.

A, Before PSM

Characteristic	Total (%)	ED (%)	Control (%)	P-value
Sample size	158	41	117	-
Age, years				0.5120
<50	48 (30.4)	12 (29.3)	36 (30.8)	
≥50	110 (69.6)	29 (70.7)	81 (69.2)	
BMI, kg/m^2				0.0155
<25	113 (71.5)	23 (56.1)	90 (76.9)	
≥25	45 (28.5)	18 (43.9)	27 (23.1)	
cT				0.6034
0-1	71 (44.9)	17 (41.5)	54 (46.2)	
≥2	87 (55,1)	24 (58.3)	63 (53.8)	
cN				0.1803
0	56 (35.4)	11 (26.8)	45 (38.5)	
≥1	102 (64.5)	30 (73.2)	72 (61.5)	
Neoadjuvant chemotherapy				0.0001
Yes	31 (19.6)	17 (41.5)	14 (12.0)	
No	127 (80.4)	24 (58.5)	103 (88.0)	
Axillary surgery				0.0004
SLNB	105(66.5)	18 (43.9)	87 (74.4)	
ALND	53(33.5)	23 (56.1)	30 (25.6)	
Reconstruction				>0.9999
Yes	8 (5.1)	2 (4.9)	6 (5.1)	
No	150 (94.9)	39 (95.1)	111 (94.9)	
ER/HER2 status				0.1039
ER$^+$/HER2$^-$	93 (58.9)	27 (65.9)	66 (56.4)	
ER$^+$/HER2$^+$	17 (10.7)	5 (12.2)	12 (10.3)	
ER$^-$/HER2$^-$	14 (8.9)	5 (12.2)	9 (7.7)	
ER$^-$/HER2$^+$	22 (13.9)	1 (2.4)	21 (17.9)	
DCIS	12 (7.6)	3 (7.3)	9 (7.7)	
LigaSure Exact Dissector		24 (58.5)		-
Harmonic Focus		17 (41.5)		-

B, After PSM

Characteristics	Total (%)	ED (%)	Control (%)	P-value
Sample size	76	38	38	-
Age, years				0.1687
<50	17 (22.4)	11 (28.9)	6 (15.8)	
≥50	59 (77.6)	27 (71.1)	32 (84.2)	
BMI, kg/m^2				0.8154
<25	45 (59.2)	22 (57.9)	23 (60.5)	
≥25	31 (40.8)	16 (42.1)	15 (39.5)	
cT				0.1536
0-1	28 (36.8)	17 (44.7)	11 (29.0)	
≥2	48 (63.2)	21 (55.3)	27 (71.0)	
cN				0.7975
0	21 (27.6)	11 (28.9)	10 (26.3)	
≥1	55 (72.6)	27 (7.1)	28 (73.3)	

Table I. Continued.

B, After PSM

Characteristic	Total (%)	ED (%)	Control (%)	P-value
Neoadjuvant chemotherapy				0.8106
Yes	27 (35.6)	14 (56.8)	13 (34.2)	
No	49 (63.4)	24 (63.2)	25 (65.8)	
Axillary surgery				0.6445
SLNB	34 (44.7)	18 (47.4)	16 (42.1)	
ALND	42 (55.3)	20 (52.6)	22 (57.9)	
Reconstruction				0.4933
Yes	2 (2.6)	2 (5.3)	0 (0)	
No	74 (97.4)	36 (94.7)	38 (100)	
ER/HER2 status				0.0391
$ER^+/HER2^-$	43 (56.6)	24 (64.3)	19 (50.0)	
$ER^+/HER2^+$	7 (9.2)	5 (13.2)	2 (5.3)	
$ER^-/HER2^-$	10 (13.1)	5 (13.2)	5 (13.1)	
$ER^-/HER2^+$	11 (14.5)	1 (2.6)	10 (26.3)	
DCIS	3 (6.6)	3 (7.6)	2 (5.3)	
LigaSure Exact Dissector		23 (60.5)		-
Harmonic Focus		15 (39.5)		-

PSM, propensity score matching; BMI, body mass index; SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; DCIS, ductal carcinoma in situ.

