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Original Article

Seroma Formation after Modified Radical Mastectomy with Flap Fixation Technique in Breast Cancer Patients: Nakhon Phanom Hospital – A Single Blinded Randomized Control Trial

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ABSTRACT

Objective: Seroma formation is the common complication after modified radical mastectomy. The purposes of this study were to evaluate seroma formation after modified radical mastectomy with flap fixation technique and to compared seroma formation after modified radical mastectomy between flap fixation technique and conventional surgery in breast cancer patients.

Patients and Methods: This study was a single-blinded randomized control trial. 68 breast cancer patients who underwent modified radical mastectomy by single surgeon were enrolled in this study between December 2023 to June 2024. The patients were randomized to the flap fixation group: group A (n = 34) and the conventional group: group B (n = 34). Group A, flaps were fixed by absorbable suture to the underlying muscle. Group B, the flaps were closed by conventional methods. All patients were followed 95–100 days after discharge and the results of seroma formation were compared between two groups. We used *t*-test to compare amount of seroma formation between group and multivariable Gaussian regression adjusted for difference factors at baseline.

Results: Seroma formation after discharge developed in 26 patients (38.24%), in flap fixation group (19.23%) lower than conventional group (80.77%), significantly. ($p < 0.001$) There was no significant difference in operative time, blood loss or serious complication between two groups. High BMI and number of axillary lymph node harvest were factors affecting prolong seroma formation after discharge, significantly. ($p = 0.002$ and 0.034)

Conclusion: Flap fixation technique in modified radical mastectomy can reduce fluid from drain after surgery and seroma formation after discharge when compare to conventional technique without the difference in operative time, blood loss or serious complication. High BMI and high number of axillary lymph node harvest are factors affecting prolong seroma formation after discharge.

Keywords: Breast cancer, modified radical mastectomy, flap fixation, seroma formation

Introduction

Breast cancer is one of the most cancer in Thai women, according to Health data center. The main treatment for breast cancer is surgery. Other treatments are chemotherapy, radiation, targeted therapy and hormonal treatment. There are different types of surgery for breast cancer patients, including breast conserving surgery, mastectomy. There are two types of axillary lymph node surgery, including sentinel lymph node biopsy (SLNB) and axillary lymph node dissection (ALND).

Modified radical mastectomy (MRM) is the most commonly performed surgery for breast cancer patients in Nakhon Phanom hospital. MRM is a procedure that remove the entire of breast and dissect axillary lymph node. Seroma formation is the common complication after modified radical mastectomy[1] in breast cancer patients with incidence varies between 15-81%.[2,3] Factors affect seroma formation include age of patients, obesity, neoadjuvant chemotherapy, tumor size, extensive axillary lymph node dissection, number of axillary lymph nodes metastasis and the use

of electrocautery.[1,3-8,11,12] Seroma causes pain at surgical site, delay wound healing, surgical site infection, skin flap necrosis and wound dehiscence.[1,4,5] Patients with seroma may need aspiration, open drainage or prolong hospital stay which also delay the start of adjuvant therapy after operation.[1,12]

Ideal wound closure after modified radical mastectomy which reduce seroma formation is obliteration of dead space between flap and chest wall.[1,6,7,12] Several techniques have been applied for reducing seroma formation. Using ultrasonic scalpel can reduce seroma formation, compared with using electrocautery.[7] Additionally, adhesive tissue glues have been used to reduce seroma and improve wound healing after mastectomy.[12]

Flap fixation technique is the one of surgical techniques which have been applied for reducing seroma formation after modified radical mastectomy. This technique can be performed without requiring any specific instruments. The subcutaneous fascia of skin flaps are sutured to the underlying chest wall muscles and closing the axillary area with absorbable suture.[1,8,12] However, this technique is not performed generally in Nakhon Phanom hospital. Previously, there was no comprehensive study that compared all data in all aspects in one study (risk factor, pathological report, fluid output in admission period and seroma after discharge.) This study aimed to study seroma formation after modified radical mastectomy with flap fixation technique and to compare seroma formation after modified radical mastectomy between flap fixation technique and conventional surgery in breast cancer patients. The result from this study can lead to surgical technique development and improve breast cancer patients care plan for seroma formation prevention and surgical complication observation in Nakhon Phanom hospital in the future.

