

Comparing the Combined Flap Fixation and Harmonic Scalpel Technique with the Harmonic Scalpel Technique Alone in Reducing Seroma Formation after a Mastectomy and Axillary Lymph Node Dissection in a Breast Cancer Patient: A Randomized Controlled Trial

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Background: Seroma is a common complication of breast cancer surgery. Seroma can also interfere with healing, increase morbidity, and lead to delayed adjuvant treatment.

Objective: To compare seroma formation, seroma volume, total drain volume, and drain duration between the combined flap fixation and Harmonic scalpel technique with the Harmonic scalpel technique alone after a mastectomy and axillary lymph node dissection in a breast cancer patient.

Materials and Methods: A randomized control trial was conducted between October 2021 and October 2023 at the Department of Surgery, Surin Hospital. Sixty-four consecutive patients underwent mastectomies and axillary lymph node dissection. The patients were randomly assigned to Group 1 as Flap fixation and Harmonic scalpel technique with 32 patients and Group 2 as Harmonic scalpel technique alone, also with 32 patients.

Results: Ninety-two patients underwent mastectomies and 28 patients were excluded. Sixty-four patients underwent mastectomies and axillary lymph node dissection. The mean age was 55.08±12.58 years. Twenty-two patients (34.4%) developed clinical seroma, with five patients (15.6%, 95% CI 5.3 to 32.8) being in the combined flap fixation and Harmonic scalpel technique group and seventeen patients (53.1%, 95% CI 34.7 to 70.9) being in the Harmonic scalpel technique alone group. The combined flap fixation and Harmonic scalpel technique could reduce seroma formation and volume significantly compared to the Harmonic scalpel technique alone ($p=0.002$ and 0.007 , respectively). No statistical significance was found in the total drain volume ($p=0.742$) and drain duration ($p=0.457$) between the two groups. The combined flap fixation and Harmonic scalpel technique was significantly correlated with longer operative time ($p=0.004$).

Conclusion: A randomized control trial showed that the combined flap fixation and Harmonic scalpel technique could reduce seroma formation and seroma volume after a mastectomy and axillary lymph node dissection in a breast cancer patient.

Keywords: Breast cancer; Mastectomy, Seroma; Flap fixation; Harmonic scalpel

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Seroma is a common complication of breast cancer surgery occurring in 3% to 85% of breast cancer patients after breast and axillary surgery⁽¹⁾. Seroma is any fluid collection in the dead space beneath the mastectomy flaps or axillae⁽²⁾. The main

pathophysiology of seroma is still poorly understood and remains controversial. One of the key factors was the extension of breast flaps and axillary dissection⁽³⁾. Seroma can also interfere with healing, increase morbidity, and lead to delayed adjuvant treatment.

Surgical techniques have been reported to reduce seroma formation⁽⁴⁻⁷⁾. The use of electrocautery was associated with increased seroma formation. However, Harmonic scalpel dissection has been shown to reduce the rate of seroma formation when compared to electrocautery⁽⁸⁻¹¹⁾. Studies have shown that flap fixation techniques in modified radical mastectomy have significantly decreased seroma formation^(3,12-17).

The Harmonic scalpel techniques in modified radical mastectomy have shown effectiveness in

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Table 1. The inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Breast cancer patients undergoing modified radical mastectomy	1. Negative sentinel lymph node biopsy
2. Breast cancer patients undergoing mastectomy with sentinel lymph node biopsy	2. Major complication during surgery (accidental tear of axillary vessel etc.)
3. Females older than 15 years	3. More surgery beyond mastectomy and axillary lymph node dissection
	4. Pregnant females
	5. Refusal to continue in the study

reducing seroma⁽⁸⁻¹¹⁾. The author hypothesized that post-mastectomy dead space closure would lead to decreased seroma formation. The combined flap fixation and Harmonic scalpel techniques might be effective in reducing seroma formation after a mastectomy and axillary lymph node dissection. The primary objective of the present study was to compare seroma formation, seroma volume, total drain volume, and drain duration between the combined flap fixation and Harmonic scalpel technique with the Harmonic scalpel technique alone after a mastectomy and axillary lymph node dissection in a breast cancer patient.