Results

Adjusting data using propensity score matching. Patient characteristics and history for both groups are listed in Table IA and B. As shown in Table IA, key characteristics included significantly higher BMI in the ED group compared to the control group (P=0.0155), a higher proportion of patients with prior preoperative chemotherapy (P=0.0001), and a greater number of patients who had received ALND (P=0.0004). PSM was performed using three parameters as covariates: BMI, presence or absence of preoperative chemotherapy, and axillary surgery (ALND vs. SLNB). The adjusted patient characteristics and history post-PSM are summarized in Table IB.

Surgical outcomes. As displayed in Table II the mean total amount of drainage was 610 ml in the device group and 812 ml in the control group, indicating a numerical decrease without a statistically significant difference (P=0.1778). No significant delay in operation time was observed with the use of ED post-PSM [ED vs. control (mean ± standard deviation); 105±42 vs. 117±35 min; P=0.1960]. Moreover, no significant difference was observed in the amount of bleeding (20±30 vs. 23±21 ml; P=0.6202), POD of drain removal (7.3±2.7 vs. 7.9±3.3; P=0.3649), and length of hospital stay (11.4±3.3 vs. 11.0±5.6 days; P=0.6737) post-PSM.

ED may reduce adverse events requiring intervention and seroma incidence. The ED group had a significantly lower frequency of AEs requiring intervention than the control group post-PSM [6/38 vs. 14/38 (15.4 vs. 36.8%); P=0.0372; Table II], although no difference was observed between the two groups regarding all AE. Most AEs were caused by seroma, with a smaller proportion attributed to infection. In univariate analysis, the risk of AEs requiring intervention was found to be reduced by the use of ED after PSM, and there were no other confounding factors [OR 0.32, 95% CI (0.10-0.93), P=0.0351; Table III]. Notably, the graph showing the average daily drainage volume from POD 1 to POD 10 revealed a general downward trend in drainage volume in the ED group after PSM. The drainage volume in the ED group was markedly lower on POD 8 post-PSM (Fig. 2A and B).

The postoperative day of drain removal correlates with the length of hospital stay. In this study, the Pearson's correlation coefficient between the drain removal date and length of hospital stay for the 158 cases analyzed was 0.701, indicating a positive correlation between the two [95% CI (0.61-0.77)]. When divided into the ED group (41 cases) and the control group (117 cases), the respective coefficients were 0.609 and 0.724, with 95% CIs (0.62-0.80) and (0.37-0.77). Both showed linear and positive correlations (Fig. 3).

Discussion

This study examined whether incorporating a simple procedure to seal the pectoralis fascia using an ED could reduce the amount of drainage and frequency of seroma formation. This technique is considered straightforward as it involves exposing the pectoralis muscle during fascia resection and sealing the

Table II. Surgical outcome.

A, Surgical outcome (before PSM)

Variable	Total	ED	Control	P-value
Sample size	158	41	117	-
Operation time, min	109±39	104±41	111±39	0.3619
Estimated blood loss, ml	24±28	19±29	26±28	0.1557
Total amount of drainage, ml	570±513	610±398	556±548	0.5137
Post operation day of drain removal, days	6.7±2.3	6.8±2.4	6.7±2.3	0.8390
Duration of hospital stay, days	10.8±3.8	11.3±3.2	10.6±4.0	0.2303
All adverse events incidence, n (%)				0.0957
Presence of adverse events	47 (29.7)	8 (19.5)	39 (33.3)	
Absence of adverse events	111 (70.3)	33 (80.5)	78 (66.7)	
Adverse events requiring intervention, n (%)				0.0675
Presence of adverse events	40 (25.3)	6 (14.6)	34 (29.1)	
Absence of adverse events	118 (74.7)	35 (85.4)	83 (70.9)	

B, Details and breakdown of AEs (before PSM)

Variable	Total	ED	Control	P-value
Sample size	40	6	34	
AEs				>0.9999
Seroma, n (%)	32	6 (100)	26 (76.5)	
Skin necrosis, n (%)	2	0 (0)	2 (5.9)	
Hematoma, n (%)	0	0 (0)	0 (0)	
Surgical site infection, n (%)	1	0 (0)	1 (2.9)	
Seroma + infection, n (%)	4	0 (0)	4 (11.8)	
Hematoma + infection, n (%)	1	0 (0)	1 (2.9)	

