Dosimetric performance of Strut-Adjusted Volume Implant: A new single-entry multicatheter breast brachytherapy applicator

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ABSTRACT

PURPOSE: To evaluate the dosimetric performance and clinical utility of the Strut-Adjusted Volume Implant (SAVI) (Cianna Medical, Aliso Viejo, CA) applicator when used as the sole method of radiation therapy for patients with early breast carcinoma.

METHODS AND MATERIALS: The dosimetric performance of a Phase II clinical trial has been reported using the SAVI applicator for patients with early breast carcinoma. Cavity volume, planning target volume, dose homogeneity, and dose for organs at risk had been calculated. As a result, the $D_{90}$ and $D_{100}$ averages had been presented especially on the distances to the skin and the chest wall because these are critical parameters using the MammoSite (Cytyc Corp., Marlborough, MA) technique.

RESULTS: $D_{90}$ and $D_{100}$ averages were 95.8% and 91.2%, respectively. The average dose homogeneity index was 55.9%. Average minimum distances to the skin and chest wall were 15.1 and 23.4 mm, respectively. The average $D_{\text{max}}$ values to the skin and ribs were 249 and 199 cGy/fraction, respectively. The mean $V_{20}$ for the lungs was 17.9 cc. The average $V_{150}$ and $V_{200}$ were 30.80 and 14.91 cc, respectively.

CONCLUSIONS: With this study, we have been able to optimize dose distribution to obtain clinically acceptable dose plans, while minimizing doses to healthy tissues. The dose sculpting versatility of SAVI in the clinical setting makes the SAVI applicator a useful addition to the tools available for accelerated partial breast irradiation. Published by Elsevier Inc. All rights reserved.

Keywords: SAVI; Accelerated partial breast irradiation; Breast brachytherapy

Introduction

Within the last 25 years, breast-conserving therapy (BCT) has become an accepted treatment modality for Stage I and II breast carcinomas. The principal disadvantage of BCT is a more complex and protracted treatment regimen that requires approximately 6 weeks of external beam radiation therapy. This time period commitment poses problems for patients, such as working women, elderly patients, and those who live significant distances from treatment centers (1–5).

In an effort to overcome this problem, a number of institutions have investigated an accelerated partial breast irradiation (APBI) regimen using interstitial brachytherapy as a 5 days alternative to whole breast irradiation. This treatment approach could potentially make BCT more accessible for many patients, as it poses fewer logistic problems. When chemotherapy is recommended, sequencing issues are avoided because all local therapy can be completed without significantly delaying systemic therapy (6–18).

Despite data demonstrating excellent 7-to-10-year outcomes, physician acceptance of interstitial brachytherapy has been slow. One reason for the slow acceptance is that substantial technical demands are required for a successful interstitial implant. The balloon catheter MammoSite (Cytyc Corp., Marlborough, MA) was developed to address this issue, and the device has been rapidly accepted by physicians and patients. However, certain patients are not candidates for the MammoSite catheter because of potentially excessive
skin radiation dosages in cases where the balloon surface is too close to the skin. Because the radiation dose is typically prescribed 1 cm from the balloon surface, the skin surface receives a much greater level of radiation than the prescribed dose when the distance from the balloon to the skin is less than 1 cm. Significant late effects, such as fibrosis, telangiectasia, poor cosmesis, and skin necrosis, become more likely when the skin separation is ≤ 7 mm from the balloon (19). Risk factors for tissue conformance to the balloon or unacceptable skin dose includes the following; small breast size, thin surgical skin flaps, augmented patients, small or irregularly shaped surgical cavities, and quadrantectomies. Balloon asymmetry can be caused by defective balloons or fibrotic cavity walls. If unacceptable skin, rib, or planning target volume (PTV) dosimetry is encountered, the MammoSite is unsuitable for APBI and should be removed.

With balloon catheters, the geometry is fixed. Dose optimization is very limited, as there are a limited number of dwell positions within a single channel. Hence, in most studies, at least 20% of the unscreened patients will require balloon removal for anatomic constraints (19–23). This issue, which is disconcerting for patients and their medical teams, can be avoided with interstitial brachytherapy because 15–30 catheters typically offer hundreds of dwell positions for the iridium-192 source, permitting exquisite control of dose delivery to the skin and target tissues.

