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Prospective analysis of toxicity in patients treated with strut-adjusted volume implant for early-stage breast cancer

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ABSTRACT

PURPOSE: We report the toxicity of patients treated with strut-adjusted volume implant (SAVI) for accelerated partial breast irradiation treated at our institution.

METHODS AND MATERIALS: Patients treated from January 2013 to July 2015 with SAVI planned for 10 b.i.d. fractions for a total dose of 34 Gy were included. Acute and late toxicities were prospectively collected on patients in followup and graded by the Common Terminology Criteria for Adverse Events, version 4.0.

RESULTS: A total of 132 patients were included, with 1 patient having synchronous breast cancer treated in each breast. Median followup was 20.0 months (range, 2.7−37.4 months). The median age at diagnosis was 61 years (range, 41−83 years). Forty-two lesions (32%) were in situ, 88 lesions (66%) were Stage 1, and 3 (2%) lesions were Stage 2. The median planning target volume was 58.2 cc (range, 24.2−109.9 cc), median V_{150} was 26.3 cc (range, 11.5−47.5 cc), and median V_{200} was 13.0 cc (range, 6.3−26.1 cc). On a pain scale of 0−10 (10 = worst pain), pain was worst on Day 2 of treatment, with an average score of 0.46. There was one acute skin infection; there were three late skin infections, two of which was Grade 3. Other late toxicities were Grade 1 or 2: hyperpigmentation (44%), telangiectasia (0.8%), seroma (9%), fat necrosis (5%), and fibrosis (12%). Crude local recurrence rate was 4%.

CONCLUSION: SAVI is a safe treatment option for patients who are candidates for accelerated partial breast irradiation. Local control seems to be excellent, but longer followup is needed.

Keywords: Accelerated partial breast irradiation; Strut-adjusted volume implant; Breast cancer

Introduction

In 2016, in the United States, an estimated 246,660 women will be diagnosed with invasive breast cancer and an additional 61,000 women will be diagnosed with noninvasive breast cancer (1). Several trials with long-term followup have validated breast conserving surgery and adjuvant radiation therapy as an alternative approach to mastectomy for the management of early-stage breast cancer (2, 3, 4). The benefit of radiation therapy was confirmed in a meta-analysis that demonstrated adjuvant radiation therapy reduced the risk of recurrence and the risk of death from breast cancer (5). Adjuvant radiation therapy historically encompassed the whole breast, but certain patients are considered appropriate candidates for accelerated partial breast irradiation (APBI), where not only is the volume of breast being treated reduced, but the length of treatment is shortened.

Data comparing whole breast irradiation (WBI) to APBI continue to mature and provide information regarding side effects and tumor control outcomes. The Randomized Trial of Accelerated Partial Breast Irradiation (RAPID) trial compared patients treated with WBI vs. APBI with external beam radiation therapy (EBRT) to 38.5 Gy in 10 twice daily fractions. This report found worse cosmesis at 3 years and higher rates of Grade 1 and 2 toxicities in the APBI

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arm compared to the WBI arm (6). In contrast, Polgar *et al.* published a trial where patients were randomized to WBI vs. APBI with multicatheter interstitial brachytherapy. After a median followup of 10 years, good or excellent cosmetic outcomes favored the APBI arm (7). More recently, Groupe Européen de Curiethérapie−European Society for Radiotherapy and Oncology (GEC-ESTRO) published their Phase 3 results comparing APBI (with interstitial multicatheter brachytherapy) to WBI. A total of 1184 patients were accrued with median followup of 6.6 years. The 5-year local recurrence rate was not different between the two arms (0.92% vs. 1.44%); there was no difference in lymph node recurrence, disease-free survival, or overall survival. Regarding toxicity, at 5 years, there was no difference in Grade 2−3 late skin side effects or Grade 2−3 subcutaneous tissue side effects for WBI and APBI (8).

