

Role of Autologous Fibrine Glue to Decrease Seroma Volume On 14th Post Operative Day in Carcinoma Mamae Patients that Underwent Simple Mastectomy

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Abstract

Background. Seroma is the most significant complication that occurred after mastectomy, happen in 25% until 60% cases. Seroma are not life threatening complications, but can lead to serious morbidity, prolonged hospital stay and delay adjuvant therapy. Autologous Fibrin Glue is a hemostatic agent that can accelerate fibrin thread formation, stop vascular oozing and decrease dead space. This research was performed to evaluate Autologous Fibrin Glue function in lowering seroma volume at 14th days after simple mastectomy.

Methods. This research is a clinical trial to compare average seroma volume between advance stage locally breast carcinoma patients group which are given Autologous Fibrin Glue on the surface of surgical wound, 14 days after simple mastectomy (trial group) and control group (without special treatment) with ultrasonography.

Result. From 42 patients who met the inclusion criteria, divided into 2 groups, 21 patients were given Autologous Fibrin Glue on the surgical wound surface in a simple mastectomy procedure, 21 patients as a control group. The number of seromas in the treatment group was measured using ultrasound on the 14th day, fewer meaningfully than the control group, the median seroma volume in the treatment group was 9,30 mL and median seroma volume in the control group was 20.90 mL. The P value in the variable number of seroma is smaller than 0.05 (P. < 0.05) which means significant, the number of seromas measured using ultrasonography (USG) on the 14th day, fewer meaningfully in the treatment group.

Conclusion. Subjects that was given Autologous Fibrin Glue on the surface of surgical wound after simple mastectomy has a lower volume of seroma compared to control group.

Keywords: Autologous Fibrin Glue, seroma, simple mastectomy

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Introduction

Breast cancer is the second leading cause of death in the United States, with an incidence of about 210,000 new cases and causing more than 40,000 deaths each year. Operative management for breast cancer are divided into breast-conserving therapy and mastectomy with or without axillary lymph node dissection depending on the stage of the disease.^{1,2}

Seroma formation is an after surgery complication that most often occurs after mastectomy, with an incidence of 3% to 50%³ according to research conducted by Junior in 2010 at the Sub Division of Oncology Surgery Dr. Hasan Sadikin Hospital Bandung, the incidence of seroma after mastectomy was 62.5%.⁷ Although seroma is not a life-threatening complication, it can lead to skin flap necrosis, pain, infection, delayed wound healing, reopening of the surgical wound, predisposing to sepsis, and lymphedema. In addition, excessive fluid collection will stretch the skin so that it becomes saggy and cause discomfort to the patient.^{2,4,5} These things can interfere with the healing process, prolong in hospital stay^{8,11} and delay the provision of further therapy.^{7,9} Fibrin glue has been used in surgical procedures for more than 30 years.

Fibrin glue as a hemostatic and tissue adhesion agent has evolved in a variety of surgical procedures, including heart, eye, blood vessel, liver, prostate, thoracic, cosmetic, orthopedic and gynecological surgery.¹⁶ Numerous studies have shown fibrin glue can help prevent seroma formation in animal mastectomy,¹⁷⁻¹⁹ these underlie the use of fibrin glue in humans. By increasing hemostasis and tissue adhesion, fibrin glue theoretically could prevent seroma formation by reducing the accumulation of seroma fluid after surgery, which occurs as a result of inflammation and transection of several small and lymphatic vessels during removal of the breast and axillary lymph nodes.¹³

Allogeneic material in commercial fibrin glue is expensive in the manufacturing process, it can also cause allergic reactions so that clinicians have begun to switch to using materials derived from the patient own blood and are cheaper in the manufacturing process but have a similar effect, namely Autologous Fibrin Glue²² is believed to have several advantages over commercial fibrin glues which are much more expensive. Autologous Fibrin Glue is taken from the patient own blood, to be used topically, safe

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from infectious diseases, and does not cause allergic reactions such as bovine thrombin contained in commercial fibrin glue.^{22,25}

The Making process of Autologous Fibrin Glue has been carried out by the Department of Clinical Pathology, Dr. Hasan Sadikin Hospital Bandung, Faculty of Medicine, Padjadjaran University.^{1,4}

Based on previous theory and research, the researcher will conduct research on giving Autologous Fibrin Glue after mastectomy surgery on the basis of surgical wounds, to see the effect of reducing seroma formation measured after the acute phase of wound healing is estimated to end on day 14.