Materials and Methods

A randomized control trial was conducted in the Department of Surgery at Surin Hospital between October 2021 and October 2023. Ethical approval was granted by the Ethics Committee of Surin Hospital (No. 50/2564). All patients were scheduled for modified radical mastectomies or mastectomies with sentinel lymph node biopsy by an experienced surgeon. Negative sentinel lymph node biopsy patients were excluded from the study. Inclusion and exclusion criteria are shown in Table 1. The sample size was calculated from a formula and calculated with a view to estimating the difference in proportions of seroma formation between the two groups, which is 40% in the control group and 10% in the flap fixation group, and the study by Sakkary⁽¹²⁾. A total of 64 cases, 32 cases in each group were calculated with 5% level of significance, 80% power of the test. The present study was a single institution, balanced randomization, and single-blind study. Patients were blinded throughout the trial.

Informed consent was obtained from all eligible patients. The patients undergoing modified radical mastectomies were randomized preoperatively. The patients who performed sentinel lymph node biopsies were randomized after positive pathological results. All eligible patients were randomized by a computer-generated number table, allocation sequences in ordered sealed envelopes and opened by the scrub nurse. The patients were randomly assigned to

Group 1 as Flap fixation and Harmonic scalpel technique, and Group 2 as Harmonic scalpel technique alone. All patients received antibiotic prophylaxis. After the pathologic reporting, axillary lymph node dissection was performed in positive sentinel lymph node patients. Axillary dissection was performed up to level 2 in all cases.

In the combined flap fixation and Harmonic scalpel technique group, axillary lymph node dissection was performed after the mastectomy with a Harmonic scalpel (Harmonic FOCUS Shears, Ethicon Inc. USA). The Harmonic scalpel settings were 3 and 5, as minimum and maximum values, respectively. The mastectomy flap was fixed to the chest wall, thus, the pectoral fascia and muscle, with absorbable suture material (No. 2-0 Polyglactin). The suture technique was placed 3 cm in each stitch throughout the flap between the subcutaneous layer and the chest wall (Figure 1).

In the Harmonic scalpel technique alone, axillary lymph node dissection was performed after the mastectomy with a Harmonic scalpel. The thoracodorsal nerve, long thoracic nerve, and some branches of the intercostobrachial nerve were identified and preserved. Electrocauterization was used to control bleeding. Two active suction drains (Redivac Drain No. 10-12) were placed at the pectoralis muscle and in the axillary area. The drains were connected to a 600-mL suction bottle. The subcutaneous tissue was sutured with absorbable suture material (No. 2-0 Polyglactin). The skin was sutured with absorbable suture material (No. 4-0 Polyglactin) using a subcuticular continuous suture technique.

The daily drain output was measured and recorded by the nurse specialist during the hospital stay. The patients were discharged once at least one of the drains had been removed. The patients were instructed by the author to monitor and observe the drain while they were at home. The daily drain output was recorded on a record sheet and the bottles were marked by the patients. The patients were scheduled for a follow-up one week after discharge and then weekly until the drain was removed. The drain was