Methods

A single-blinded randomized control trial was conducted between December 2023 to June 2024. All operable breast cancer patients who were 18 years old and over, early and locally advance breast cancer who underwent modified radical mastectomy by single surgeon who has responsibility at breast clinic in Nakhon Phanom hospital were screened. Exclusion criteria are pregnant women, patients who did not consent to participate in this study, immunocompromise patients, patients who need oncoplastic reconstruction or previous aesthetic breast surgery, patients with coagulopathy problems such as liver cirrhosis or bone marrow dysfunction. However, patients taking aspirin were included. Patients who were lost to follow up or have serious medical complication during admission were excluded from this study.

The institutional ethics committee was approved this study with approval number NP-ECC 11-No.39/2566. This study was registered in the ClinicalTrial.gov of National Library of Medicine with a unique ID NCT06243796.

Locally advanced breast cancer patients will receive neoadjuvant chemotherapy about 4 cycles until the size of tumors have decreased before surgery. The sample size was 68 patients. All patients were divided randomly to 2 groups, flap fixation group (group A) and conventional group (group B), equally (34 in each group). All patients were checked before general anesthesia according to anesthetic guideline and received antibiotic prophylaxis 30 minutes before surgery. MRM was performed, skin flaps were dissected by monopolar electrocautery, axillary lymph node dissection was performed by ligation and monopolar electrocautery. Bleeding was checked and stopped by ligation and monopolar electrocautery. Close suction drainages (Radivac drain) were placed above pectoralis muscle and at axillary area. In flap fixation group, absorbable suture (polyglactin 3-0) were sutured between skin flaps and pectoralis muscle. Sutures were fixed about 2-3 cm intervals in two or three rows, upper and lower skin flap. The lateral wall of axillary area was sutured with the same materials between the fascia of the serratus anterior and axillary wall. In conventional group, skin was closed without fixation technique. Both groups, skin was closed subcuticular layer and dermis with absorbable suture (polyglactin 3-0 and 4-0) in two layers. (Figure 1 and 2). All assistant nurse were nurses who have the experience in this operation.

The post-operative period, fluid from drains was recorded daily. All patients were admitted at surgery ward and were cared as standard nursing care guideline. All patients were consulted to physiotherapist for exercise. The drains will be removed at the 7^{th} day after operation. After discharge from hospital, all patients were followed up at out patient department on the 7^{th} – 10^{th} day, 15^{th}- 20^{th} day, then every 3 weeks until 3 months. (based on previous study)[10] Distance metastasis work up was investigated and adjuvant therapy was considered for all patients if indicated.

During follow up period, seroma formation and late-post operative complication were observed, including wound infection, wound dehiscence, hematoma and joint stiffness. Seroma was examined by clinical examination, bedside ultrasound or tap aspiration. Asymptomatic seroma which not require any treatment is labelled as grade 1. Symptomatic seroma requiring needle aspiration is labelled as grade 2. Symptomatic seroma requiring surgical intervention is labelled as grade 3.[9,10]

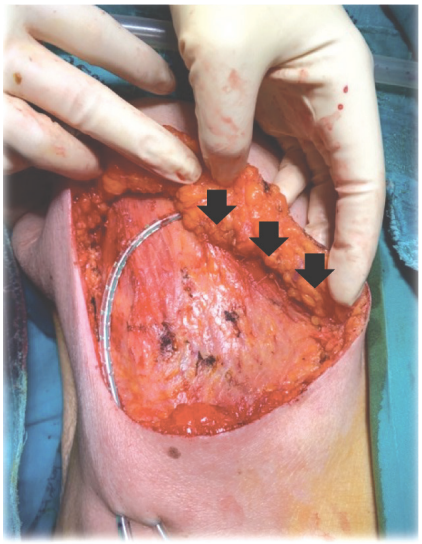

Figure 1 Sutured between skin flaps and pectoralis muscle. (arrow = fixation point)