Method

Experimental study design and was conducted in a single blind randomized controlled trial in both groups, the locally advanced breast carcinoma group that was given Autologous Fibrin Glue topically on the wound surface after simple mastectomy surgery and the control group without special treatment with 5 days of treatment. After surgery, the control group patient on day 7th went to the oncology surgical clinic and assessed whether there were any exclusion criteria for the patient, namely the state of the surgical wound. On 14th day,

control patient undergo an ultrasound examination of the surgical wound area performed by 1 person equal to the level of Chief Resident under the supervision of the ultrasonography consultant. The data obtained were recorded in a special form and then processed through the SPSS version 24.0 for Windows program.

Result

The number of research subjects for each group amounted to 20 people so that the total subjects in this study were 40 people. In this study, 10% of patients were excluded, 4 patients out of 44 patients due to flap necrosis and intact wounds due to infection. This has met the minimum required sample size. Research subjects were grouped into 2 groups, namely: the control group and the treatment group. The control group is a group of patients with breast carcinoma who underwent simple mastectomy and were not given special treatment. The treatment group was a group of patients with breast carcinoma who underwent a simple mastectomy and then given 4cc topical Autologous Fibrin Glue on the surface of the surgical wound. Then the two groups of research subjects performed surgical wound closure with

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layer by layer stitches. The characteristics of research subjects in general can be seen in (Table 4.1). Table 4.1 describes the characteristics of research subjects based on age, weight, height, body mass index and chest circumference.

The overall average age of the study subjects was $47.35 \pm 10,329$ years, the average overall body weight of the study subjects was $56.03 \pm 8,248$ kg. The overall mean height of the research subjects was 1.56 ± 0.047 meters, and the overall mean BMI of the study subjects was 23.13 ± 3.205 . The average chest circumference of research subjects was $85.03 \pm 15,129$ cm.

For this numerical data analysis, unpaired T-test is used if the data is normally distributed, namely Height, BMI and Chest Circumference, as well as an alternative to the Mann-Whitney test if the data is not normally distributed, namely Age and Weight. Test results statistics on research subjects obtained P-value information on variable Age, Weight, Height, BMI and Chest greater than 0.05 ($P \text{ value} > 0.05$) which means insignificant or insignificant statistically, it can be explained that there is no mean statistically significant difference between the variables Age, Weight, Height, BMI and Chest in the

Autologous Fibrin Glue group with the Control Group.

Based on characteristics comparison between two groups, it can be concluded that the two groups are the same or homogeneous so that it is feasible to be compared and further statistical hypothesis testing is carried out.

In treatment groups, the mean hemoglobin level was $11.39 \pm 1,577$ g / dL, mean PT was 11.33 ± 1.292 seconds, the mean APTT was $27.61 \pm 3,700$ seconds, the mean INR was 0.90 ± 0.053 . While the mean platelet count was 283.45 ± 79.607 / uL, the mean fibrinogen level was 399.47 ± 117.650 mg / dL and the average albumin level was 3.38 ± 0.463 g / dL.

In the control group, the mean hemoglobin level was 11.14 ± 1.628 g / dL, the mean PT was 12.55 ± 2.397 seconds, the mean APTT was 28.09 ± 4.603 seconds, the mean INR was 0.92 ± 0.076 . While the average platelet count was $251.55 \pm 108,965$ / uL, the mean fibrinogen level was 375.71 ± 47.190 mg / dL and the average albumin level was 3.35 ± 0.395 g / dL.

For this numerical data analysis, it was tested using an unpaired T-test if the data were normally distributed, namely Hemoglobin, APTT, Fibrinogen and Albumin and the alternative Mann Whitney

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test if the data were not normally distributed, namely PT, INR and the number of platelets.

In the Treatment group, the median number of seromas examined using ultrasound on day 14 was 9.30 mL. Whereas in the control group, the median number of seromas examined using ultrasound on day 14 was 20.90 mL.

