Case Report

Accelerated partial breast irradiation using the strut-adjusted volume implant single-entry hybrid catheter in brachytherapy for breast cancer in the setting of breast augmentation

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ABSTRACT

PURPOSE: Accelerated partial breast irradiation (APBI) has gained popularity as an alternative to adjuvant whole breast irradiation; however, owing to limitations of delivery devices for brachytherapy, APBI has not been a suitable option for all the patients. This report evaluates APBI using the strut-adjusted volume implant (SAVI) single-entry catheter to deliver brachytherapy for breast cancer in the setting of an augmented breast.

METHODS AND MATERIALS: The patient previously had placed bilateral subpectoral saline implants; stereotactic core biopsy revealed estrogen receptor- and progesterone receptor-positive ductal carcinoma in situ of intermediate nuclear grade. The patient underwent needle-localized segmental mastectomy of her left breast; pathologic specimen revealed no residual malignancy. An SAVI 8-1 device was placed within the segmental resection cavity. Treatment consisted of 3.4 Gy delivered twice a day for 5 days for a total dose of 34 Gy. Treatments were delivered with a high-dose-rate 192Ir remote afterloader.

RESULTS: Conformance of the device to the lumpectomy cavity was excellent at 99.2%. Dosiometric values of percentage of the planning target volume for evaluation receiving 90% of the prescribed dose, percentage of the planning target volume for evaluation receiving 95% of the prescribed dose, volume receiving 150% of the prescribed dose, and volume receiving 200% of the prescribed dose were 97.1%, 94.6%, 22.7 cc, and 11.6 cc, respectively. Maximum skin dose was 115% of the prescribed dose. The patient tolerated treatment well with excellent cosmetic results, and limited acute and late toxicity at 8 weeks and 6 months, respectively.

CONCLUSIONS: Breast augmentation should not be an exclusion criterion for the option of APBI. The SAVI single-entry catheter is another option to successfully complete APBI using brachytherapy for breast cancer in the setting of an augmented breast. © 2011 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords: Accelerated partial breast irradiation; Breast augmentation; Brachytherapy; SAVI

Introduction

Accelerated partial breast irradiation (APBI) has gained popularity as an alternative to adjuvant whole breast irradiation (WBI) in select patient populations with early stage breast cancer (1). In 2005, the National Surgical Adjuvant Breast and Bowel Project and the Radiation Therapy Oncology Group activated National Surgical Adjuvant Breast and Bowel Project Protocol B-39/Radiation Therapy Oncology Group Protocol 0413, a randomized Phase III study of conventional WBI vs. partial breast irradiation.
(PBI) for women with Stage 0, I, or II breast cancer. This trial is still enrolling patients. However, in January 2007, the study discontinued accrual of patients considered to have low risk of local recurrence: patients ≥50 years old with ductal carcinoma in situ (DCIS), regardless of hormone-receptor status; and patients ≥50 years old with invasive breast cancer that is node negative and hormone-receptor positive (2).

The closure to enrollment of these patient populations prompted the publication of consensus guidelines on APBI by the American Brachytherapy Society (3), the American Society of Breast Surgeons (4), and, most recently, the American Society for Radiation Oncology (5). These guidelines outline selection criteria for patients to whom it is reasonable to offer APBI as a treatment alternative to WBI, with the caveat that long-term randomized data are not yet available to confirm that APBI and WBI are equivalent in terms of treatment efficacy.

The longest-term data on the efficacy of APBI are for multicatheter interstitial brachytherapy (6–8); however, the use of single-entry breast brachytherapy devices has markedly increased in recent years because they offer a treatment option that is simpler for both patient and physician (1). The MammoSite balloon (Hologic, Bedford, MA) led the way with a single-catheter device with single-dwell loading (9). However, the limitations of a single-catheter, single-dwell loading device soon became apparent. First, its use required a minimum balloon-to-skin spacing of 0.5 cm (preferably 0.7 cm) (9). Moreover, removal of the device was sometimes necessary because of insufficient distance from the skin and/or nonconformance of the breast tissue to the surface of the balloon. Nonconformance was because of air or fluid collecting near the balloon, pushing the targeted breast tissue out of the high-dose region. As a result, some patients were unable to receive APBI with the MammoSite balloon (10).

