

Can Gentamicin-collagen Sponges Prevent Seroma Formation Following Mastectomy?

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Abstract

A retrospective cohort study was performed and showed that gentamicin-collagen sponges significantly lower the seroma incidence following breast cancer surgery. The incidence of surgical site infections was halved, although this was not significant.

Background: The aim of this study was to investigate whether gentamicin-collagen (GC) sponges can lower the incidence of seroma and surgical site infections following breast cancer surgery. **Patients and Methods:** A retrospective cohort study was performed. Two consecutive cohorts of patients who underwent a mastectomy with or without an axillary lymph node dissection were compared. The first cohort was treated conventionally (n = 38), the second cohort received GC sponges (n = 39). Endpoints were the incidence of clinical significant seroma (CSS) and surgical site infections (SSI), the mean number of aspirations, and the mean aspirated volume. **Results:** GC sponges lowered the CSS incidence from 73.7% to 38.5% ($P = .002$). The mean number of aspirations and the mean aspirated volume were not affected. SSI incidence was 15.8% in the conventional cohort compared with 7.7% in the GC cohort ($P = .23$). **Conclusion:** Application of GC sponges significantly lowered the incidence of CSS. The incidence of SSI was halved, although this was not significant.

Clinical Breast Cancer, Vol. ■, No. ■, ■-■ © 2018 Elsevier Inc. All rights reserved.

Keywords: Axillary lymph node dissection, Breast cancer surgery, Garacol, Surgical site infections, Wound complications

Introduction

Seroma is the most frequently reported complication following breast cancer surgery, varying from 15.5% to 88.3%.^{1,2} Seroma is a source of secondary problems such as pain, discomfort, and impairment of shoulder movement, often necessitating repeated aspirations to ease the symptoms. Furthermore, seroma increases the risk for surgical site infections (SSI) and skin flap necrosis.^{3,4} In some cases, resection of the seroma pseudo capsule is needed.⁵ Wound healing problems might be a reason for postponing adjuvant therapy. Considering the above and the accompanying budgetary impact of repeated visits to the outpatient clinic, decreasing the incidence of seroma has clinical and economic relevance.

The etiology of seroma formation is subject of ongoing research. Laboratory tests show that seroma fluid is most similar to inflammatory exudate and is different from serum and lymph fluid.⁶ The

size of the dead space under skin flaps and a large wound surface thus are promoting factors in seroma formation.⁷

A myriad of methods for prevention of seroma have been studied. Most methods are ineffective or show inconsistent results. Wound closure to reduce dead space seems to be a consistently effective intervention but may be an expensive method because of the time investment in the operation room.^{8,9} A barely investigated method for seroma prevention is the use of gentamicin-collagen (GC) sponges. One randomized controlled trial has been performed investigating the use of these biologically absorbable sponges in breast cancer surgery.¹⁰ Significant differences in seroma incidence were found between patients receiving a GC sponge and the control group.

We performed a power-based retrospective analysis of 2 consecutive cohorts of patients with breast cancer following mastectomy (simple or in combination with axillary lymph node dissection). The first group underwent conventional wound closure, the second group received GC sponges placed under the skin flap before wound closure. The incidence of seroma and SSI were compared between the 2 groups.

Patients and Methods

We retrospectively analyzed 2 consecutive cohorts of patients who underwent a simple mastectomy (ME) or a ME in combination with an axillary lymph node dissection (ALND). In 1 cohort, 39

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Submitted: Dec 8, 2017; Revised: Feb 23, 2018; Accepted: Feb 26, 2018

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patients received 2 GC sponges, which were placed on top of the pectoral muscle prior to wound closure. No sponges were placed in the axilla. In a second cohort, conventional wound closure was performed on 38 patients. The research was reported to and approved by the local medical ethical committee; female patients of 18 years and older who underwent mastectomy with or without an ALND were eligible for inclusion. All surgery was performed by 4 dedicated breast surgeons (FvdW, FP and LS) from September 2009 to January 2013 in a high-volume breast clinic. GC sponges were placed starting from January 2012. Patients receiving an immediate breast reconstruction were excluded. Data was retrospectively extracted from the electronic patient file, according to the code of conduct for medical research. Per protocol, each patient visited a nurse practitioner or surgeon at the outpatient clinic within 10 to 14 days following surgery. Drain policy, type of pressure dressing, and advice regarding shoulder movement were the same in both cohorts.

