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Sealants after axillary lymph node dissection for breast cancer: good intentions but bad results

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Abstract

BACKGROUND: This study was conducted to evaluate the effect of 2 surgical sealants on postsurgical drainage and lymphocele formation after axillary surgery for breast cancer.

METHODS: This was a prospective, randomized study. Seventy-seven consecutive patients with breast cancer were included and randomized into a control group (18F vacuum drain) and 2 study groups (18F vacuum drain plus COSEAL or BioGlue).

RESULTS: The 3 groups were matched. Neither postsurgical drainage nor time to drain removal was affected by the use of either of the 2 sealants. Although no statistically significant difference in lymphocele formation and wound infection was noted, complications caused by intense foreign-body reaction that led to surgical intervention occurred in both study groups.

COMMENTS: The use of surgical sealants is not recommended after axillary lymph node dissection for breast cancer. Complications of their use may lead to reoperation.

Prolonged postsurgical drainage and lymphocele formation are significant complications after axillary lymph node dissection (ALND) for breast cancer. Lymphocele formation ranges from 3% to 50% in different series.[1] Known sequelae of these complications are increased rate of wound infection, dehiscence, and possibly delayed delivery of adjuvant therapy.[2] It can also cause minor problems, such as decreased mobility, arm swelling, poor cosmetic results, and prolonged hospitalization, which can be quite disturbing to the emotionally fragile, postsurgical breast cancer patient. The decrease in postsurgical drainage and early removal of the axillary drain would lead to early discharge from the hospital, decreased postsurgical morbidity, and less discomfort to the patient. Different methods of preventing lymphocele formation and decreasing drainage after ALND have been used (ie, surgical obliteration of axilla dead space,[3] shoulder immobilization,[4] or the use of pressure dressings),[5] but none has been proved to be beneficial.

In this context, many investigators have evaluated fibrin glue as an adjunct to the conventional vacuum drain with conflicting results.[6–10] In a small series of 40 patients, Vaxman et al prospectively evaluated fibrin glue in conjunction with a vacuum drain after axillary dissection for breast cancer and concluded that its use does not decrease postsurgical drainage. Furthermore, the rate of complication was significantly higher in the study group.[6] Ulusoy et al prospectively studied 54 patients with breast cancer that underwent modified radical mastectomy. He found no benefit of the use of fibrin glue in postsurgical axillary drainage and no difference in lymphocele formation or wound infection was noted.[7] Dinsmore et al reported on the effect of fibrin glue after modified radical mastectomy and found that its use increased time to drain removal as well as the complication rate. However, these differences did not reach

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statistical significance because of the small size of the series (27 patients).[8] In a prospective, randomized study of 82 patients, Johnson et al compared the use of fibrin glue with the use of Jackson-Pratt drain after several elective procedures for breast cancer (including simple mastectomy and SLND). No statistical difference was noted in lymphocele formation rate between the 2 groups; however, poor cosmetic results and extensive flap necrosis were noted in patients of the study group, which led to the withdrawal of 2 principal surgeons.[9] Moore et al concluded that the use of fibrin glue decreased total drainage and time to drain removal.[10] In that study, the mean time to drain removal for lumpectomy patients was 14.8 ± 9.6 days for the control group and 7.9 ± 3.4 days for the study group ($P < .05$). The period during which the drain was left in place for the control group was considerably longer that usual (14 vs 7 to 8 days in the literature). All wound infections in this study occurred in fibrin glue–treated lumpectomy patients.

COSEAL (Baxter Healthcare Inc., USA) is a completely synthetic sealant composed of 2 polyethylene glycol polymers that bond together to form a hydrogel. COSEAL has been mainly used for vascular anastomotic sealing. BioGlue (CryoLife Inc., USA) is an albumin-based compound in conjunction with glutaraldehyde. It has been used as an adjunct to standard methods of repair in vascular, pulmonary, and alimentary system surgery. Both products are Food and Drug Administration–approved for the previously mentioned indications and are available in the United States. The rationale behind their use is based on their ability to seal soft tissues. These 2 products were considered candidates for use after axillary surgery for breast cancer because of the possible sealing effect on small lymphatic vessels of the axilla damaged during ALND.

Based on the preceding concept, this study aimed at evaluating the effect of COSEAL and BioGlue on volume and duration of postsurgical drainage after ALND for breast cancer. Possible complications, such as lymphocele formation and wound infection, were also end points of this study.

Patients and Methods

A prospective, randomized study was conducted between October 2003 and November 2005 in the Breast Cancer Unit of the Department of Surgical Oncology of our hospital.

Eligibility

Patients were considered eligible if they were female, >18 years, and had undergone elective ALND for breast cancer that had been performed through a separate incision (mastectomy patients were excluded). Exclusion criteria were the systematic use of steroids or anticoagulation therapy, immediate breast reconstruction, and pregnancy. All patients signed an informed consent, and the study was approved by the Ethical Committee of our hospital.

Randomization

Patients were randomized into 3 groups. Group A was the control arm in which an 18F vacuum drain was placed in the axilla after ALND. Group B and C were the study arms in which BioGlue or COSEAL were used respectively after the placement of the vacuum drain. The surgeon was unaware of stratification until completion of the procedure. The attending nurse was responsible for randomization, which was made known to the operating surgeon just before wound closure.

Technique

All patients underwent levels I and II ALND. The patients in group A had the vacuum drain placed in the axilla after the completion of the ALND. Participants in groups B and C had 4 mL BioGlue or 4 mL COSEAL, respectively, applied to the axilla before the drain was placed and the skin closed. The material was applied mainly to the floor of the axilla cavity and the thoracic wall.

Drainage was measured daily, and postsurgical complications were systematically recorded. Patients were followed-up by the Breast Cancer Unit Outpatient Clinic. Drain removal took place when the daily drainage became <50 mL or on postsurgical day 15.

Data collection

Preoperative data included age, weight, and body mass index (BMI). Surgical data included type of surgery performed, number of lymph nodes removed, and pathologic staging of the patients. Postsurgical data included drainage through postsurgical day 4, total drainage, time to drain removal, duration of hospitalization, and occurrence of complications (lymphocele formation and infection of the axillary wound). Postsurgical day 4 was chosen because sealants presumably reach maximum efficacy at that time.

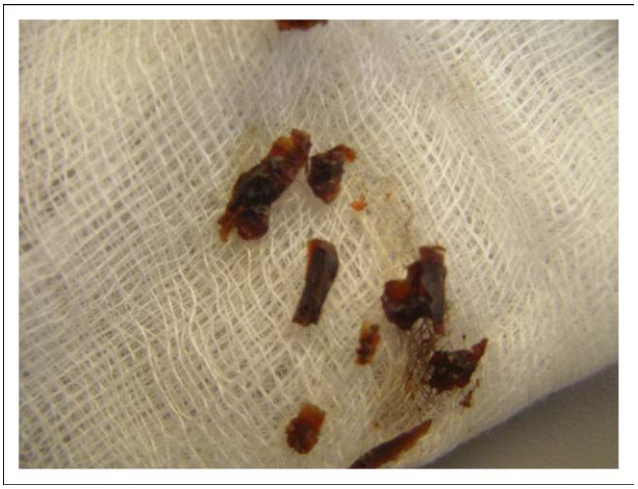

Figure 1 Reaction to sealants after axillary surgery.