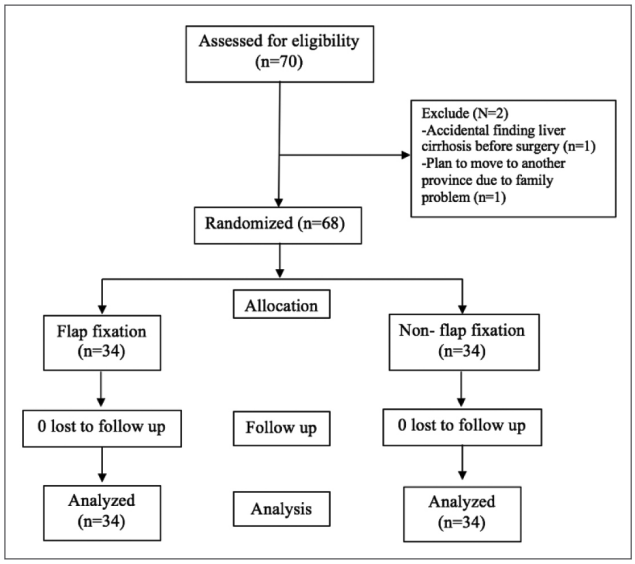

Figure 3 Flow diagram of this study

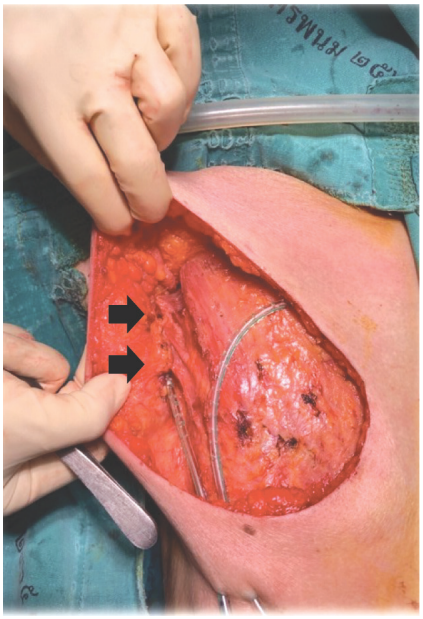

Figure 2 Suture between the fascia of the serratus anterior and axillary wall. (arrow = fixation point)

Statistic analysis

The study was performed with STATA. Patients characteristics, operative information and pathologic characteristics were collected and analyzed by statistical distribution, frequency, mean and standard deviation (SD). The data were tested for normal distribution and the statistically significant variances was *p*-value < 0.05. Quantitative variables were compared by Independent *t*-test and Wilcoxon Mann-Whitney test. Nominal categorical data was compared by Chi-square or Fisher's exact test. Multilevel mixed-effect Gaussian regression was used account for repeated measures for outcomes of interest. Logistic regression analysis was used to analyze the factors affecting prolong seroma formation after discharge.

Results

70 patients with breast cancer were screened but 2 patients were excluded from this study due to accidental finding liver cirrhosis before surgery and one patient who plan to move to another province. There were 68 patients were included. (Figure 3) Characteristics of patients of this study were summarized and compared in Table 1. Average age of patients in group A and group B were 53 ± 14 and 58 ± 10 years. 26 patients with class I obesity (BMI ≥ 25kg/m^2) and above (13 patients in each group). Most of patients had co-morbidity which hypertension was found the most in both groups. Only 14 patients received neoadjuvant chemotherapy, 5 (14.71%) in group A and 9 (26.47%) in group B. Average operative time were 57 ± 10 minutes in group A and 58 ± 10 minutes in group B. Average blood loss was 33.53 ± 13.23 ml in group A and 35.88 ± 17.60 ml in group B. There was no significant difference between the two studies groups in age, BMI, comorbid, previous treatment by neoadjuvant therapy, operative time and blood loss.

