DOSIMETRICAL EVALUATION AND CLINICAL IMPLEMENTATION OF A STRUT-ADJUSTED-VOLUME-IMPLANT SAVI DEVICE USED FOR ACCELERATED PARTIAL BREAST IRRADIATION

Ş. MORCOVESCU1,2, C. COSMA2, J. D. MORTON3

1Texas Oncology Denton, Radiation Department, Denton, TX
2Babeș-Bolyai University, Faculty of Environmental Science, School of Doctoral Studies, Cluj-Napoca, Romania

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The SAVI (the Strut Adjusted Volume Implant) device is one of the most novel devices used in Accelerated Partial Breast Irradiation (APBI). Various dosimetric parameters, as well as doses to adjacent critical structures, have been evaluated in 121 patients in this single institution 5-year retrospective study, using dose volume histogram (DVHs): Coverage Index (CI), cavity and planning target volumes (PTV and PTV_EVAL), Max Skin Dose (MSD), Max Chest Wall Dose (MCWD), Skin Bridges (SB), Chest-Wall Bridges (CWB). Our analysis demonstrates the dosimetric versatility and outlines the clinical implementation process of the SAVI brachytherapy device, especially for APBI cases that require more flexible dose optimization, for both coverage of PTV volumes and sparing of dose to adjacent critical structures.

Key words: breast cancer, APBI, strut adjusted volume implant, SAVI, DVH, brachytherapy.

1. INTRODUCTION

Over the last two decades, breast conservation therapy (BCT) has been accepted as one of the standard treatment regimens in patients with early-stage breast cancer. Especially since the early 2000s, Accelerated Partial Breast Irradiation (APBI) has been embraced with great interest by both cancer care providers and breast cancer patients as a great and efficient treatment alternative to conventional whole-breast irradiation. There is data that indicates that APBI is an acceptable option of treatment for properly selected patients [1–8].
Historically, partial breast irradiation was first performed with interstitial implantation using multi-catheter brachytherapy that typically triggered the tumor bed plus a generous margin of 2.0–2.5 cm. Because of its procedural complexity, interstitial brachytherapy was not widely adopted in the United States and eventually led to the development of a number of other methods of delivering APBI, including intraoperative radiotherapy with photons and electrons and conformal three-dimensional external-beam approaches [9–10]. The MammoSite approach was eventually developed, allowing for the delivery of hypofractionated high-dose rate brachytherapy to the tumor bed in a relatively straightforward manner, which eliminated many of the technical difficulties inherent to traditional double-plane interstitial implants.

After the launch and initial use of the single-lumen MammoSite, many other treatment multicatheter devices such as the multilumen MammoSite, Contura, ClearPath or Strut Adjusted Volume Implant (SAVI) were developed, in order to allow better targeting of the primary tumor site and better sparing of the adjacent normal tissues and organs. Among those, the SAVI device proved to be a unique solution for cases where other APBI devices are not a fit [11–16]. Because of its design, the miniSAVI version of the SAVI applicator allowed excellent dosimetric conformance and skin sparing for cases where the size of the breast and the location of the lumpectomy site hindered the use of balloon-type devices, like MammoSite or Contura.

Strut-based applicators have been widely adopted in United States as an alternative to balloon-type applicators in APBI, and were increasingly used at our practice since early 2008. The applicator studied (Cianna Medical, Aliso Viejo, CA), is the smallest of its kind (6–1 mini), and it has been especially used on patients with reduced breast or/and lumpectomy cavity size. A comprehensive dosimetric evaluation of various coverage parameters was performed, and doses to adjacent critical structures have been estimated in all patients included in this 5 year retrospective study. Our current standard daily treatment clinical QA guidelines and workflow are also presented and discussed.

2. MATERIALS AND METHODS

2.1. THE SAVI DEVICE DESCRIPTION

The SAVI device is shown in Fig. 1 and it comes in four different sizes, as displayed in Fig. 2. It consists of a central strut surrounded by 6, 8, or 10 peripheral struts, depending on the size of the device. The configuration of the struts allows for a differential radioactive source dwell-time loading, which translates in optimal dose modulation around the lumpectomy cavity and sparing of adjacent normal tissues.
The major advantage of the SAVI device is patient-specific dose optimization from the multiple dwell positions in each strut to minimize dose to normal tissues, including skin, chest wall, and lung. A fixed hub located near the base of the implant and an expansion tool that slides over the central strut allows for the expansion of the device once inside the lumpectomy cavity, and for the collapsing of the device upon removal. The device is inserted through the incision site in the collapsed position and is expanded when fully inserted in the lumpectomy cavity. The fully expanded peripheral struts anchor the device against the cavity walls securing the struts in place and a very stable position, if the SAVI device size elected for the implant properly fits the lumpectomy cavity size and shape.
The expansion tool of the SAVI device is used at the time of the surgical placement in the lumpectomy cavity, and then reinserted and engaged prior to each treatment, for quick collapse and removal of the device in case of an emergency. Radio-opaque markers are built-in on three of the peripheral struts (numbers 2, 4, and 6) for identification during the reconstruction process, the one on number 2 strut (M2) being located distally, closest to the tip of the implant, the one on number 4 (M4) being located midway along the length of the device and the number 6 marker (M6) being located most proximally.

