

Title Seroma formation after modified radical mastectomy with flap fixation technique in breast cancer patients: Nakhonphanom hospital – a single blinded randomized control trial.

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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 Nakhonphanom hospital were screened.

Inclusion criteria

1. All operable breast cancer patients who were 18 years old and over.
2. Early and locally advance breast cancer who underwent modified radical mastectomy.
3. Operable case, resectable case.

Exclusion criteria

1. Pregnant women.
2. Patients who did not consent to participate in this study.
3. Immunocompromise patients.
4. Patients who need oncoplastic reconstruction, previous aesthetic breast surgery or previous lymphatic system surgery at axillary area.
5. Patients with coagulopathy problems such as liver cirrhosis or bone marrow dysfunction. (patients taking aspirin were included)
6. Patients who were lost to follow up or have serious medical complication during admission.

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. 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 7th day after operation. After discharge from hospital, all patients were followed up at outpatient department on the 7th – 10th day, 15th- 20th day, then every 3 weeks until 3 months. 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.

Data collection format

Data were collected from history talking, medical records, operative notes and records and information in follow up period. Data collection format is con-current prospective randomization, divide participants into two groups randomly. The first group is the conventional group. (non-flap fixation group, n=34) The second group is the intervention group (flap fixation group, n=34)

Randomization process

After inform and sign in information sheet, each participant was numbered randomly. This number was randomized by computer as 1:1 ratio. The random table was created as block of four by the statistician who had no involvement in this study.

Concealment information and declaration

The participants were randomized into two groups. They were uninformed of their own group. Each participant was numbered, respectively. The identification number for this study was created randomly by the statistician and enveloped then sent to the nurse. There was no one who recognized the number and groups. All information was kept in the cabinet in the research office, Nakhonphanom hospital where no one can access. In case of the researcher suggesting that there is a necessity to declare any information of the participants, the researcher will report to the institutional ethics committee.

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 were $p\text{-value} < 0.05$. 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 to account for repeated measures for outcomes of interest. Logistic regression analysis was used to analyze the factors affecting prolonged seroma formation after discharge.

Statistical analysis plan

Patient's 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 were $p\text{-value} < 0.05$. 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 to account for repeated measures for outcomes of interest. Logistic regression analysis was used to analyze the factors affecting prolonged seroma formation after discharge.