Most of breast cancer cell type in this study was invasive ductal carcinoma, total 63 in both groups. (32 in group A and 31 in group B) Average tumor size in group A was 3.5 cm. and 4.09 cm. in group B. There was no significant different between the two groups in specific details in pathological report whether there was cell type, tumor grade, lymphoinvasion, angioinvasion, skin and muscle invasion. There was significant different between the two groups in number of lymph nodes harvest (p = 0.038). But there was no significant different between the two groups in number of lymph nodes metastasis and extranodal extension. Most of patients in this study were diagnosed in stage 2A, total 26 patients, 14 (41.18% in group A) and 12 (35.29% in group B) Only 5 patients had distance metastasis, 1 (2.94%) in group A and 4 (11.76%) in group B. Metastasis to lung and liver were found in both groups but there was no significant between the two group.

At admission period, fluid from drains in flap fixation group started to decrease at post operative day 3rd significantly (p = 0.040 and 0.005 by control number of axillary lymph node harvest), but increase in two days later then decrease at day 6th and 7th, significantly. (p = 0.028 and 0.018 with 0.009 and 0.004 by control confounding factor). From analysis by repeated measure from evaluate volume of seroma at admission in day 0 to day 7th after surgery with control confounding factor (number of axillary lymph node harvest) found that patients in conventional group developed fluid from drain output in the first day 106.53 ml. (95%CI: 90.47–122.60) (p < 0.001), patients in flap fixation group developed fluid from drain less than group B, 15.01ml (95%CI: 3.83–26.19) (p = 0.009) and decrease in the next day 14.18 ml per day (95%CI: 13.22–15.14) (p < 0.001).

After discharge, seroma formation developed

in 26 patients (38.24%), 5 in flap fixation group (19.23%) and 21 in conventional group (80.77%). ($p < 0.001$) According to data in Table 2, volume of seroma in patients with flap fixation technique was less than patients with conventional group since the first time follow up after discharge and disappear at the third time after discharge, significantly. Follow up after discharge at day 95th-100th, there was no seroma in both groups. All patients who developed seroma had symptom and required needle aspiration at out patient department. (seroma grade 2)

2 patients in conventional group had wound infection and 5 patients had joint stiffness. (3 in group A and 2 in group B). There were 6 patients in conventional group visited the doctor before appointment date because of seroma develop after discharge and required needle aspiration. All the outcome data were shown in Table 2.

According to this study, flap fixation technique reduced seroma formation after MRM 98%, significantly ($p < 0.001$). High BMI and high number of axillary lymph node harvest affected seroma formation after discharge significantly. ($p = 0.002$ and 0.034) BMI and number of axillary lymph node dissection increased chance of seroma formation after discharge 1.30 (95%CI; 1.08-1.56) and 1.14 (95%CI;1.03-1.26) times respectively. Tumor size, number of node metastasis, neoadjuvant chemotherapy and staging did not affect prolong seroma formation after discharge. (Table 3)

Table 1 Patients, operation and pathology characteristics (n = 68)

Characteristics	Flap fixation (n = 34)	Conventional (n = 34)	*p*-value
Age (years) Mean (SD)	53 (14)	58 (10)	0.076
BMI (kg/m^2) Mean (SD)	24.59 (3.84)	23.92 (4.49)	0.507
BMI (kg/m^2)			
< 18.5	0 (0)	5 (14.71)	0.145
18.5 – 22.9	11 (32.35)	10 (29.41)	-
23 – 24.9	10 (29.41)	3 (17.65)	-
25 – 29.9	11 (32.35)	9 (26.47)	-
≥ 30	2 (5.88)	4 (11.76)	-
Co morbid	18 (52.94)	22 (64.71)	0.460
Diabetes	6 (17.65)	7 (20.59)	1.000
Hypertension	14 (41.18)	16 (47.06)	0.807
Chronic kidney disease	0(0)	1 (2.94)	1.000
Others	6 (17.65)	8 (23.53)	0.765