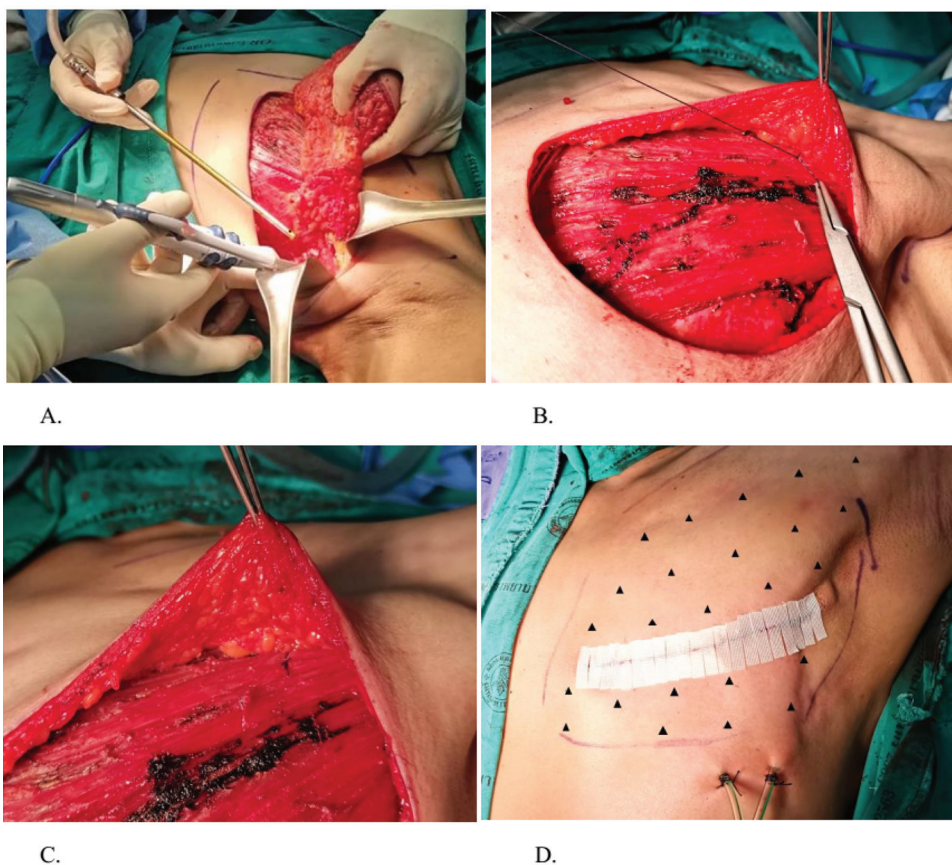


Figure 1. The combined flap fixation and Harmonic scalpel technique. A) Axillary lymph node dissection was performed with a Harmonic scalpel. B-C) The mastectomy flaps were fixed to the chest wall 3 cm. apart. D) The wound after the combined flap fixation and Harmonic scalpel process was performed (▲ = Fixation points).

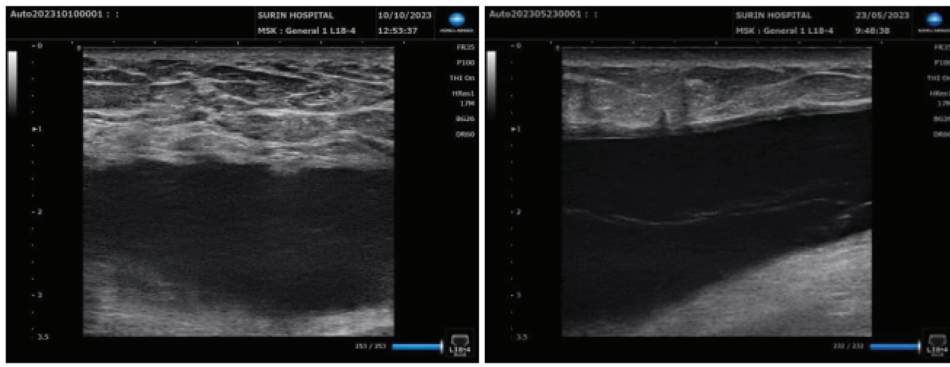
removed when output was less than 30 mL for at least two consecutive days. A week after the drains were removed, the author evaluated the seroma by clinical examination and bedside ultrasonography. The severity of seroma by ultrasonography and clinical in the present study was defined by the Common Terminology Criteria for Adverse Events v3.0 grades seroma as Grade 1 if asymptomatic with no fluid collection by palpation on clinical examination, but small amounts of seroma seen by ultrasonography, Grade 2 if symptomatic and seroma seen by ultrasonography and palpation on clinical examination, and Grade 3 if intervention radiology or operative intervention was indicated⁽¹⁸⁾ (Figure 2). Needle aspiration under ultrasound guidance was performed and recorded as seroma volume in all the patients with Grade 2 symptomatic seroma. All patients were followed for three months for incidence of seroma that required aspiration, volume of seroma, and other wound-related complications such as hematoma, skin necrosis, and surgical site infection

(SSI). The incidence was recorded and treated according to the severity of the complications. All patients received the adjuvant treatment if indicated by an oncologist.