To address these issues, multidwell loading of a single catheter was implemented, providing some improvement in dosimetric control of the prescription isodose and the dose to normal tissues (9). Such hybrid catheters have been developed specifically for delivering breast brachytherapy. They attempt to combine the dosimetric versatility of multicatheter interstitial brachytherapy with the ease of placement of a single-entry device (10). The use of multiple catheters within the single-entry device improves the dose coverage of the targeted tissue while limiting the dose to the skin, pectoralis muscle, and rib cage. In addition, the newer catheters try to minimize the risk of nonconformance of the breast tissue to the device either by using vacuum ports to aspirate air or fluid near the device or by eliminating the balloon in hopes of improving drainage of air and fluid.

The strut-adjusted volume implant (SAVI) device (Cianna Medical, Aliso Viejo, CA) is a non–balloon-based, single-entry hybrid catheter designed specifically for delivering breast brachytherapy (11). The SAVI device consists of an expandable bundle of catheters with peripheral struts and is available in four different sizes. Its benefits include easier insertion and the ability to apply modulated radiation dosing to minimize the exposure of normal tissue.

Initial clinical experience with the SAVI in APBI has been promising (12). However, to our knowledge there are no published case reports in the peer-reviewed literature on the use of the SAVI to deliver brachytherapy for breast cancer in a patient with breast augmentation implants. Thus, we here present such a case to show that breast augmentation should not be an immediate exclusion criterion for single-entry catheter-based APBI.

**Methods and materials**

**Patient**

The patient was a 55-year-old postmenopausal woman who presented for her routine screening mammogram in July 2009, with a history of bilateral breast augmentation. The implants had been replaced several times, most recently with subpectoral saline implants that had been in place for 8 years. The patient had developed some capsular contracture and fibrosis, which was more noticeable in the left breast. Her mammogram results were abnormal and revealed suspicious calcifications at the 6 o’clock position in the left breast. A stereotactic core biopsy had been performed, and the pathologic examination had revealed DCIS of intermediate nuclear grade, solid and cribriform type, with necrosis and associated calcifications. Immunohistochemical studies showed the tumor cells were positive for estrogen receptor at 95% and for progesterone receptor at 95%.

In September 2009, the patient came to The University of Texas M. D. Anderson Cancer Center for further evaluation and treatment. A bilateral diagnostic mammogram showed punctate calcifications measuring 1.2 cm × 1.2 cm × 0.8 cm, with an associated postbiopsy marker clip, in the left breast at the 6 o’clock position, 4 cm from the nipple. Ultrasound scans of the left breast and regional lymph nodes confirmed a 1 cm × 0.6 cm × 0.5 cm hypoechoic, irregular mass approximately 5 cm from the nipple. This finding likely represented a postbiopsy hematoma. A few internal calcifications were noted. No suspicious axillary, infraclavicular, or internal mammary lymph nodes were noted.

The treatment options originally discussed were a total mastectomy with sentinel-node dissection, with or without breast reconstruction, or a segmental mastectomy followed by WBI. The patient was concerned about the potential for unpredictable cosmetic results after WBI in the setting of an augmented breast, especially with her history of capsular contracture and fibrosis. She initially elected to proceed with a total mastectomy with immediate reconstruction using a latissimus dorsi muscle flap and adjustable implant. However, after learning about the additional option of APBI with the SAVI device, the patient became committed to conserving her breast if possible.
Treatment

In October 2009, a needle-localized segmental mastectomy was performed on the left breast. The pathologic examination revealed changes consistent with the previous biopsy site, but no residual DCIS or invasive disease was noted. The marker clip was centrally positioned within the excised specimen on specimen radiograph. A postoperative mammogram of the left breast confirmed that there were no residual suspicious calcifications at the 6 o’clock position.