Table 1 (cont.) Patients, operation and pathology characteristics (n = 68)

Characteristics	Flap fixation (n = 34)	Conventional (n = 34)	*p*-value
Neoadjuvant chemotherapy			
No	29 (85.29)	25 (73.53)	0.369
Yes	5 (14.71)	9 (26.47	-
Operative time (min.) Mean (SD)	57 (10)	58 (10)	0.676
Blood loss (ml.) Mean (SD)	33.53 (13.23)	35.88 (17.60)	0.535
Blood loss Median (IQR)	30 (20, 50)	30 (20, 50)	0.710
Pathological report Mean (SD)			
Invasive ductal carcinoma	32 (94.12)	31 (91.18)	1.000
Solid papillary carcinoma	2 (5.88)	2 (5.88)	-
Invasive lobular carcinoma	0 (0)	1 (2.94)	-
Tumor grade Mean (SD)			
Grade 1	3 (8.82)	4 (11.76)	0.098
Grade 2	21 (61.76)	27 (79.41)	-
Grade 3	10 (29.41)	3 (8.82)	-
Lymphoinvasion present Mean (SD)	14 (41.18)	12 (35.29)	0.803
Angioinvasion present Mean (SD)	7 (20.59)	6 (17.65)	1.000
Skin invasion present Mean (SD)	7 (20.59)	12 (35.29)	0.280
Muscle invasion present Mean (SD)	3 (8.82)	3 (8.82)	1.000
Tumor size (cm) Mean (SD)	3.5 (1.83)	4.09 (1.90)	0.196
Tumor size (cm) Median (IQR)	3.5 (2.2, 4.3)	3.9 (2.6, 5)	0.120
T stage Mean (SD)			
T1	5 (14.71)	1 (2.94)	0.285
T2	21 (61.76)	20 (58.82)	-
T3	2 (5.88)	2 (5.88)	-
T4	6 (17.65)	11 (32.35)	-
Number lymph nodes harvest Mean (SD)	25 (8)	21 (9)	0.081
Number lymph nodes harvest Median (IQR)	24 (20, 28)	18.5 (14, 26)	0.038
Node metastasis			
No	18 (52.94)	12 (35.29)	0.222
Yes	16 (47.06)	22 (64.71)	-
Number of node metastasis Median (IQR)	3.5 (2, 12)	6 (2, 10)	0.621

Table 1 (cont.) Patients, operation and pathology characteristics (n = 68)

Characteristics	Flap fixation (n = 34)	Conventional (n = 34)	*p*-value
N stage Mean (SD)			
N0	18 (52.94)	12 (35.29)	0.374
N1	8 (23.53)	8 (23.53)	-
N2	3 (8.82)	7 (20.59)	-
N3	5 (14.71)	7 (20.59)	-
Extra nodal extension Mean (SD)			
No	25 (73.53)	24 (70.59)	1.000
Yes	9 (26.47)	10 (29.41)	-
Distance metastasis Mean (SD)**			
No	33 (97.06)	30 (88.24)	0.356
Yes	1 (2.94)	4 (11.76)	-
Lung	1 (2.94)	4 (11.76)	0.356
Liver	0 (0)	1 (2.94)	1.000
Stage Mean (SD)			
1A	3 (8.82)	0 (0)	0.342
1B	0 (0)	0 (0)	-
2A	14 (41.18)	12 (35.29)	-
2B	7 (20.59)	4 (11.76)	-
3A	2 (5.88)	4 (11.76)	-
3B	3 (8.82)	3 (8.82)	-
3C	4 (11.76)	7 (20.59)	-
4	1 (2.94)	4 (11.76)	-

*Some patients had more than one co morbidity

**Some patients had more than one distance metastasis

Table 2 Outcome between two groups at admission and after discharge (n = 68)