The Strut-Adjusted Volume Implant (SAVI) (Cianna Medical, Aliso Viejo, CA) was designed to address the shortcomings of the balloon catheter, while maintaining its simplicity and ease of use. Like single-catheter breast brachytherapy devices, such as balloon catheters, SAVI is placed into a lumpectomy cavity through a single skin incision. The SAVI applicator has a central catheter as well as 6, 8, or 10 peripheral catheters that are expanded from their central position outward to the periphery of the lumpectomy cavity (24).

Each of these peripheral catheters and the central channel contain a large number of potential dwell positions for the radiation source. These peripheral source channels are in direct contact with the lumpectomy cavity edge, providing flexibility in terms of modulating the 3-dimensional dose distribution. Lumpectomy cavities near the skin or chest wall may be treated with good target coverage and acceptable skin, chest wall, rib, and lung exposure to radiation (100% or less of the prescribed dose).

Our Arizona team was the first team in the United States to implement SAVI into its treatment for APBI, and patients were enrolled in the study if they fit the eligibility criteria and signed institutional review board (IRB)-approved informed consent forms.

This study reports the dosimetric performance of a single institution participating in a Phase II IRB-approved clinical trial. Nineteen patients were enrolled and 15 of them were treated. The objective of this study was to evaluate the dosimetric performance and clinical utility of the SAVI applicator when used as the sole method of radiation therapy for patients with early breast carcinoma.

Methods and materials

Eligibility criteria included patients with invasive breast cancer or ductal carcinoma in situ, up to 3 cm tumor size that were node negative, age ≥ 18 years, and excised with negative surgical margins according to the National Surgical Adjuvant Breast And Bowl Project (NSABP) definition. This study reports the results for the first 15 patients treated during this IRB-approved protocol study.

The SAVI 6-1 (six peripheral and one central catheter) or the larger SAVI 8-1 (eight peripheral and one central catheter) were chosen for each patient based on lumpectomy cavity size, as determined by ultrasound or CT after lumpectomy. Ultrasound-guided insertion of the collapsed SAVI applicator was tracked through a 1-cm incision in the skin into the cavity. A screwing mechanism expanded the peripheral catheters symmetrically until they reached the inner edge of the cavity. CT scans were obtained for 3-dimensional dosimetric planning using PLATO high-dose rate (HDR) treatment planning software (Nuclertron Corp., Columbia, MD). The lumpectomy cavity and normal structures, including the skin and ipsilateral lung and heart, were outlined for all patients. PTVs and normal structures were contoured according to the guidelines of NSABP B-39/Radiation Therapy Oncology Group (RTOG) 0413 protocol. For the 4 of 15 patients who had left breast cancer, the entire heat was contoured beginning just below the level in which the pulmonary trunk branches into the left and right pulmonary arteries.

The planning CT scans used in these cases were performed on a 4-slice scanner without the use of i.v. contrast and without attempts to gate the scan acquisition to the respiratory cycle. The ability to precisely define the individual coronary arteries on such a scan is highly variable. Of all the coronary arteries, the left anterior descending (LAD) artery is closest to the left breast and therefore at risk for radiation exposure. The LAD is a branch of the left main coronary artery and typically runs inferiorly along the interventricular groove (over the septum separating the left and right ventricle). Proximally, near its origin from the left main coronary artery, the location of the LAD may be inferred from the presence of calcifications within its wall; these calcifications are a consequence of age-related atherosclerosis. At more distal (inferior) levels, where calcifications are less common, the LAD can often be discerned as a distinct structure within the epicardial fat over the interventricular groove. Using these features, we contoured the LAD coronary artery on sequential axial slices for each patient. We must emphasize that all of these coronary artery contours demonstrate significant cardiac motion artifact; and as a consequence, it is impossible to define, with great precision, a reliable and reproducible dose—volume histogram for the actual LAD in each patient. However, the volumes can serve as a rough guide for the typical exposure received by the LAD in each patient. Figure 1 shows SAVI 6-1 and SAVI 8-1 and their corresponding dimensions.
Dose prescription and delivery

HDR brachytherapy was initiated within 2 calendar days of device placement. The patient’s treatment position was identical to the planning CT position. The SAVI applicator remained expanded throughout the course of the treatment. In each case, an HDR iridium-192 remote afterloader delivered the prescribed dose of 3.4 Gy per fraction, twice daily, separated by at least 6 h, for a total dose of 34 Gy in 10 fractions over 5 treatment days. The SAVI device was removed immediately after administration of the last fraction.