Ninety-two patients were evaluated for the study, of whom 28 patients were excluded. Twenty-seven patients were excluded as they had negative sentinel lymph node biopsies. One patient was excluded as she needed to have her pectoralis muscle removed due to tumor invasion. The summary of the participant's flow is shown in Figure 3.

Statistical analysis

The studies were performed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA) and data on characteristics were compared by using a t-test. The Mann-Whitney U test was used to assess the statistical significance between the two groups. Chi-square and Fisher's exact tests were applied to analyze the categorical variables.



A. Grade 1: ultrasonography

B. Grade 2: ultrasonography



C. Grade 1: clinical examination



D. Grade 2: clinical examination

Figure 2. The severity of seroma by ultrasonography and clinical examination. A) Grade 1 by ultrasonography. B) Grade 2 by ultrasonography. C) Grade 1 by clinical examination. D) Grade 2 by clinical examination.

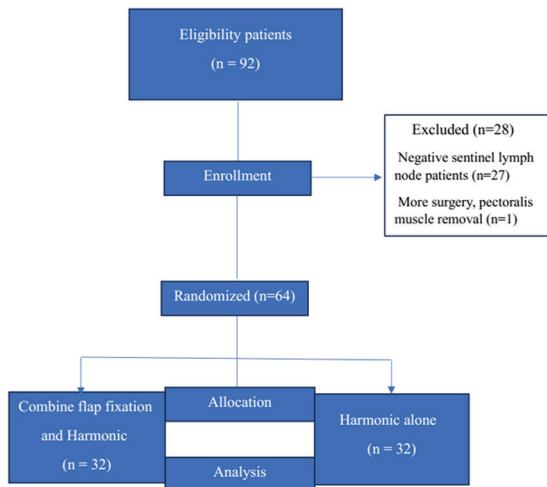


Figure 3. CONSORT 2010 flow diagram.

Results

Sixty-four patients underwent mastectomies and axillary lymph node dissection, the mean age was 55.08 ± 12.58 years. Thirty-two patients were

randomly assigned to the combined flap fixation and Harmonic scalpel technique, and 32 patients were randomly assigned to the Harmonic scalpel technique alone. No statistically significant differences were found between the two groups in terms of age, body mass index, side, tumor size, number of positive lymph nodes, number of resected lymph nodes, TNM staging, molecular subtypes, or neoadjuvant chemotherapy received (Table 2).

No statistically significant differences were found between the two groups in terms of sentinel lymph node biopsy, blood loss, or drain dislodgement. The operative time in the combined flap fixation and Harmonic scalpel technique group was longer than that of the Harmonic scalpel technique alone group with statistical significance at 128.81 ± 19.27 versus 114.88 ± 17.67 ($p=0.004$). The total drain volumes in the combined flap fixation and Harmonic scalpel technique and the Harmonic scalpel technique alone groups were not different at 995 versus 1,037.5 ($p=0.742$). The drain durations in the combined flap fixation and Harmonic scalpel technique and the