Parameters	Flap fixation (n = 34)	Conventional (n = 34)	*P*-value	*P*-value*
Drain output at admission (ml) **Mean** (SD)				
Drain output Day 0	54.27 (27.47)	59.56 (49.78)	0.589	0.452
Drain output Day 1st	102.21 (40.02)	117.94 (43.14)	0.124	0.107
Drain output Day 2nd	85.00 (40.82)	94.24 (39.06)	0.344	0.102
Drain output Day 3rd	63.38 (26.90)	82.50 (45.75)	0.040	0.005
Drain output Day 4th	53.68 (24.81)	60.29 (29.64)	0.322	0.198
Drain output Day 5th	45.59 (23.05)	55.00 (28.37)	0.138	0.063
Drain output Day 6th	30.59 (18.37)	42.06 (23.36)	0.028	0.009
Drain output Day 7th	15.44 (14.27)	26.18 (21.61)	0.018	0.004
Seroma at follow up				
After discharge day 7th-10th				
No	30 (88.24)	13 (38.24)	<0.001	0.001
Yes	4 (11.76)	21 (61.76)	-	-
Volume of seroma (ml)				
Mean (SD)	40.00 (18.26)	86.19 (56.88)	0.127	< 0.001
After discharge day 15th-20th				
No	33 (97.06)	22 (64.71)	0.001	0.012
Yes	1 (2.94)	12 (35.29)	-	-
Volume of seroma (ml)				
Mean (SD)	20 (-)	72.5 (55.00)	-	0.001
After discharge day 35th-40th				
No	34 (100)	30 (88.24)	0.114	-
Yes	0 (0)	4 (11.76)	-	-
Volume of seroma (ml)				
Mean (SD)	0 (-)	86.25 (31.98)	-	0.017
After discharge day 75th-80th				
No	34 (100)	33 (97.06)	1.000	-
Yes	0 (0)	1 (2.94)	-	-
Volume of seroma (ml)				
Mean (SD)	0 (-)	30 (0)	-	0.237
After discharge day 95th-100th				
No	34 (100)	34 (100)	-	-
Yes	0 (0)	0 (0)	-	-
Complication				
Wound infection	0 (0)	2 (5.88)	0.493	-
Joint stiffness	3 (8.82)	2 (5.88)	1.000	0.644
Visit before the appointment date	0 (0)	6 (17.65)	0.025	-

*Multivariable Gaussian regression adjusted for number of node harvest

Table 3 Factors affecting prolong seroma formation after discharge

Factors	Seroma (n=26)	Non-seroma (n=42)	*P* value	Univariate		Multivariate	
				OR (95%CI)	*P* value*	OR (95%CI)	*P* value**
Age (Years) (Mean ± SD)	57 (12)	55 (13)	0.399	1.02 (0.98, 1.06)	0.394		
Surgical technique							
Flap fixation technique	5 (19.23)	29 (69.05)	< 0.001	0.11 (0.03, 0.35)	< 0.001	0.02 (0.002, 0.13)	< 0.001
Conventional technique	21 (80.77)	13 (30.95)	-	-	-		
BMI (kg/m^2) (Mean ± SD)	26.17 (3.76)	23.06 (3.98)	0.002	1.23 (1.07, 1.42)	0.005	1.30 (1.08, 1.56)	0.005
Tumor size (cm) (Mean ± SD)	3.75 (1.86)	3.82 (1.91)	0.876	0.98 (0.75, 1.28)	0.874		
Number of node harvest (Mean ± SD)	26 (12)	21 (6)	0.034	1.07 (1.00, 1.32)	0.046	1.14 (1.03, 1.26)	0.013
Number of Node metastasis median (IQR)	0.5 (0, 7)	1 (0, 4)	0.874	1.03 (0.96, 1.10)	0.465		
Neoadjuvant chemotherapy	3 (11.54)	11 (26.19)	0.219	0.38 (0.09, 1.47)	0.157		
Lymphoinvasion present	9 (34.62)	17 (40.48)	0.798	0.78 (0.28, 2.15)	0.629		
Angioinvasion present	2 (7.69)	11 (26.19)	0.110	0.24 (0.05, 1.16)	0.076		
Skin invasion present	6 (23.08)	13 (30.95)	0.583	0.67 (0.22, 2.06)	0.483		
Muscle invasion present	2 (7.69)	4 (9.52)	1.000	0.79 (0.14, 4.66)	0.796		
Extra nodal extension	6 (23.08)	13 (30.95)	0.583	0.67 (0.22, 2.06)	0.483		
Stage							
1A	2 (7.69)	1 (2.38)	0.309	0.94 (0.72, 1.22)	0.620		
1B	0 (0.00)	0 (0.00)	-	-	-		
2A	11 (42.31)	15 (35.71)	-	-	-		
2B	3 (11.54)	8 (19.05)	-	-	-		
3A	3 (11.54)	3 (7.14)	-	-	-		
3B	0 (0.00)	6 (14.29)	-	-	-		
3C	4 (15.38)	7 (16.67)	-	-	-		
4	3 (11.54)	2 (4.76)	-	-	-		

