

Clinical Science

Effectiveness of an absorbable fibrin sealant patch to reduce lymphoceles formation after axillary lymphadenectomy for breast cancer: a matched-pair analysis



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Abstract

BACKGROUND: This study evaluated the use of TachoSil as an adjunctive therapy for reducing axillary lymphocele formation.

METHODS: Eighty-six patients diagnosed with breast cancer N+ and treated with axillary lymphadenectomy received a TachoSil patch in the axillary wound. Using a database of patients without placing a hemostatic patch, we applied a matched case-control in a 1-to-2 fashion. Multiple and logistic regression analyses were used to evaluate postoperative results.

RESULTS: Patient group with TachoSil showed a significantly lower drainage volume ($P < .001$) and the length of stay was significantly shorter ($P < .001$). The number of patients with evacuative punctures was 24.5% in the group with patch versus 51.2% in the control group ($P < .001$). In multivariate analysis, the use of TachoSil was a significant predictor of reducing axillary drainage volume ($P < .001$), mean length of hospital stay ($P = .001$), and number of evacuative punctures of lymphocele (odds ratio .264, 95% confidence interval .144 to .484, $P < .001$).

CONCLUSION: The use of TachoSil in axillary lymphadenectomy may be a safe and useful treatment option for reducing axillary drainage volume, incidence of symptomatic lymphocele, and hospital stay.
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Sentinel lymph node biopsy has become a revolutionary procedure for axillary evaluation and staging in patients with early breast cancer. However, a large group of breast cancer patients with metastatic sentinel lymph node or clinically positive axilla are candidates for a standard level I and II axillary lymphadenectomy for prognostic and curative purposes.¹ The anatomic disruption caused by axillary lymph node dissection may result in complications that compromise

functionality and quality of life. Lymphocele is the most common problem after breast cancer surgery, with reported incidence rates ranging from 15% to 90%,²⁻⁵ although many authors view it as an unavoidable nuisance rather than a serious complication. Excessive collection of serous fluid is associated with wound infection, dehiscence, and skin flap necrosis, resulting in discomfort, prolongation of hospital stay, and a delay in adjuvant therapy, and most cases require multiple visits with manual evacuation of accumulated fluid.⁵⁻⁷

The etiology of this fluid collection seems to be multifactorial,⁸ such as oozing consequences on small vessels and lymphatic vessels injuries, the creation of a cavity caused by extensive dissection in axillary lymphadenectomy, surgical management, and several individual factors.^{9,10} Most studies have associated this subcutaneous accumulation of fluid with an inflammatory exudate, which may also be prolonged and intensified by the permanence of suction drainage.^{2,11} The surgical removal of draining lymph nodes may indicate that seroma might not represent a mere exudate and it has also been considered as an accumulation of afferent lymph.^{12,13} To date, no practical guidelines exist on conducting suction drainage and several approaches have been used to prevent lymphocele formation, including the use of skin flaps to seal the dead space,^{14,15} fibrin glue,¹⁶ fibrin sealant,¹⁷ and bovine thrombin application, using external compression dressing,¹⁸ ultrasound cutting devices,¹⁹ suction drainage systems,^{20,21} and others.

Fibrin glue-coated collagen path (TachoSil) is a sterile absorbable patch that consists of an equine collagen patch coated with fibrin glue components, human fibrinogen, and human thrombin. All coagulation and fibrinolytic factors are produced and secreted by lymphatic endothelial cells and are involved in the sealing of lymphatic capillaries. The efficacy and safety of TachoSil have been demonstrated in liver resection,²² pulmonary lobectomy,^{23,24} and kidney tumor resection²⁵ trials. Recent reports showed the efficacy of TachoSil with regard to accumulative chest drain volume, as well as the duration of chest intubation in patients undergoing mediastinal lymph node dissection for lung cancer.²⁴

The aim of the study is to evaluate the efficacy of TachoSil as an adjuvant treatment for reducing the volume and duration of postoperative axillary drainage after axillary node dissection in patients with breast cancer. Hospital stay and factors involved in the incidence and volume of lymphocele formation were secondary endpoints.

Patients and Methods

The study was conducted at a single center with a specialist breast unit. From March 2008 to December 2011, after obtaining signed informed consent, we evaluated 86 patients who had axillary lymph node positive breast carcinoma scheduled for either modified radical mastectomy or a quadrantectomy with complete axillary lymph node dissection plus TachoSil patches in the axillary bed (Group A). Using a database of 342 patients with N+ breast cancer

which required the same surgical procedure without TachoSil patch, performed during the same time period, matched case-control were identified in a 1-to-2 fashion (Group B). Each patient associated with TachoSil was matched to 2 patients without patch control. Cases were matched sequentially by applying the following criteria: American Society of Anesthesiologists category, patient age, surgical procedure (mastectomy or quadrantectomy), histologic type, tumor size, and neoadjuvant chemotherapy. Ethic approval was granted by the institutional ethics committee.

The exclusion criteria included the following a personal history of hypersensitivity or allergic reactions to fibrin glue components, human fibrinogen or human thrombin, evidence of coagulation disorders, planned breast reconstruction, bilateral mastectomy, previous surgery on the axillary lymphatic system, and have liver disease.

In all patients, the dissection involved the 3 axillary lymph node levels, preserving the long thoracic nerve and the thoracodorsal package. For the axillary lymphadenectomy, the vascular-lymphatic branches were ligatured or monopolar electrocoagulation was used. In Group A, TachoSil was placed at the axillary fossa, when axillary wound surface was too wide to be covered by a single patch, 2 TachoSil patches were used. In both patient groups, a suction drain was applied to the axillary wound, in which patients with modified radical mastectomy received 2 suction drains. Two wounds were closed with subcutaneous interrupted suture and a continuous intradermal suture line with an absorbable 3/0 thread. A strong compressive bandage was applied to the scar and axillary fossa for about 48 hours. Arm and shoulder exercises were started 8 hours after the surgery. Drains were connected to a suction bottle for measuring the daily drain output and were removed when the drainage volume was less than 50 mL/day. Some patients were discharged and controlled the drainage at outpatient clinic carrying with them the drain.

The variables recorded were hospital stay, postoperative days of drainage removal and daily drainage volume, number of lymphocele aspirations needed, body mass index (BMI), and postoperative complications. Continuous variables were compared using Student *t* test. Categorical data were compared using chi-square test and converted to proportions before analysis when applicable. Multiple and logistic regression analyses were used to investigate postoperative outcomes. Factors with a significance level of *P* less than .05 on bivariable analysis were included in the regression analyses. Forward logistic regression models and stepwise multiple regression models were used to determine significant predictors. A *P* value of less than .05 was considered statistically significant.

Results

Characteristics of the TachoSil cohort

Patient demographics are summarized in Table 1. Between March 2008 and December 2011, a total of 86 breast cancer

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