Table 2. Demographic data of the patients

Factors	Flap fixation + Harmonic scalpel (n=32)	Harmonic scalpel alone (n=32)	p-value
Age (years); mean±SD	53.91±12.18	56.25±13.05	0.460
Body mass index (kg/m ²); mean±SD	23.59±3.88	23.64±3.24	0.950
<18.5 kg/m ² ; n (%)	1 (3.1)	3 (9.4)	0.110
18.5 to 22.9 kg/m ² ; n (%)	16 (50.0)	8 (25.0)	
≥23.0 kg/m ² ; n (%)	15 (46.9)	21 (65.6)	
Side; n (%)			0.616
Left	18 (56.3)	16 (50.0)	
Right	14 (43.7)	16 (50.0)	
Primary tumor (T); n (%)			0.681
T0	0 (0.0)	1 (3.1)	
T1	7 (21.9)	4 (12.5)	
T2	20 (62.5)	19 (59.4)	
T3	4 (12.5)	6 (18.8)	
T4	1 (3.1)	2 (6.3)	
Pathologic lymph nodes (N); n (%)			0.781
N0	8 (25.0)	6 (18.8)	
N1	15 (46.9)	18 (56.3)	
N2	6 (18.8)	4 (12.5)	
N3	3 (9.4)	4 (12.5)	
Tumor size (cm); median (IQR)	2.85 (2, 4.38)	3 (2.1, 4.65)	0.501
Number of positive lymph nodes; median (IQR)	1.5 (0.25, 4.75)	2 (1, 2.75)	0.956
Number of resected lymph nodes; mean±SD	18.00±7.25	20.00±8.33	0.309
TNM staging; n (%)			0.951
IIA	6 (18.8)	8 (25.0)	
IIB	14 (43.8)	12 (37.5)	
IIIA	7 (21.9)	8 (25.0)	
IIIB	1 (3.1)	1 (3.1)	
IIIC	4 (12.5)	3 (9.4)	
Molecular subtypes; n (%)			0.968
Her 2-enriched	6 (18.8)	6 (18.8)	
Basal-like	4 (12.5)	5 (15.6)	
Luminal A	11 (34.4)	9 (28.1)	
Luminal B	11 (34.4)	12 (37.5)	
Neoadjuvant chemotherapy' n (%)	14 (43.8)	9 (28.1)	0.193

SD=standard deviation; IQR=interquartile range

* Statistical significance at 0.05 ($\alpha=0.05$)

Harmonic scalpel technique alone groups were not different at 15.5 versus 14 ($p=0.457$)

Complications occurred in six patients (9.4%), including three cases of surgical site infection, one post-operative bleeding, one hematoma, and one skin necrosis. Complications in the two groups were not different (Table 3).

The seroma formation in the combined flap fixation and Harmonic scalpel technique group was significantly lower when compared to the Harmonic scalpel technique alone group ($p=0.001$). Clinical seroma (Grade 2) developed in 22 patients (34.4%)

with five patients (15.6%, 95% CI 5.3 to 32.8) being in the combined flap fixation and Harmonic scalpel technique group and 17 patients (53.1%, 95% CI 34.7 to 70.9) being in the Harmonic scalpel technique alone group. The combined flap fixation and Harmonic scalpel technique could reduce seroma formation and volume significantly compared to the Harmonic scalpel technique alone ($p=0.002$ and 0.007 , respectively) (Table 4).

Discussion

Seroma can interfere with the healing process,

Table 3. Operative data of the patients

Factors	Flap fixation + Harmonic scalpel (n=32)	Harmonic scalpel alone (n=32)	p-value
Sentinel lymph node biopsy; n (%)	5 (15.6)	11 (34.4)	0.083
Operative time (minutes); mean±SD	128.81±19.27	114.88±17.67	0.004
Blood loss (mL); median (IQR)	30 (20, 50)	30 (20, 50)	0.654
Total drain volume (mL); median (IQR)	995 (607.5, 1,472.5)	1,037.5 (660, 1,503.8)	0.742
Drain duration (days); median (IQR)	15.5 (13, 22)	14 (12.3, 20)	0.457
Drain dislodgement; n (%)	0 (0.0)	2 (6.3)	0.151
Complications; n (%)	3 (9.4)	3 (9.4)	1.000
Surgical site infection	2	1	
Postoperative bleeding	0	1	
Hematoma	0	1	
Skin necrosis	1	0	

SD=standard deviation; IQR=interquartile range

* Statistical significance at 0.05 ($\alpha=0.05$)**Table 4.** Comparison of seroma formation

Factors	Flap fixation + Harmonic scalpel (n=32)	Harmonic scalpel alone (n=32)	p-value
Seroma grade; n (%)			0.001
No seroma	11 (34.4)	2 (6.3)	
Grade I	16 (50.0)	13 (40.6)	
Grade II	5 (15.6)	17 (53.1)	
Clinical seroma; n (%)	5 (15.6)	17 (53.1)	0.002
Seroma volume (mL); median (IQR)	0 (0, 0)	30 (0, 50)	0.007

IQR=interquartile range

* Statistical significance at 0.05 ($\alpha=0.05$)

prolong treatment, increase patient discomfort, and delay adjuvant treatment. The extent of the dissection of breast flaps and axillae seems to be one of the crucial factors relating to seroma formation. Hashemi et al.⁽¹⁹⁾ and Gonzalez et al.⁽²⁰⁾ found the type of surgery to be a predicting factor for seroma formation in breast cancer patients, with seroma formation in the modified radical mastectomy group being higher than that of the breast-conserving therapy group at 39% versus 23% ($p=0.04$), and 19.9% versus 9.2% ($p=0.01$), respectively.