*Univariable logistic regression, **Multivariable logistic regression adjusted for number of axillary lymph node harvest.

Discussion

According to this study, obliteration of dead space between flap and chest wall by flap fixation technique in MRM can reduce the volume of fluid from drain after surgery and seroma formation after discharge.[1,6,7,12] Seroma formation affects prolong hospital stay, increase patient discomfort and wound infection.[1,4,5,9]

Overall incidence of seroma formation after discharge in this study was 38.24% (19.23% in flap fixation group and 80.77% in conventional group) which makes it comparable to other literatures that reported the incidence of seroma varies between 15-81%.[2,3] Patients who have undergo MRM with flap fixation technique can discharge from the hospital earlier than patients who have undergo conventional technique as the data from this study shown the fluid from drain output in flap fixation group decreased significantly after day 5th after surgery, which several literatures supported this result.[8,12]

In assessing the severity of seroma[8,9], all patients in this study developed seroma grade 2 which required needle aspiration. However, patients who has grade 1 seroma may underestimate due to no any symptom or impact on specific treatment.[9] Flap fixation technique can reduce the number of times for visiting the doctor and reduce the chance of visiting the doctor before the appointment date, according to the data shown that there was no seroma develop in flap fixation group at the 3rd time follow up. No patients with seroma in this study require operative intervention, the literatures[8,10] supported this result. There were 6 patients in conventional group visited the doctor before appointment date because of seroma develop after discharge and required needle aspiration. 2 patients in conventional group had wound infection because seroma formation. According to the result support that flap fixation technique can reduce the incidence of wound infection, as the literatures[1,4,5] supported. However, patients with wound infection in this study had mild symptom and were treated by oral antibiotic drug. The infection did not affect to delay post operative adjuvant therapy.

Flap fixation technique can be performed without serious complication. There is no difference in operative time or blood loss, compare with conventional technique.[3,8,9] However, operative time may affect from varies factors in the operating room such as assistance's expertise, size of breast removal or circulating nurse. Joint stiffness occurred in 5 patients, 3 in flap fixation group. However, this study found that all patients who had joint stiffness were old age, between 71-85 years old. Some patients needed the assistive device, such as a walking stick, before surgery. Therefore, patients who use the assistive device may be excluded from the study if there is further study in the future.

BMI and number of axillary lymph node harvest were the factors affecting prolong seroma formation after discharge, the literatures[1-3,7,10,13]

supported the results. In contrasted, some literatures[8,9] reported that BMI did not affect to seroma formation. Other specific pathology reports (tumor size, number of lymph node metastasis, lympho-vascular invasion, skin and muscle invasion, extra nodal extension) and neoadjuvant chemotherapy were not factors affecting prolong seroma according to this study and the literatures reported.[8-10,15]

Conclusion

Flap fixation technique can reduce volume of fluid from drain and the incidence of seroma when compare to conventional technique. BMI and number of axillary node harvest were factors affecting prolong seroma formation after discharge. The complications were not different between two groups. Flap fixation can be performed safely without requiring any specific instruments and there is no effect on the additional operative time. Flap fixation technique is recommended generally due to uncomplicated procedure.

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