C, Surgical outcome (after PSM)

Variable	Total	ED	Control	P-value
Sample size	76	38	38	-
Operation time, min	111±39	105±42	117±35	0.1960
Estimated blood loss, ml	21±26	20±30	23±21	0.6202
Total amount of drainage, ml	650±75	610±407	812±818	0.1778
Post operation day of drain removal, days	7.1±2.4	6.8±2.4	7.5±2.3	0.1599
Duration of hospital stay, days	11.6±4.6	11.4±3.3	11.9±5.6	0.6737
All adverse events incidence, n (%)				0.0805
Presence of adverse events	23 (30.3)	8 (21.1)	15 (39.5)	
Absence of adverse events	53 (69.7)	30 (78.9)	23 (60.5)	
Adverse events requiring intervention, n (%)				0.0372
Presence of adverse events	20 (26.3)	6 (15.8)	14 (36.8)	
Absence of adverse events	56 (73.7)	32 (84.2)	24 (63.2)	

D, Details and breakdown of AEs (after PSM)

	Total (%)	ED (%)	Control (%)	P-value
Sample size	20	6	14	
AEs				>0.9999
Seroma, n (%)	17 (85.0)	6 (100)	11 (78.6)	

Table II. Continued.

D, Details and breakdown of AEs (after PSM)

	Total (%)	ED (%)	Control (%)	P-value
Skin necrosis, n (%)	0 (0)	0 (0)	0 (0)	
Hematoma, n (%)	0 (0)	0 (0)	0 (0)	
Surgical site infection, n (%)	1 (5.0)	0 (0)	1 (7.1)	
Seroma + infection, n (%)	2 (10.0)	0 (0)	2 (14.3)	
Hematoma + infection, n (%)	0 (0)	0 (0)	0 (0)	

Data are presented as mean ± SD unless otherwise indicated. ED, energy device; AE, adverse event; PSM, propensity score matching.

Table III. Univariate analysis for AE requiring interventions.

A, Before PSM

Variable	Factor	OR	95% CI	P-value
Age, years	≥50 vs. <50	2.51	1.07-6.63	0.0335
BMI, kg/m^2	≥25 vs. <25	1.09	0.51-2.29	0.8133
cT	≥2 vs. 0-1	1.14	0.56-2.38	0.7196
cN	≥1 vs. 0	0.89	0.42-1.90	0.7536
Neoadjuvant chemotherapy	Yes vs. no	1.27	0.51-2.97	0.5998
Axillary surgery	ALND vs. SLNB	1.26	0.59-2.65	0.5421
ED/Control	With device vs. without device	0.42	0.15-1.02	0.0570

B, After PSM

Variable	Factor	OR	95% CI	P-value
Age, years	≥50 vs. <50	3.29	0.81-22.28	0.1001
BMI, kg/m^2	≥25 vs. <25	0.96	0.33-2.67	0.9333
cT	≥2 vs. 0-1	1.51	0.52-4.80	0.4554
cN	≥1 vs. 0	1.74	0.54-6.77	0.3633
Neoadjuvant chemotherapy	Yes vs. no	1.72	0.60-4.93	0.3072
Axillary surgery	ALND vs. SLNB	1.73	0.61-5.21	0.3042
ED/Control	With device vs. without device	0.32	0.10-0.93	0.0351

AE, adverse event; PSM, propensity score matching; BMI, body mass index; ALND, axillary lymph node dissection; SLNB, sentinel lymph node biopsy; ED, energy device.

microscopic lymphatic vessels within the fascia. Two types of EDs were used in this study. The first was the LigaSure Exact Dissector (Covidien Japan, Tokyo, Japan), a radiofrequency ablation device that coagulates tissue using Joule heat and separates it with an integrated knife. A randomized controlled study indicated that using this ED could reduce the time until drain removal and amount of drainage (8). The second was Harmonic Focus (Harmonic, Ethicon Inc., Johnson & Johnson, Tokyo, Japan), an ultrasonic coagulation and dissection device that uses friction heat engendered by ultrasonic vibrations of the blade. A meta-analysis reported that its use reduces operating time, bleeding volume, drainage volume, and hospital stay (9). Both devices are covered by health insurance in Japan and are widely used in clinical practice. Furthermore, a recent meta-analysis observed no significant differences in complications between the two EDs (10), confirming their comparability.