The Harmonic scalpel dissection technique has been shown to reduce the rate of seroma formation, intraoperative blood loss, and wound complications when compared to electrocautery⁽⁸⁻¹¹⁾. The Harmonic scalpel can be recommended as a preferential surgical instrument in a modified radical mastectomy⁽⁹⁾. The Harmonic scalpel is not used routinely at the institute; however, breast surgeons began to use the technique in a modified radical mastectomy due to evidence showing its effectiveness in reducing seroma.

Studies have shown that flap fixation techniques in modified radical mastectomies significantly decrease the rate of seroma formation^(3,12-17). A

meta-analysis has demonstrated the potential of flap fixation in reducing seroma formation, with 12 included studies where the flap fixation approach has shown a good safety profile in terms of reduction of seroma formation at 22.41% versus 43.61% ($p=0.001$)⁽²¹⁾.

The author hypothesized that post-mastectomy dead space closure would lead to a decrease in seroma formation. The combined flap fixation and Harmonic scalpel technique might be a good effective technique in terms of reduction of seroma formation.

The severity of seroma formation, which was defined as Grade 1 if asymptomatic, Grade 2 if symptomatic as medical intervention or simple aspiration indicated, and Grade 3 if intervention radiology or operative intervention was indicated^(12,18) was assessed. According to these definitions, all clinical seroma formations in the present study were categorized as Grade 2, therefore Grade 1 assessments in the study had no impact on clinical care.

The incidence of seroma formation in the present study was 34.4%, which made it comparable to other literature⁽²¹⁾. The primary outcome of the present study showed that the combined flap fixation and

Harmonic scalpel technique could reduce seroma formation and seroma volume when compared to the Harmonic scalpel technique alone after a mastectomy and axillary lymph node dissection in a breast cancer patient. This outcome supports the flap fixation technique in terms of its ability to reduce the incidence of seroma formation.

The operative time in the combined flap fixation and Harmonic scalpel technique was longer than the Harmonic scalpel technique alone by about 14 minutes at 128.81 ± 19.27 versus 114.88 ± 17.67 minutes due to more operation being required in the combined flap fixation and Harmonic scalpel technique.

The complications in the two groups were not different at 9.4%, with no mortality, which makes the present study comparable to other literature⁽¹⁷⁾. This outcome supported the theory that the combined flap fixation and Harmonic scalpel technique is safe after a mastectomy and axillary lymph node dissection in a breast cancer patient.

The present study was a single institution, and it was a single-blind study. Patients were blinded throughout the trial, but the surgeon could not be blinded due to the patients' need to be evaluated by their own surgeon during follow up. The limitations of the present study include the single-blind study and the single-center study factor, as it was prone to centripetal bias. The results of multi-center studies and double-blind study could further strengthen the outcomes of the present study.

Conclusion

A randomized control trial showed the combined flap fixation and Harmonic scalpel technique could reduce seroma formation and seroma volume after a mastectomy and axillary lymph node dissection in a breast cancer patient when compared to the Harmonic scalpel technique alone. The operative time in the combined flap fixation and Harmonic scalpel technique was longer than that of the Harmonic scalpel technique alone group.

What is already known on this topic?

Harmonic scalpel dissection has been shown to reduce the rate of seroma formation. The flap fixation techniques in modified radical mastectomy significantly decreased seroma formation.

What does this study add?

This randomized controlled trial has shown that the combined flap fixation and Harmonic scalpel

technique is safe and effective in reducing seroma formation and seroma volume after a mastectomy and axillary lymph node dissection in a breast cancer patient.

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Conflicts of interest

The author declares no conflict of interest.

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