This numeric data tested using *Mann-Whitney test* because the data is not normally distributed. Results of statistical tests in the research group above obtained a P value on variable Seroma number less than 0.05 (P value <0.05) which means significant.

Thus, it can be concluded that the number of seromas measured using ultrasound on day 14 was significantly less in the group receiving Autologous Fibrin Glue compared to the control group.

Discussion

This study involved 42 research subjects who met the inclusion criteria. The research subjects were then divided into 2 groups, namely a control group of 21 subjects, who did not receive special treatment and a treatment group of 21 subjects who received 4 cc of topical

Autologous Fibrin Glue on the surface of the surgical wound.

P value obtained from (**Table 4.3**) ($p > 0.05$) it can be concluded that the variables of hemoglobin levels, PT, APTT, INR, platelet counts, fibrinogen levels and albumin levels in the treatment and control groups were not significantly different.

Result of the statistical calculations from (**Table 4.2**) show that the two groups were homogeneous based on BMI, so there is no bias caused by obesity as one of the factors affecting seroma production, and hypoalbumin (**Table 4.3**) as a factor that can inhibit wound healing. As suggested by Karakaya et al⁹, obesity has a direct relationship to the number of seromas. Another study, from Barnejee et al.⁴³ where there is a linear relationship between BMI addition and seroma production.

(**Table 4.4**) points out that seroma count in the treatment group which was measured using ultrasound at day 14, was significantly less compared to the control group, where in the median total seroma volume on day 14 in the treatment group was 9.30 ml, and the median in the control group was 20.90 ml. P value in the seroma variable amount less than 0.05 (P value <0.05) which means significant. Thus number of seromas measured using USG on

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day 14 was significantly less in the treatment group.

This result is in line with a study conducted by Mahmood Reza et al., 2012¹⁸ which sprayed 4 cc commercial fibrin glue on the wound bed of patients after mastectomy, where the result was that 16% formed seromas in the treatment group and 24% in the control group.

The systematic review and meta-analysis conducted by Carless, 2006²⁵ showed that no significant differences were found between patients who were given fibrin glue and patients who were not given fibrin glue. There are several factors that influence this, namely the heterogeneity of the research patients carried out, the inadequacy of research methods such as varying the volume of fibrin glue given ranging from 2 ml - 24 ml, varying types of breast surgeries performed such as modified radical mastectomy, lumpectomy, axillary lymph node dissection, segmental mastectomy and total mastectomy.

The same thing was explained in research by Lyneette, 2005²¹ who gave fibrin glue to post mastectomy patients, the result did not show a significant difference to patients who were not given fibrin glue. In this study, the cause of the absence of significance was known because various

methods were used in the mastectomy technique. Of the 82 participants, 10 participants (12.2%) underwent a simple mastectomy alone, 22 participants (26.8%) underwent simple mastectomy simultaneously with axillary lymph node dissection or sentinel lymph node biopsy, 25 participants (30.5%) underwent surgery breast conservation, 23 participants (28.1%) underwent modified radical mastectomy, and 2 participants (2.4%) underwent nodule dissection, this causes bias in the form of heterogeneity of research methods. In addition, this study compared patients who were given fibrin glue without drainage and patients who were not given fibrin glue but used drain. Therefore, in this study, although fibrin glue tended to have more seromas.

Limitation of this study is the study subjects were only patients who underwent a simple mastectomy, whereas based on the study from Kuroi et al.¹⁵ one of the main risk factors for seroma formation was the radicality of surgery and axillary lymph node dissection, due to the amount of lymphovascular leakage and oozing of small blood vessels from the procedure..

In this research the patient response to chemotherapy must be measured and grouped because the residual tumor is

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attached to the muscle tissue so that the border of the incision is not tumor-free which will affect the number of seromas. In this study, the amount of Aquabides liquid used when washing the base of the surgical wound was not equalized in order to reduce bias for surgery. This study was also not accompanied by data on how to treat wounds and dressings patient wound and data on the type of antibiotic consumed by the patient.

Conclusion

Applying Autologous Fibrin Glue to the surface of the surgical wound can reduce the number of seromas in simple mastectomy patients.