The pectoralis major muscle is the largest muscle covering the chest wall (11). In Asians, who are generally smaller than Westerners, the average width of the pectoralis major muscle was 11.6 cm (12). The extent to which the mammary gland tissue is separated from the pectoralis major muscle during total mastectomy depends on the patient's physique; however, it tends to be extensive. Moreover, lymphatic vessels that penetrate the pectoralis fascia are not as major a drainage route as those flowing to the axilla or parasternal region,

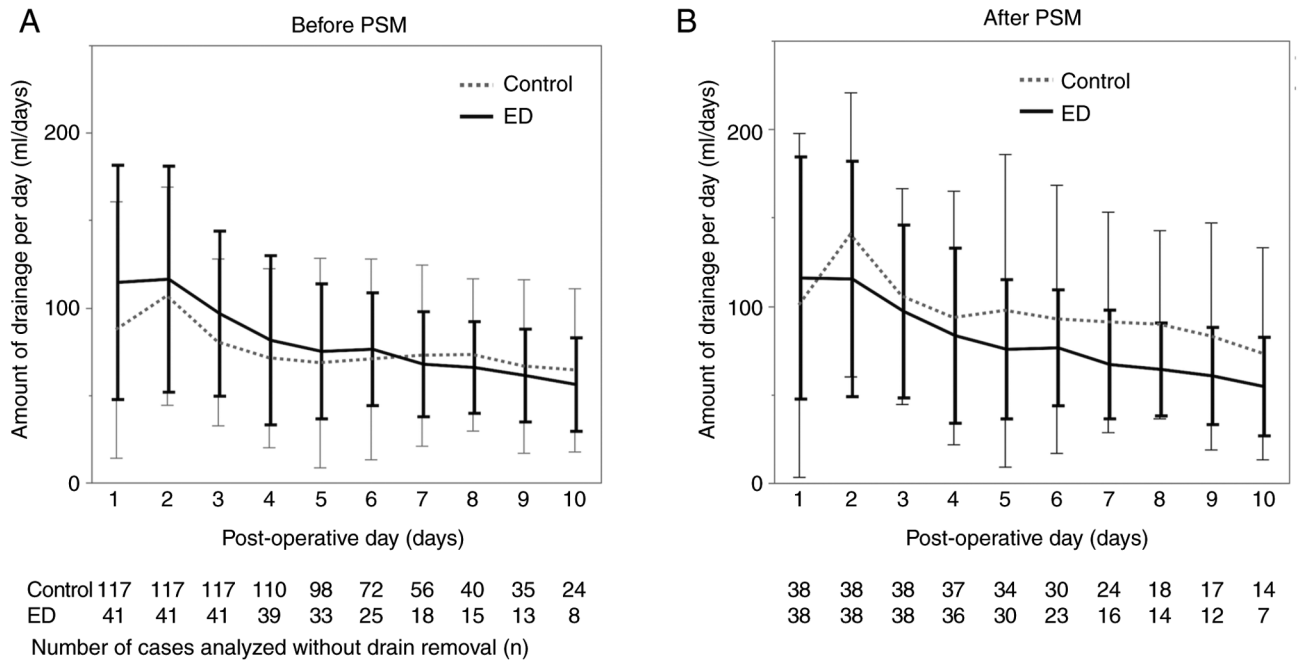

Figure 2. Average amount of drainage per day was assessed from 1 to 10 days after total mastectomy. Error bars are standard deviations. (A) Pre-PSM and (B) post-PSM. ED, energy device; POD, post-operative day; PSM, propensity score matching.