2.2. PATIENT SELECTION CRITERIA

Patient eligibility criteria for a SAVI implant verify those currently and widely accepted and employed in the industry. As a rule, only patients with invasive breast cancer or ductal carcinoma in situ, up to 3 cm tumor size, and excised with negative lymph nodes involvement, age $\geq 45$ years, were accepted. Device selection and appropriateness is assessed and done by the breast surgeon during surgery, after the tumor is excised and the lumpectomy cavity is created.

2.3. IMAGING AND DOCUMENTATION FOR TREATMENT PLANNING

The imaging sequence is an important part of the planning process. In our clinic, a patient is usually scheduled for a CT planning simulation and a CT is acquired the day following the implant surgery. The acquired images become the reference set of images all subsequent pre-fractional images will be compared against. It is important to have a thorough verification process of the position and placement of the SAVI device because the patient should be treated in the same position as planned.

During the initial planning scan done using a GE Lightspeed, large-bore, 4 slice CT scanner (GE Medical Systems, Waukesha, Wisconsin), two CT scouts, one anterior and one lateral, are acquired. For a high quality image reconstruction, we use 2.5 mm slice thickness for CT planning scan, extending at least 5 cm superiorly and inferiorly to the SAVI defined cavity area, typically resulting in a number of transverse images of around 65 slices. We employ a breath-hold during the CT scan, or at least we instruct the patients having breathing difficulties to exert a shallow breath pattern during the actual scan, in order to minimize respiratory motion artifacts.

An in-house form was developed in order to document and record relevant position parameters for the initial planning scan and for all subsequent pre-treatment verification scans. We evaluate distances between the three pairs of strut markers in the AP or Lateral CT scouts, Fig. 3, and compare, record and review these values prior to each fractional treatment.
Fig. 3 – Pre-fractional comparison and review of implant placement: daily CT scout (right image) compared against original planning CT scout (left image).

2.4. TREATMENT PLANNING

The CT images are sent to a BrachyVision treatment planning computer (Varian Medical Systems, Inc., Palo Alto, California) where a full three-dimensional reconstruction of the SAVI device is performed. Planning is performed only once, as re-planning is only employed and necessary if intra-fractional in-out or rotational motion of the device is assessed and confirmed.

Treatment planning is usually more time consuming than for a typical MammoSite balloon applicator, but planning times are not prohibitive as standard template plans are created for each of the SAVI device types. This allows for quick digitization and reconstruction of the multiple struts. The lumpectomy or SAVI cavity is defined by the physician, as this becomes the reference structure from which all planning target volumes are eventually obtained.

The **Planning Target Volume** (PTV) is generated by a 1 cm uniform expansion of the lumpectomy cavity volume, and it is defined as the difference between the expanded volume and the cavity volume. The **Planning Target Volume for Evaluation** (PTV_EVAL) is, according to the definition given by the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-39/Radiation Therapy Oncology Group (RTOG) 0413 Protocol [17], the same as the PTV but limited to 5 mm from the skin surface and by the posterior breast tissue extent (chest wall and pectoralis muscles not included).

Other structures are created, including but not limited to these: **Air/Seroma, Heart, Normal Tissue, Chest Wall, Ipsilateral Lung and Skin Surface**.

The standard fractional dose is of 340 cGy to the outer surface of PTV_EVAL. The total dose of a full course of treatment is of 3400 cGy, delivered
in 10 fractions, twice daily, with daily pair-fractions at least six hours apart. The planning criteria used for planning are matching the once recommended by the NSABP B-39/ RTOG 0413 protocol guidelines for APBI irradiation with respect to D90, V100, V150, V200 and conformity indexes, as well as to Maximum Skin Dose (MSD). V100, V150 and V200 represent the volumes (in cm³) covered by the respective (IL) isodose line (in %).

For the purpose of this study, only results for patients implanted with the smallest of the SAVI devices, i.e., the 6-SAVID mini device, are reported. Our dosimetric coverage criteria for this study was V90 > 90%, V150 < 50 cm³, V200 < 20 cm³. Additional constraints are placed to try limiting the chest wall and skin doses to 100%. All dosimetric data was stratified using 5 mm skin-bridge intervals, therefore differentiating among cases with major or no PTV volume reduction.

3. RESULTS AND DISCUSSIONS

The total number of patients included in this single-institution study is 121, acquired over the span of 5 years, from 2009 to 2014. The Task Group TG43 formalism was employed on all dosimetric evaluations.

3.1. QUALITY ASSURANCE

There is need for a very detailed quality assurance program for SAVI treatments, patient specific, that is performed in addition to the routine daily and quarterly HDR machine QA.