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Conflict of Interest

None

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Tables and Pictures

Table 4.1 Characteristics of Research Subjects

Variable	N = 40
Age (years)	
Mean ± Std	47.35 ± 10,329
Range (min-max)	26.00-84.00
Weight (Kg)	
Mean ± Std	56.03 ± 8,248
Range (min-max)	44.00-80.00
Height (m)	
Mean ± Std	1.56 ± 0.047
Range (min-max)	1.45-1.65
BMI (%)	
Mean ± Std	23.13 ± 3.205
Range (min-max)	17.60-33.30

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Chest diameter (cm)

Mean \pm Std 85.03 \pm 15.129

Range (min-max) 52.00-114.00

Note: Categorical data are presented with number / frequency and percentage, while numerical data are presented with mean, median, standard deviation and range.

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Table 4.2 Comparison between the Characteristics of the Study Subjects of patients in the Treatment and Control Groups.

Variable	Group		P value
	Autologous Fibrin Glue N = 20	Control N = 20	
Age (years)			0.602
Mean ± std	49.00 ± 12,118	45.70 ± 8,151	
Range (min-max)	26.00-84.00	28.00-54.00	
Weight (Kg)			0.779
Mean ± std	55.80 ± 8,995	56.25 ± 7,656	
Range (min-max)	44.00-75.00	44.00-80.00	
Height (m)			0.277
Mean ± std	1.56 ± 0.046	1.55 ± 0.049	
Range (min-max)	1.45-1.65	1.45-1.65	
BMI			0.434
Mean ± std	22.73 ± 3.070	23.53 ± 3.365	
Range (min-max)	18.70-29.30	17.60-33.30	

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Chest diameter (cm) 0.491

Mean ± std 86.70 ± 16,986 83.35 ± 13.244

Range (min-max) 52.00-114.00 55.00-110.00

Note: For numerical data, the p value is tested using unpaired t test if the data is normally distributed with the alternative Mann Whitney test if the data is not normally distributed. Significance value based on p value <0.05 Sign * indicates p value <0.05 means significant or statistically significant.

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Table 4.3 Comparison between Laboratory Results research subject in the treatment group and the control group.

Variable	Group		P value
	Treatment N = 20	Control N = 20	
Hemoglobin (g / dL)			0.625
Mean ± std	11.39 ± 1,577	11.14 ± 1,628	
Range (min-max)	8.80-13.90	8.30-13.80	
PT (seconds)			0.060
Median	11.35	12.35	
Range (min-max)	9.80-13.30	10.10-21.10	
APTT (seconds)			0.718
Mean ± std	27.61 ± 3,700	28.09 ± 4,603	
Range (min-max)	20.00-36.00	20.10-41.70	
INR			0.583
Median	0.90	0.90	
Range (min-max)	0.80-1.01	0.83-1.12	

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Platelets (10⁵ / uL)			0.165
Median	263.50	238.50	
Range (min-max)	158.00-429.00	103.00-597.00	
Fibrinogen (mg / dL)			0.407
Mean ± std	399.47 ± 117,650	375.71 ± 47.190	
Range (min-max)	151.50-678.00	270.90-496.60	
Albumin (g / dL)			0832
Mean ± std	3.38 ± 0.463	3.35 ± 0.395	
Range (min-max)	2.50-4.00	2.66-4.29	

Note: For numerical data, the p value is tested by using an unpaired t test if the data is normally distributed, with the alternative Mann Whitney test if the data is not normally distributed. Significance value based on p value <0.05 Sign * indicates p value <0.05 means significant or statistically significant.

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Table 4.4 Comparison of Seroma Number on day 14 with USG in the Treatment and Control groups.

Variable	Group		P value
	Treatment	Control	
	N = 20	N = 20	
Seroma count (mL) on 14th day by ultrasound			0.005 *
Median	9.30	20.90	
Range (min-max)	0.33-50.30	0.00-40.40	

Note: For numerical data the p value is tested by using unpaired t test if the data is normally distributed with the alternative Mann Whitney test if the data is not normally distributed. The significance value was based on p value <0.05. The * sign indicates a p value <0.05, which means that it is significant or statistically significant.