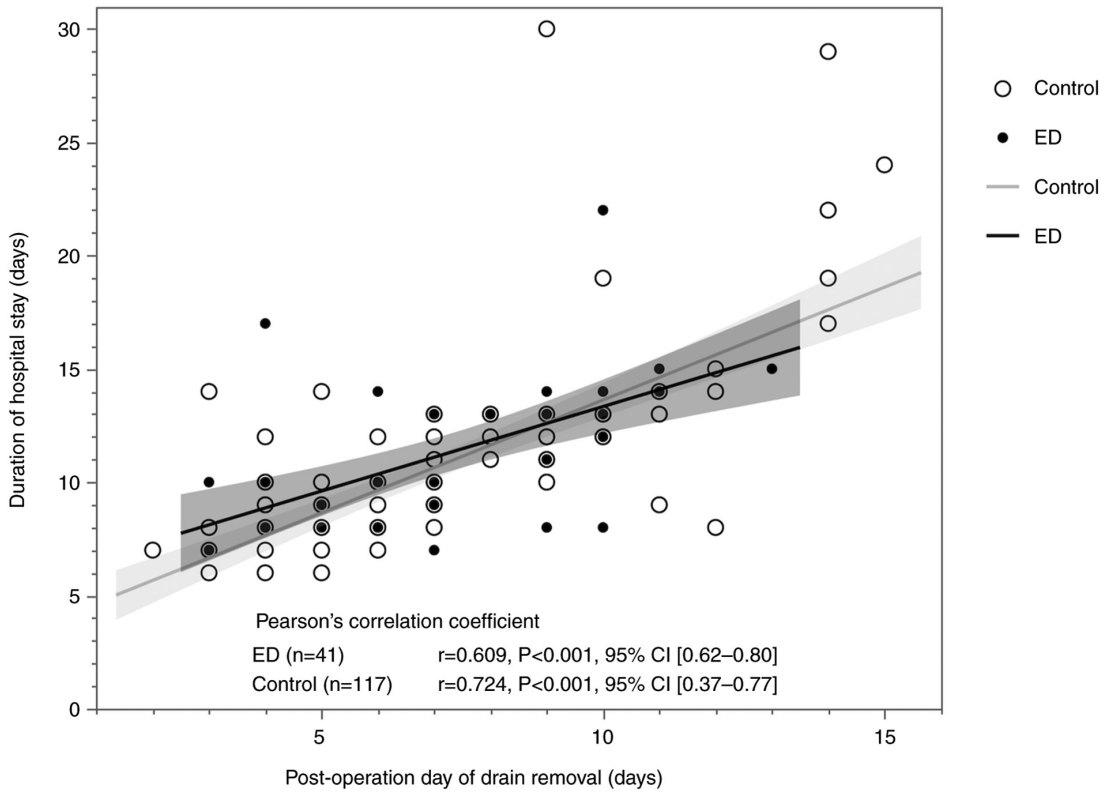

Figure 3, Plots indicate the correlation between the drain removal date and length of hospital stay. The shaded area around the linear model represents the 95% CI. The Pearson's correlation coefficient was 0.701, indicating a significant correlation between the drain removal date and length of hospital stay (95% CI 0.61-0.77; P<0.0001). The respective coefficients for the ER group and the control group were 0.609 (41 cases) and 0.724 (117 cases), with 95% CIs of (0.62-0.80) and (0.37-0.77), respectively. CI, confidence interval; ED, energy device.

although their existence has been documented (13). Therefore, sealing the pectoralis major fascia may help reduce lymphatic fluid accumulation in the dead space created during surgery. Overall, numerically the ED group tended to have lower drainage volumes than the control group, and a markedly difference was likely detected only on POD 8. On the other

hand, in the ED group, the timing of drains removal was numerically earlier than the control group. A reduction in drainage volume after the 8th postoperative day may allow for earlier drain removal. Therefore, it is suggested that the discharge is possibly showing a slight decrease, and indirectly leading to anticipated improvements in clinical course. It is also expected to potentially contribute to the reduction in length of stay discussed later.