Surgical Technique

Breast cancer surgery was performed according to a standardized technique. Per protocol, all patients undergoing ALND received prophylactic antibiotics (cephazolin 1 gram) 15 to 60 minutes before incision. Patients undergoing simple ME did not receive antibiotic prophylaxis. In both cohorts, ME was performed with electrocautery, preserving thin skin flaps and the major pectoral muscle, preferably leaving the pectoral fascia intact. Choosing the incision 1 to 2 cm cranial of the inframammary fold resulted in a relatively large cranial skin flap and a low lying scar. In all patients, a low-vacuum drain was placed in the direction of the axilla. The skin flaps were brought together and sutured with a running 4/0 glyconate suture (Monosyn, B. Braun, Melsungen, Germany), after a subcutaneous polyglycolic acid 0 (Safil, B. Braun) running suture. The bandage consisted of butterfly stitches and thin adhesive strips, applied longitudinally. A large surgical gauze was placed on top, held in place with an elastic adjustable compressive bandage for 5 days (Tubigrip Abdominal Support R). The drain was removed within 36 hours following surgery, regardless of the production. All patients received the same written advice promoting progressive shoulder mobilization from the first postoperative day.

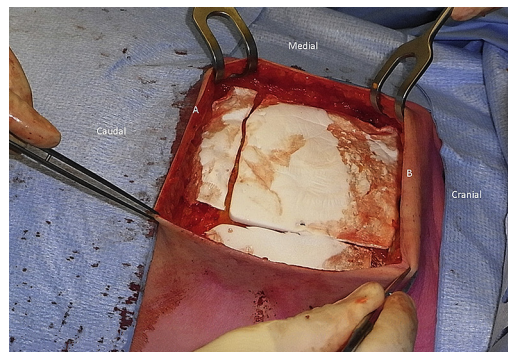
GC Sponges

Prior to wound closure, 2 GC sponges (Garacol) were placed on top of the major pectoral muscle, providing complete coverage (10 × 10 cm; 130 mg gentamicin each) (Figure 1). Gentamycin is a member of the aminoglycoside antibiotics. Nephro- and ototoxicity are feared complications of overdosing aminoglycosides. The application of 2 sponges results in a local dose of 260 mg. This dose is lower than the average indicated systemic treatment for adults, but the local gentamicin concentration that is reached is higher. The risk for overdose-related complications is virtually nonexistent.¹¹

Endpoints

The main endpoint was clinical significant seroma (CSS) formation, defined as a clinical palpable subcutaneous collection aspirated at least once after removal of the drain. Secondary endpoints were the median frequency and volume of aspirations and surgical site infection (SSI). Because we are reluctant to perform an aspiration, only symptomatic seromas were aspirated, depending on the patient's burden and after

Figure 1 Left simple mastectomy, a 10 × 10 cm gentamicin-collagen sponge lies central-medial, and the 2 halves of another sponge lie infero-lateral and cranio-lateral, thus completely covering the thoracic wall muscles. A, Caudal skin flap; B, cranial skin flap



consultation with the patient. SSI was diagnosed based on the Centers for Disease Control guidelines and included cellulitis.¹²

Patients' Characteristics

The patient characteristics were selected based on the assumed risk factors found in the literature. Age, body mass index, hypertension, ALND, neoadjuvant chemotherapy, and lymph node positivity were selected.^{1,8,9,13,14}

Statistical Analyses

Statistical analyses were performed using SPSS version 19. Statistical significance was defined as a *P*-value < .05. Data was compared using the Student *t* test, the Mann-Whitney *U* test, and χ^2 analysis. Patient characteristics and results were presented as median, mean value with standard deviation, and frequencies with percentages.

Results

Seventy-seven patients were included in the GC group. The patient characteristics showed no significant differences between the GC and the conventional group (Table 1).

Table 1 Patient Characteristics

| | GC Group (n = 39) | Conventional Group (n = 38) | P Value |
|--|----------------------|--------------------------------|------------------|
| Age, y | 63.21 ± 14.84 | 64.47 ± 13.13 | .69 |
| BMI, kg/m ² | 25.28 ± 4.79 | 26.01 ± 3.76 | .27 ^a |
| Hypertension | 16 (41.0) | 16 (42.1) | .55 |
| Breast tissue removed, cm ³ | 1674 ± 1218 | 2139 ± 1012 | .09 |
| Neoadjuvant therapy | 3 (7.7) | 2 (5.3) | .51 |
| ALND | 6 (15.4) | 4 (10.5) | .39 |

Data presented as mean ± standard deviation and frequencies with percentages. Abbreviations: ALND = axillary lymph node dissection; BMI = body mass index; GC = gentamicin-collagen.
^aMann-Whitney *U*.

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