Twenty days after the segmental mastectomy, a computed tomography (CT) scan was obtained on our CT simulator (LightSpeed RT 4, GE Healthcare, Milwaukee, WI). The patient was positioned supine with both arms abducted and rotated above her head. The CT images were transferred to our Pinnacle planning computer (Philips, Andover, MA). The resection cavity was outlined; its volume was 12.7 cc, and its dimensions were 5.0 cm × 1.5 cm × 5.4 cm. The distance from the skin to the resection cavity was 0.4 cm. These measurements were used to plan the direction of placement of the SAVI catheter and to determine what size to use. These findings were shared with the surgeon by electronically transmitting axial, coronal, and sagittal images in both two-dimensional and three-dimensional renderings (Fig. 1). On the basis of the initial cavity measurements, a SAVI 6-1 (with six peripheral struts and one central catheter) was recommended.

The next day, the breast surgeon placed the SAVI 6-1 device within the segmental resection cavity under ultrasound guidance. The breast tissue bordering the resection cavity appeared to have good conformance to the initial temporary sizing balloon used to evaluate size of SAVI to use for optimal conformance to the lumpectomy cavity. The sizing balloon was filled with 30 cc of fluid, confirming that a SAVI 6-1 appeared to be the appropriate size.

Forty-eight hours after placement of the SAVI 6-1 catheter, the patient underwent a CT scan centered on the SAVI. Volumes of nonconformance of the breast tissue to the device were seen inferior and medially to the device (Fig. 2, top). Therefore, the device was exchanged for a larger SAVI 8-1 (with eight peripheral struts and one central catheter) in the CT simulator under local anesthesia. A followup CT scan confirmed improved conformance of the breast tissue to the device. A limited volume of nonconformance at the caudal aspect of the device was possibly because of the introduction of air when the devices were exchanged.

The patient returned the next day, and a full Vac-Lok cradle (MedTec, Orange City, IA) was manufactured to ensure identical positioning of the patient each day, with both arms abducted and rotated above her head. A CT scan through the SAVI confirmed excellent conformance of the tissue around the resection cavity to the device (Fig. 2, bottom). Therefore, a 100-slice CT scan at 0.125 cm slice thickness was obtained through the breast at the level of the SAVI. The images were transferred to the PLATO planning computer (Nucletron, Veenendaal, The Netherlands) for treatment planning.

A dose of 3.4 Gy was delivered twice a day in 10 fractions, for a total dose of 34 Gy, with a high-dose-rate 192Ir source used with the microSelectron afterloader (Nucletron). The dose was prescribed to the planning target volume for evaluation (PTV_EVAL), defined as the volume of breast tissue encompassed from the periphery of the SAVI device with a 1.0 cm expansion, excluding the segmental resection cavity volume, the tissue within 0.2 cm of the skin, and the muscle beyond the posterior breast tissue. The PTV_EVAL was 48.2 cc, and the volume

Fig. 1. Axial, coronal, and sagittal images of the segmental resection cavity in both two-dimensional and three-dimensional renderings.
of nonconformance was 0.39 cc (0.8%). The volume of nonconformance was defined as the air and/or seroma located between the periphery of the struts of the SAVI device and the lumpectomy cavity edge. The percentage of nonconformance was calculated by the equation (volume of air/seroma over PTV_EVAL) x 100. We calculated $V_{90}$ and $V_{95}$ (percentage of the PTV_EVAL receiving 90% and 95% of the prescribed dose, respectively). $V_{90}$ and $V_{95}$ were 97.1% and 94.6% (96.3% and 93.8% when the volume of nonconformance was taken into account). We also calculated $V_{150}$ and $V_{200}$ (volume receiving 150% and 200% of the prescribed dose, respectively). $V_{150}$ was 22.7 cc, and $V_{200}$ was 11.6 cc. For calculating maximum skin dose, skin was defined as a 0.2 cm layer from the skin surface into breast tissue. The maximum skin dose to a 0.1 cc volume was 115% of the prescribed dose, and the maximum skin dose to a 1 cc volume was 99% of the prescribed dose. All dose parameters were within acceptable plan criteria for breast brachytherapy when the SAVI device is used (11). Although we are not aware of guidelines published for acceptable dose criteria to the breast augmentation in APBI, the following dose volume information was recorded. The total implant volume was 452.7 cc. $V_{50}$, $V_{75}$, $V_{100}$, $V_{150}$, and $V_{200}$ (volume of implant receiving x% of the prescribed dose) was 18.4% (83.3 cc), 9.8% (44.5 cc), 5.9% (26.7 cc), 2.3% (10.5 cc), and 0.9% (4.0 cc), respectively. The minimum distance from the periphery of the SAVI to the implant was less than 1 mm (Fig. 3).