Determination of appropriateness of treatment

The appropriateness of treatment with the SAVI applicator was dependent on the device geometry and resultant dose homogeneity. Device placement and expansion needed to allow the selection of dwell positions and dwell times so that the HDR 3-dimensional planning system satisfied the dosimetric requirements listed in Table 1.

The PTV was defined as the volume of the excision cavity that was uniformly expanded by a 1-cm margin. When the 1-cm expansion extended beyond the skin surface or into the pectoralis muscle of the chest wall, those portions of the PTV were subtracted, creating the “PTV-Eval” (Planning Target Volume-Eval). Dose—volume histogram analyses were performed on the PTV-Eval values and are enumerated in Table 2.

Results

Nineteen patients were enrolled in this SAVI trial. Two patients withdrew from the study before device placement (one because of lack of applicator availability and the other because she selected mastectomy). Two patients had the applicator removed after placement (for the first patient, small, six-week-old fibrotic cavity prevented the applicator from expanding; the second patient had the device removed at the discretion of the treating physician). Of the remaining 15 patients, 6 were treated with SAVI 6-1 and 9 were treated with SAVI 8-1.

Figure 2 shows CT images of a SAVI 8-1 within a lumpectomy cavity for 1 of the patients. Over the course of 10 fractions, CT scans performed before each fraction showed no significant change in the relationship between the cavity and the SAVI applicator (i.e., no rotation or in—out change). Consequently, no change in dosimetry was necessary during any treatment course.

The mean cavity volume was 27.1 cm³ (range, 14.9–42.7 cm³). The mean PTV-Eval volume was 98.5 cm³ (range, 44.1–151.2 cm³). On average, the proportion of PTV-Eval receiving 90% of the prescribed dose (V90) was 95.8% (range, 90.9–99.1%). The percentage of PTV-Eval receiving 100% of the prescribed dose (V100) averaged 91.2% (range, 83.9–94.8%; see Fig. 3 for individual values). Dose homogeneity index was 0.559 (range, 0.52–0.60).

The mean minimum distance to the skin surface was 15 mm (range, 4–44 mm). The mean minimum distance to the chest wall was 23 mm (range, 4–62 mm). Skin doses were less than 100% of the prescribed dose in all patients. The mean skin dose was 249 cGy/fraction (fx) (range, 78–303 cGy).

Complete ipsilateral lung CT data were obtained for all patients, and only 4 patients had left breast treatment. The mean ipsilateral lung volume was 1293 cc (range, 950–2100 cc). The mean cardiac volume was 757 cc (range, 742–856 cc).

The maximum radiation doses to the heart, lung, and ribs were <100% of the prescribed doses in all cases. The mean maximum radiation dose to the heart was 69 cGy/fx, to the ipsilateral lung was 186 cGy/fx, and to the closest rib was 199 cGy/fx. The mean left coronary volume receiving 5%
The mean area receiving 30% of the prescribed dose ($S_{30}$) was 70.2 cm$^2$, receiving 50% of the prescribed dose ($S_{50}$) was 29.8 cm$^2$, and receiving 80% of the prescribed dose ($S_{80}$) was 1.0 cm$^2$. No skin surface received 100% of the prescribed radiation dose.

The mean volume receiving 100% of the prescribed dose ($V_{100}$) was 70.0 cm$^3$, receiving 150% ($V_{150}$) was 30.8 cm$^3$, receiving 200% ($V_{200}$) was 14.9 cm$^3$, and receiving 250% ($V_{250}$) was 8.2 cm$^3$.

**Discussion**

The present study was designed to evaluate the dosimetric characteristics of the SAVI device. Compared with MammoSite, the multicatheter design of the SAVI device makes it possible to contour the dose and therefore minimize the risk to nontarget tissues and body structures. Compared with Contura (SenoRx, Inc., Aliso Viejo, CA), the struts are touching the target tissue with no spacer, and SAVI has an open structure that allows air or seroma
to be present inside the struts. As the central channel is surrounded by multiple struts, each of which contains multiple potential dwell positions for the radioactive source, the device can be loaded preferentially to one side the other, allowing skin and chest wall-sparing, and preferential treatment to the side of the cavity closer to the surgical margin. Thus, many of the advantages of interstitial brachytherapy can be exploited with a device that is simple to place in the lumpectomy cavity.