These data lend support to the use of APBI for properly selected patients. Strut-adjusted volume implant (SAVI) is another technique used for APBI, although there is less robust long-term data with SAVI, and no randomized prospective data comparing WBI to APBI with SAVI. Treatment with SAVI has been implemented in our institution since 2013 for delivery of APBI. SAVI has a central catheter with 6, 8, or 10 catheters on the periphery. SAVI has potential advantages over other methods of delivering APBI in its ability to conform the dose better around the target and spare skin and the chest wall, therefore minimizing toxicity. Yashar *et al.* published outcomes for a series of 102 patients treated with SAVI with a median followup of 21 months. The most common toxicity reported was hyperpigmentation (in less than 10% of patients), and the recurrence rate was 1% (9). Yashar *et al.* subsequently published (in abstract form) the results of 200 patients with median followup of 52.3 months. Late grade ≥2 toxicity was low (less than 5%), cosmesis was excellent (>93% reported good or excellent), and 4-year actuarial rates of local recurrence (either true recurrence or marginal miss) was 1.8% (10). The largest report available is from the SAVI Collaborative Research Group (abstract form) on 596 patients with a median followup of 39 months, which again confirmed excellent local control with low rates of late toxicity (11). With our present study, we aim to summarize our institutional experience with SAVI and report toxicity and preliminary local control results to contribute to the published SAVI data.

Methods and materials

An institutional review board-approved retrospective review was performed on patients treated with APBI using the SAVI device. The first patient at our institution was treated in January 2013, and we included patients through July 2015. A total of 133 cancers in 132 patients were included; 1 patient who was diagnosed with synchronous left and right breast cancers and underwent SAVI treatment to each breast. All patients had at least 30 days of followup, either with radiation oncology, medical oncology, and/or a surgeon.

Surgical management

All patients underwent a lumpectomy. All patients with invasive cancer underwent a sentinel lymph node biopsy, except for 1 patient. Patients with in situ disease did not undergo a routine sentinel lymph node biopsy. One patient had microscopic tumor cells in the nodes. Surgical margins were negative but close (≤1 mm) in 1 patient; the remainder of patients had negative margins either at the time of initial lumpectomy or following re-excision for close or positive margins.

Radiation therapy

Patients were evaluated by a radiation oncologist after the patient's definitive breast conserving surgery. The decision for the patient to undergo APBI was at the discretion of the treating radiation oncologist, based on our institutional guidelines for patients suitable for APBI. In general, our institutional APBI criteria include the following: age ≥40 years, tumor ≤3 cm, negative margins, node negative, unifocal tumor, ductal carcinoma in situ allowed if ≤ 3 cm, no lymphovascular space invasion, no neoadjuvant systemic therapy, and treated with APBI within 8 weeks of breast conserving surgery. No patients were known to have a deleterious BRCA mutation. Placement of the SAVI brachytherapy device was performed by the radiation oncologist via ultrasound guidance and local anesthetic in the outpatient setting. The SAVI is available in a variety of sizes categorized based on the number of peripheral catheters surrounding a central catheter (6−1 mini, 6−1, 8−1, or 10−1). The size of implant used, orientation, and positioning were based on estimation of cavity size and location determined by ultrasound and SAVI prep balloon. After insertion of the SAVI, a CT simulation was performed.

A planning target volume (PTV) was created from the tumor bed with a 1-cm expansion. This volume was edited to exclude the chest wall, the skin minus 5 mm, and the volume of the implant to create a new structure called PTV_eval. The prescription dose was 34 Gy delivered in 10 fractions given twice daily (3.4 Gy per fraction) separated by approximately 6 hours. The plan was optimized for coverage of the PTV_eval. Treatment goals included covering 90% of the PTV_eval with 100% of the prescription dose, covering 95% of the PTV_eval with 95% of the prescription dose, and covering 100% of the PTV_eval with 90% of the prescription dose. Further treatment goals included keeping the volume receiving ≥150% of the prescription dose or more below 50 cc and the volume receiving ≥200% of the prescription dose below 20 cc.

Patients generally started treatment within 2 working days of SAVI placement. Imaging consisting of plain films