In this study, AE incidence was significantly reduced in the ED group compared with the control group. Notably, seroma was the most common AE requiring postoperative intervention (14,15). Furthermore, surgical site infections and hematomas were not observed, and ED use may potentially reduce their frequency. As for seroma, which are the most common adverse events. With the increasing frequency of breast cancer surgeries, ED use may help minimize AEs. This study suggested that extensive sealing due to ED potentially reduces exudate and decreases seroma formation. Moreover, no disadvantages were observed in terms of intraoperative blood loss. In addition, although breast surgeons accustomed to dissecting with electrocautery may be concerned about the additional time when using ED, the overall duration of surgery was not extended. Since ED is a simple technique that can reduce seroma incidence without any significant disadvantages, such as an increased operative time, it has potential to reduce patient discomfort, follow-up visits, and events requiring intervention for complications, while also alleviate the workload of surgeons.

The precise mechanism by which energy devices reduce seroma formation remains unclear, but it has been suggested that they suppress lymphatic fluid retention by sealing vessels. Sealing integrity of the ED in vessels up to 7 mm approximates the burst strength of ligation and clips, resists dislodgement, and is unaffected by proximal thrombus (16,17). Further investigation of the mechanism is necessary.

Most healthcare organizations allow patients to be discharged only after drain removal, making the length of hospital stay closely tied to the duration of drain use (2). Some reports recommend that patients can be discharged with the drain in places with appropriate support or that they are seen monitored as outpatients after discharge (6,18-20). At our hospital, patients are typically discharged the day after drain removal. Earlier drain removal was positively correlated with a shorter hospital stay in this study, and suggests that earlier drain removal due to the use of ED may reduce the length of hospital stay, potentially improving healthcare system efficiency and cost-effectiveness. However, it is also argued that discharge often occurs due to non-clinical reasons such as social factors rather than the patient's clinical course. Discharge protocols vary across studies, contributing to significant heterogeneity (2).

This study has some limitations. First, this was an observational study conducted at a single institution with a small number of patients. And the use of historical controls might have introduced bias due to time differences. However, precisely because it is a single-center study, usage and techniques are performed according to consistent methods. The surgeries were performed by a well-trained board-certified breast surgeon and the procedures themselves have not changed significantly. Despite the small sample size, a clear trend was observed, suggesting that minor adjustments in surgical technique may help prevent seroma formation. Future research should involve prospective observational studies across multiple institutions. Based on the foundational data from this study, we aim to conduct a multicenter study comparing the use of ED across various sites, including the axilla and anterior pectoralis major muscle. Second, the primary focus of this study was on surgical outcomes rather than oncological outcomes, necessitating future studies for a more comprehensive understanding. Nevertheless, definitive oncological resection was achieved in all patients, with no pathologically positive margins. Additionally, compared with non-removal, resection of the pectoralis major fascia remains essential as it significantly lowers the recurrence rate in the chest wall (3).

In conclusion, this study suggests that using an ED during pectoralis fascia dissection in total mastectomy may reduce the AEs incidence requiring the intervention and the incidence of seroma. This relatively simple procedure has the potential to enhance the quality of breast surgery. Therefore, further investigation into the applications of EDs is justified.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

HS conceived and planned the present study in detail. YK, KS, AN and AW extracted the entirety of patient data, performed the data acquisition and inputted the data into the data platform. NN, SU, DK, TN and TM performed analysis and interpretation of the patient data with HS. Additionally, DK and TN revised the manuscript critically for important intellectual content. TM provided overall supervision and gave final approval for the publishable version. HS and TN confirm the authenticity of all the raw data. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study adhered to ethical tenets of The Declaration of Helsinki and Ethical Principles for Medical Research Involving Human Subjects, was approved by the Clinical Trial Center of Sapporo Medical University (approval number 352-93) and is registered with UMIN-CTR (UMIN000056764). An opt-out consent process was used, and disclosures were made on the University's website (https://web.sapmed.ac.jp/byoin/rinshokenkyu/koukai/).

Patient consent for publication

An opt-out consent process was used, and disclosures were made on the University's website (https://web.sapmed.ac.jp/byoin/rinshokenkyu/koukai/).

Competing interests

The authors declare that they have no competing interests.

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