In this study, 15 patients were treated with SAVI. If breast brachytherapy using a MammoSite had been the only option, 9 of the 15 patients (60%) would have been ineligible because of skin separation and other anatomical restrictions (Fig. 4a and b). Two of the 15 patients had a skin spacing <5 mm, and 4 of the 15 patients had a skin spacing <7 mm. Skin dosage did not exceed the prescribed dosage in any of the 15 patients included in this study. The mean radiation dose to the skin observed in this study was 249 cGy/fx, which is 10–15% lower than the mean skin dose observed with a carefully selected cohort of MammoSite patients (25). The mean skin dose (249 cGy/fx) is comparable to that found in a recent report by Yashar et al. (26).

Although the previously detailed dose levels to skin surface areas ($S_{50}$, $S_{80}$, and $S_{100}$) have not been presented in any previous study, we believe such an analysis is critical to the understanding of late skin cosmetic and toxicity effects. Telangiectasia, for example, is probably related to skin surface areas that exceed a certain radiation dose level. Further evaluations need to be performed to prove these hypotheses. The maximum skin dose should also be investigated. Figure 5a and b show the skin surface exposed to 50% of the prescribed dose with both MammoSite and SAVI.

**Table 3**

Dose to left coronary in 4 patients treated with SAVI brachytherapy for left breast cancer

<table>
<thead>
<tr>
<th>Dosimetric parameters</th>
<th>Mean</th>
<th>Range</th>
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</thead>
<tbody>
<tr>
<td>$D_{max}$</td>
<td>5.4 Gy</td>
<td>(2.6–7.8 Gy)</td>
</tr>
<tr>
<td>$V_{10}$ (cc)</td>
<td>0.0 cc</td>
<td>(0–0 cc)</td>
</tr>
<tr>
<td>$V_{10}$ (%)</td>
<td>0.0%</td>
<td>(0–0%)</td>
</tr>
<tr>
<td>$V_{20}$ (cc)</td>
<td>0.2 cc</td>
<td>(0–0.4 cc)</td>
</tr>
<tr>
<td>$V_{20}$ (%)</td>
<td>10%</td>
<td>(0–23.4%)</td>
</tr>
<tr>
<td>$D_{50}$</td>
<td>3.9 Gy</td>
<td>(1.8–5.1 Gy)</td>
</tr>
<tr>
<td>$D_{10}$</td>
<td>4.5 Gy</td>
<td>(2.1–5.8 Gy)</td>
</tr>
<tr>
<td>$D_{5}$</td>
<td>4.8 Gy</td>
<td>(2.2–6.5 Gy)</td>
</tr>
</tbody>
</table>

SAVI = Strut-Adjusted Volume Implant.

**Table 4**

Dose to ipsilateral lung in 15 patients treated with SAVI brachytherapy for breast cancer

<table>
<thead>
<tr>
<th>Dosimetric parameters</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>$D_{max}$</td>
<td>18.6 Gy</td>
<td>(11.7–29.6 Gy)</td>
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<tr>
<td>$V_{50}$ (cc)</td>
<td>0.7 cc</td>
<td>(0–5.6 cc)</td>
</tr>
<tr>
<td>$V_{20}$ (%)</td>
<td>0.06%</td>
<td>(0–0.5%)</td>
</tr>
<tr>
<td>$V_{10}$ (cc)</td>
<td>16.2 cc</td>
<td>(0–49.2 cc)</td>
</tr>
<tr>
<td>$V_{10}$ (%)</td>
<td>1.2%</td>
<td>(0–4.6%)</td>
</tr>
<tr>
<td>$V_{5}$ (cc)</td>
<td>86.3 cc</td>
<td>(5.9–183 cc)</td>
</tr>
<tr>
<td>$V_{5}$ (%)</td>
<td>6.5%</td>
<td>(0.5–9.5%)</td>
</tr>
<tr>
<td>$D_{50}$</td>
<td>8.6 Gy</td>
<td>(2.1–143 Gy)</td>
</tr>
<tr>
<td>$D_{10}$</td>
<td>10.1 Gy</td>
<td>(4.4–17.6 Gy)</td>
</tr>
<tr>
<td>$D_{5}$</td>
<td>11.1 Gy</td>
<td>(3.8–17.7 Gy)</td>
</tr>
</tbody>
</table>

SAVI = Strut-Adjusted Volume Implant.