One important test to be performed on the day of the planning CT simulation is the verification of the SAVI device catheter lengths. This is usually performed while connecting the re-usable treatment catheters to the device and measuring and confirming the treatment lengths, usually found to be approximately within ± 2 mm of the manufacturer’s expected values. In parallel with the device positioning reproducibility test evaluated using the anterior or lateral CT scouts, we employ a more visual verification process of the device position, by recording the distance from the hub to the skin and marking the position of the 2nd strut on the skin.

3.2. TREATMENT PLANNING

The lumpectomy cavity volumes for the 6-SAVID mini device, the device of interest for this study, averaged 8.4 ± 1.3 cm³. PTV_EVAL and PTV volumes averaged 44.7 ± 7.9 cm³ and 49.9 ± 3.4 cm³, respectively. V90 values averaged 98.8 ± 1.7% of the PTV_EVAL
volume, which is well within the criteria imposed by the NSABP B-39/RTOG 0413 protocol. V95 averaged 97.8 ± 2.5% and V100 averaged 95.3 ± 4.8%. V150 averaged 25.0 ± 4.3 cm³ while V200 averaged 14.4 ± 2.7 cm³.

PTV reduction mounted up to 36.0 ± 12.0% for the cases where the skin bridge (SB) was < 5 mm, especially where combined with reduced Chest Wall bridges (CWB). This can result in dramatic drops of the CI (conformity index) values for PTV_EVAL, where air/seroma is present, down to 61.1%. Though, across the entire cohort, CI values averaged 96.6 ± 5.7%.

Skin and CW sculpting of PTV is always employed when creating PTV_EVAL structures. The PTV volume reduction PTV-VR averaged 11.0 ± 14.0%, with min and max values of 0.0% (no reduction) and 59.0% (when both SB and CWB were < 5 mm) respectively. We proposed and used this equation for calculating PTV-VR:

$$PTV-VR \ (\%) = \frac{PTV \ \text{volume} - PTV_{\text{Eval}} \ \text{volume}}{PTV \ \text{volume}}$$

Dosimetric data for all 121 patients included in this study is shown in Table 1. Sixteen (16) patients had a skin bridge (SB) of less than 5 mm. For these patients, the maximum skin dose (n = 16) was 96.3 ± 2.3% (mean±standard deviation). Chest wall bridge (CWB) varied widely, ranging from 0.3 mm to 61.0 mm (15.2 ± 11.7 mm). The maximum dose to the chest wall, over the entire cohort of patients, was 90.5 ± 44.3% of the prescription dose.

The V150 “hotspots” averaged 20.6 ± 6.1 cm³, while V200 averaged 18.8 ± 6.6 cm³. The average minimum skin distance was 13.5 mm, but the applicator was used in patients where the skin bridge was as low as 1 mm. The average maximum skin dose (MSD) was 72.8% of the prescription dose. The average minimum CWB was 15.2 mm, with the shortest of less than 0.3 mm, and the average maximum dose to the chest wall of 90.5% of the prescription dose.

Table 1

<table>
<thead>
<tr>
<th>Skin Bridge (mm)</th>
<th># Patients</th>
<th>Max Skin Dose (Gy)</th>
<th>V90 (%)</th>
<th>V200 (cm³)</th>
<th>PTV-VR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5</td>
<td>16</td>
<td>35.94</td>
<td>96.3±2.3</td>
<td>10.1±1.7</td>
<td>36.0±12.0</td>
</tr>
<tr>
<td>5 &lt;SB &lt;10</td>
<td>34</td>
<td>33.25</td>
<td>98.4±1.2</td>
<td>13.4±1.7</td>
<td>16.0±7.0</td>
</tr>
<tr>
<td>10 &lt;SB &lt;15</td>
<td>31</td>
<td>31.78</td>
<td>99.3±1.2</td>
<td>16.0±1.9</td>
<td>3.0±6.0</td>
</tr>
<tr>
<td>15 &lt;SB &lt;20</td>
<td>14</td>
<td>26.66</td>
<td>99.9±0.2</td>
<td>15.7±2.2</td>
<td>4.0±12.0</td>
</tr>
<tr>
<td>20 &lt;SB &lt;25</td>
<td>16</td>
<td>18.87</td>
<td>99.6±2.5</td>
<td>15.6±2.1</td>
<td>1.0±3.0</td>
</tr>
<tr>
<td>SB &gt; 25</td>
<td>10</td>
<td>18.16</td>
<td>99.6±0.4</td>
<td>16.4±2.3</td>
<td>0.0±1.0</td>
</tr>
</tbody>
</table>

The PTV-VR values are largest for the cases with reduced skin bridges, where there is a significant reduction of the volume of PTV_EVAL compared to
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PTV. Dose coverage in those marginal cases was still excellent, with average V90 of 96.3%.

4. CONCLUSIONS

The SAVI-mimi strut-based device proves to be a highly adaptable and versatile APBI solution for patients with reduced breast and lumpectomy cavity volumes, and skin and/or chest wall bridges. Inside the framework of a detailed and clear QA program, when it is appropriately elected as the APBI device of choice, optimally implanted, and comprehensively monitored during the course of treatment, this device indeed offers a very effective and highly reproducible tool for the treatment of complex breast cancer cases.

REFERENCES