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# Intraoperative placement of MammoSite for breast brachytherapy treatment and seroma incidence

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#### ABSTRACT

**PURPOSE:** To identify possible risk factors for development of clinically significant seroma (CSS) (seroma requiring intervention) and to report on incidence of infection after intraoperative placement of MammoSite for breast brachytherapy.

METHODS AND MATERIALS: Fifty-eight postmenopausal patients with early stage breast cancer and no nodal metastases, treated with partial breast irradiation using the MammoSite catheter from June 2003 to November 2007 were analyzed retrospectively for CSS predictive factors and incidence of infection. After a lumpectomy, a MammoSite catheter was placed by intraoperative open-cavity technique (OCT). All the patients received wound care and prophylactic antibiotics. A dose of 3400 cGy was prescribed at 1 cm from the surface of the balloon and was delivered at 340 cGy twice daily 6 h apart for 5 days. The patients with seroma who underwent intervention were considered to have CSS. On the basis of the characteristics and symptoms associated with seroma, interventions, such as aspiration, core biopsy, or re-excision of the lumpectomy cavity were performed either to relieve symptoms or to rule out a local recurrence.

**RESULTS:** Fifty-seven of the 58 patients were eligible for analysis. One patient, who died 4 weeks after treatment from unrelated causes, was excluded from final analysis. All the patients were postmenopausal, with a median age of 71 years (range, 53–88 years). Eighteen of the 57 patients (31.5%) had CSS; 9 of them had re-excision of the lumpectomy cavity. Pathology in all revealed evidence of fat necrosis, chronic inflammatory cells, and fibrosis. There was no evidence of tumor recurrence in any of these patients. Technical and nontechnical parameters were analyzed to determine possible risk factors for CSS, and none were found to be statistically significant. No patient developed acute postprocedural infection.

**CONCLUSIONS:** Meticulous wound care and postoperative antibiotics prevented acute infection. Infection was not a contributing factor for seroma formation in these patients. Placement of the MammoSite catheter by OCT did not increase the risk of CSS development, in postmenopausal breast cancer patients. Published by Elsevier Inc.

Keywords:

MammoSite; Accelerated partial breast irradiation; Seroma; Breast brachytherapy; Open-cavity technique

#### Introduction

Accelerated partial breast irradiation (APBI) is a treatment option for breast conservation therapy. The National Surgical Adjuvant Breast and Bowel Project and The Radiation Therapy Oncology group are investigating regarding the optimal target volume of whole breast vs. partial breast irradiation in early breast cancer patients. There are several techniques and applicators available for APBI, including multicatheter interstitial brachytherapy, MammoSite device (Cytyc Corp., Marlborough, MA), newer multilumen catheters namely SAVI, Contura, ClearPath, intraoperative irradiation with HAM applicator, intraoperative electron beam therapy, computerized tomography—based three-dimensional external beam, intensity modulated radiation therapy, and proton beam therapy. Multicatheter interstitial brachytherapy has a low recurrence rate and favorable cosmesis (1—3), but requires significant training

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and expertise. MammoSite is a single catheter balloon device, which is placed intraoperatively by the open-cavity technique (OCT) or postoperatively by closed-cavity technique. Published pooled multi-institutional results using the MammoSite Radiation System demonstrated favorable local control and cosmesis (4). However, acute skin reactions, infections, seroma formation, telangectasia, breast pain, edema, and pigmentation continue to be reported (4).

Seroma development after MammoSite brachytherapy has incidence rates ranging from 9% to 79% (5–7). The incidence of seroma and infection is higher when OCT is used (7). Herein, we examine the incidence of infection, as well as contributing factors for clinically significant seroma (CSS), in postmenopausal patients treated with APBI using the MammoSite Catheter.