**Results**

The patient tolerated her treatment well, and the device was removed without complication after the last radiation fraction was delivered. She completed a course of prophylactic antibiotics started when the catheter was placed. At her 8-week followup, the patient had limited toxicity with a 3 cm x 2 cm area of mild hyperpigmentation (Grade 1 according to the Common Terminology Criteria for Adverse Events (13) of the skin overlying the former location of the SAVI). Overall, the patient had a good cosmetic result by the Harvard Scale (14) at 8 weeks (Fig. 4). No palpable seroma was noted on examination. At 6-month followup, the patient has an excellent cosmetic result by the Harvard Scale (14), with no evidence of recurrence by physical examination and diagnostic mammogram (Fig. 5).

**Discussion**

As data accumulate on the efficacy and toxicity of APBI delivered by brachytherapy devices, patients and physicians continue to become more interested in this method of adjuvant treatment for early stage breast cancer. Of importance, patients should not be excluded from APBI because of non–tumor-related issues such as breast size, the location...
of the resection cavity in relation to the skin or ribs, or the presence of breast implants. The number of women who present with breast cancer and have had previous breast augmentation is expected to increase because the number of breast augmentations has increased (15). The APBI brachytherapy method with the greatest versatility in dosimetric coverage and the best ability to limit the dose to normal structures is multicatheter brachytherapy (16). However, not all radiation oncology clinics are equipped to offer multicatheter brachytherapy because they lack training, skills, and/or equipment.

The case presented in this report shows that the recent technical improvements in single-entry hybrid catheters for breast brachytherapy have made APBI available to more patients who are clinically appropriate candidates according to the guidelines of American Brachytherapy Society (3), American Society of Breast Surgeons (4), and American Society for Radiation Oncology (5). With only 0.2 cm distance between the periphery of the SAVI and skin surface, a SAVI 8-1 (measuring 4 cm × 6.7 cm) could be fully expanded between the skin and the implant in this case. This may not be possible in all the patients with breast augmentation. The location of the resection cavity, the amount of residual breast tissue, and the location of the implant relative to the cavity all determine the feasibility of placing a catheter that can be expanded and obtain adequate conformance of the tissue around the resection cavity to the device. In this case, the conformance of the resection cavity to the SAVI was excellent: 99.2%. When taking into account the 0.8% volume of nonconformance of the device to the PTV_EVAL, the $V_{90}$ was 96.3%, well within acceptable breast brachytherapy treatment guidelines. The $V_{150}$ and $V_{200}$ were of limited volume, and the maximum skin dose (0.1 cc to 115% of prescribed dose) was also well within acceptable treatment guidelines.

**Conclusion**

Breast augmentation should not be an exclusion criterion for the option of APBI therapy. The SAVI is a single-entry breast brachytherapy device that can be used to deliver APBI safely in a patient with breast implants. To our knowledge, this is the first peer-reviewed case study on SAVI in a patient with an augmented breast. The clinical outcome has been optimal, with limited acute and late toxicity and excellent cosmetic results that pleased the patient. APBI should be considered as a possible treatment for patients with breast implants with early stage breast cancer.

**References**