**High-dose volumes**

When this study was designed, we hypothesized that doses to contiguous volumes at the device surface would be dose limiting for this type of treatment. There are insufficient data in the literature to provide appropriate guidance, specifically with respect to contiguous high-dose volumes, such as $V_{50}$, $V_{200}$, and $V_{250}$. A recent paper by Wazer et al. (8) analyzing 75 interstitial breast cases showed a significant correlation between clinically evident fat necrosis when the tissue volume was irradiated to 150% and 200% of the prescribed dose, using a dose/fractionation schedule identical to the schedule used herein. The NSABP B-39/RTOG 0413 (27) protocol guidelines state that $V_{150}$ must be less than 70 cc, $V_{200}$ must be less than 20 cc for interstitial brachytherapy, and that $V_{20}$ must be less than 10 cc for MammoSite.

In this study, the mean volume receiving 100% of the prescribed dose ($V_{100}$) was 70.0 cc, that receiving 150% ($V_{150}$) was 30.8 cc, that receiving 200% ($V_{200}$) was 14.9 cc, and that receiving 250% ($V_{250}$) was 8.2 cc, which are well within NSABP/RTOG stipulations. However, according to our experience, the dose homogeneity index (28) with SAVI tends to be lower than with interstitial or balloon brachytherapy, but the clinical significance of this difference is not yet established, especially when skin doses, $V_{150}$, and $V_{200}$ values are so favorable.

**Critical structure doses**

There are no clear guidelines in the literature regarding chest wall and rib dose limits, but because of reports of rib...
Fig. 4. (a) One of the protocol cases was ineligible for MammoSite because of skin separation less than 5 mm with a maximum skin dose exceeding \( >145\% \) of the prescribed dose. (b) Isodose distribution when Mammosite was replaced with Strut-Adjusted Volume Implant device. Maximum skin dose was below prescribed dose.
fracture (29), we tried to minimize the rib doses as much as possible by using the dose-tailoring abilities of the SAVI device. Four of 15 patients had rib distances $<6$ mm $\approx 6$ mm. The maximum dose to the closest rib was 363 cGy/fx. None of these patients reported treatment-related chest wall tenderness. We strongly encourage the collection and examination of chest wall and rib dosimetric data for patients treated with APBI in future prospective clinical trails.

In this study, low lung and heart radiation dose levels were observed using the SAVI applicator. In all cases, less than 1% of the ipsilateral lungs received less than 20 Gy. For comparison, our patients receiving conventional targeted-field whole-breast irradiation have $V_{20} = 12–20\%$ for the total lung. In patients with lung cancer, it has been shown that late toxicity rates increase as the volume of total lung receiving over 20 Gy increases (30, 31).

For the 4 of 15 patients who had left breast cancer, the mean left coronary $D_{\text{max}}$ was 54 cGy/fx, with a 10% $V_5$. The risk of late cardiovascular events, Hodgkin’s lymphoma, and left breast cancer has long been associated with higher cardiac doses of external beam radiotherapy. More recently, it has been shown that there is an increased risk of radiation-induced heart disease at lower levels of exposure (32, 33), inspiring our group and others to strive for coronary artery doses that are as low as reasonably achievable.

Conclusions

In our study, the first 15 patients receiving SAVI brachytherapy for select breast cancers showed clinically acceptable dose planning. In comparison with MammoSite, we noted a remarkable reduction of radiation exposure to the skin, ribs, heart, and lungs. SAVI offers APBI to patients who cannot receive MammoSite, which is the most common technique for APBI. There were 6 of 15 patients who would have been ineligible for MammoSite and another 3 patients who would have been marginal candidates. The multiple peripheral source channels of the SAVI allow tailored dose distribution. Radiation exposure to the skin and ribs is maintained below 100% of the prescribed dose. Both the simplicity of insertion and the dose contouring capability of SAVI make it a useful addition to the tools available for APBI.

Acknowledgment

The authors thank Dr. Scott Tannehill for his thoughtful discussions and input.

References


[27] Randomized phase III study of conventional whole breast irradiation (WBI) versus partial breast irradiation (PBI) for women with stage 0, I, or II breast cancer. NSABP protocol B-39, RTOG protocol 0413 Version: November 2, 2009.