#### Methods and materials

#### **Patients**

Fifty-seven patients were included in the analysis; 1 patient was excluded because she expired 4 weeks after her treatment because of causes unrelated to her breast cancer. The patients were eligible for APBI with Mammo-Site if they were postmenopausal, had either invasive ductal carcinoma or ductal carcinoma *in situ*, had tumors no larger than 3 cm, had no evidence of nodal metastases or lymphovascular invasion, had margins of 1 mm or greater, had a balloon surface to skin distance of 7 mm or greater, and air gaps of 10% or less of the treatment volume.

#### Patient treatment

A radiation oncologist was present and actively participated in the placement of the catheter in the operating room. After lumpectomy and sentinel lymph node biopsy, the MammoSite catheter was placed into the lumpectomy cavity through a small lateral incision. In all the cases, a spherical balloon measuring 4–5 cm was used. A computerized tomography scan was performed 1–5 days after surgery for treatment planning. Three-dimensional images were evaluated to assess the conformality, skin distance from surface of balloon, air gaps, and highest dose regions in the target area.

Planning was performed using Eclipse Brachyvision planning system. Before each treatment, imaging was performed using X-ray or fluoroscopy to assure integrity of the balloon. The high-dose-rate brachytherapy treatments were delivered using <sup>192</sup>Ir as the source. A total dose of 3400 cGy in 10 treatments, delivered twice daily 6 h apart in 5 days, was prescribed at 1 cm from the surface of the balloon.

Treatment began within 2–9 days (mean, 5.2 days) of MammoSite placement. Prophylactic antibiotics were prescribed from the day the catheter was placed through the last day of treatment. Based on allergy profile of the

patient, the antibiotic was either cephalexin 500 mg every 6 h or levofloxacin 500 mg once a day taken orally. Meticulous wound care using betadine and dressing change was performed at least once a day and twice a day depending on the dry status of the dressing. The patients were instructed to avoid showers or baths to keep the breast dry during the course of the treatment. After the last treatment, the balloon was deflated and removed. The patients were instructed to return for a followup appointment in 48–72 h to evaluate the closure of the lateral incision of catheter placement. When margin status was not satisfactory, the balloon was removed and the patients underwent re-excision of the lumpectomy cavity followed by a new attempt at MammoSite balloon placement.

A followup examination of the patients was performed after 1 month, followed by appointments every 3 months for the first 2 years, and every 6 months thereafter, either by the radiation oncologist or the surgeon. The median followup time of the 57 patients eligible for analysis was 28 months (range, 4-53 months). Mammograms were performed at 6 months and annually thereafter. Sonograms and/or magnetic resonance imaging of the breast were performed at the discretion of the radiologist, radiation oncologist, or surgeon. Detection of seroma was documented either clinically or by radiology. The decision to perform a specific intervention was based on the recommendation of the individual surgeon to either relieve the symptoms of seroma or to rule out a local recurrence from a persistent seroma. Persistent seroma was defined as seroma that was clinically detectable more than 6 months after radiation therapy (6).

Intervention was based on the characteristics and symptoms associated with seroma. The patients were considered to have CSS when they underwent interventions, such as aspiration, core biopsy, or re-excision of the lumpectomy cavity, either to relieve symptoms or to rule out a local recurrence.

### Data collection

Overall rate of seroma development was assessed by clinical examination or radiology. The patients with seroma requiring intervention were categorized as patients with CSS and the others as without CSS. (Patients with minimal postoperative fluid in the lumpectomy bed detected only by radiology and patients without any palpable seroma were categorized as patients without CSS.) Variables analyzed include nontechnical parameters such as tumor size, stage, laterality, quadrant location, adjuvant chemotherapy, hormone therapy, and postprocedure infection rate. The technical parameters, related to the MammoSite procedure, were balloon size, balloon volume, the number of days the balloon was in place (dwell time), balloon-to-skin distance, percentage volume of tissue enclosed by the 100%, 150%, and 200% isodose lines ( $V_{100}$ %,  $V_{150}$ %,  $V_{200}$ %), and the dose homogeneity index (calculated as  $[V_{100} - V_{150}] / V_{100}$ ).

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