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Three-year clinical outcome using the Contura multilumen balloon breast brachytherapy catheter to deliver accelerated partial breast irradiation (APBI): Improving radiation standards for the optimal application of APBI

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ABSTRACT

PURPOSE: We reviewed our institution's 3-year clinical experience in treating patients with the Contura multilumen balloon (SenoRx, Inc., Aliso Viejo, CA) breast brachytherapy catheter to deliver accelerated partial breast irradiation (APBI).

METHODS AND MATERIALS: Forty-six patients treated with breast-conserving therapy received adjuvant radiation using the Contura catheter (34 Gy in 3.4 Gy fractions). Fourteen patients had Stage 0, 24 had Stage I, and 8 had Stage II breast cancer. Median follow-up was 36 months (range, 1–44 months).

RESULTS: Only one local recurrence developed (2%). The rate of persistent seroma formation at latest reported follow-up was 4.3% (2 patients) and the incidence of any clinically detectable telengiectasias was 2.2%. No major toxicities (0% Grade III) have occurred. The median skin dose (% of the prescribed dose) was 99.7. The median dose to 95% of the planning target volume for evaluation was 98.8%. The percentage of patients with excellent/good cosmetic results at 24 ($n = 23$) and 36 ($n = 22$) months was 100% and 97%, respectively.

CONCLUSION: Adjuvant APBI using the Contura multilumen balloon catheter exhibited similar locoregional control, cosmesis, and toxicities to other forms of APBI with similar lengths of follow-up. In addition, improved radiation standards for the delivery of APBI were demonstrated.

Keywords: Balloon brachytherapy; Partial breast irradiation; Breast cancer; Contura MLB; MammoSite

Introduction

Accelerated partial breast irradiation (APBI) continues to be explored as an option to deliver adjuvant irradiation after lumpectomy in selected patients undergoing breast-conserving therapy (1). Most Phase I/II studies (and recent Phase III data) demonstrate excellent 5- and 10-year rates of local control and cosmesis using this treatment approach in selected patients (2, 3). Studies using multicatheter interstitial brachytherapy as the APBI technique provide the largest group of patients with the longest follow-up to date, establishing the efficacy of this approach (4, 5) Other forms of APBI have been developed to reduce the complexity of this procedure and improve its reproducibility and attractiveness to patients.

The MammoSite applicator (Hologic Inc., Bedford, MA) was one of the first devices designed to address these issues (6). In the first Phase I/II clinical study with the catheter, 43 patients received APBI as their sole treatment (7). The study demonstrated that the device was safe and well tolerated, resulting in Food and Drug Administration clearance in May 2002. Five-year cosmetic results in 83% of these patients have been good-to-excellent and no local recurrences have been observed to date (median follow-up, 66

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months) (8). Additional larger studies have also confirmed the advantages and efficacy of the device and technique.

One of the major limitations with the use of the MammoSite to deliver APBI relates to its single lumen design and the fixed relationship between the geometry of balloon placement and the dose delivered. The Contura multilumen balloon (MLB) (SenoRx, Inc., Aliso Viejo, CA) was designed to provide additional options to achieve more idealized dosimetric goals. Through the use of four additional lumens that are offset from the single central catheter lumen, dose shaping is possible. Published dosimetric data have demonstrated the device's ability to significantly reduce skin and rib doses and improve on other treatment restrictions (as a result of insufficient skin spacing or suboptimal conformance). In addition, preliminary experiences with the new device have revealed excellent early tolerance and toxicities as good or better than those observed with the original single-lumen MammoSite device. This report examines 3-year clinical efficacy data (i.e., locoregional control, cosmesis, and toxicity) using the Contura applicator at our institution to deliver APBI.

Methods and materials

This retrospective analysis has been given an exempt determination granted under 45 CFR 46 101(b) (4) by the Western Institutional Review Board. Patients were treated from June 25, 2007 to May 23, 2008 and follow-up was complete through May 2011.

Patient selection and eligibility criteria

Initial results on patients reported in this analysis were previously published (9). Patients were selected for APBI at the discretion of the treating physician and preference (if eligible) of the patient. The American Society of Breast Surgeons and/or the American Brachytherapy Society guidelines for the treatment of patients with APBI off-protocol were followed at that time (10). Patients were not enrolled on an Institutional Review Board-approved protocol.

Treatment planning

Patients referred for possible APBI underwent a CT scan (with the Contura MLB in place) to assess appropriateness for treatment and for treatment planning purposes. Adequate tissue-to-balloon conformance was confirmed under ultrasound guidance and adjustments made (i.e., use of vacuum port and/or additional fluid added to the balloon) if necessary. Final determination as to adequate conformance was made by CT scan examination before treatment planning. At the time of the planning CT, the rotational orientation of the Contura catheter was documented so that before each treatment the proper orientation could be reproduced.

Target volumes

As per the National Surgical Adjuvant Breast and Bowel Project (NSABP) B39-Radiation Therapy Oncology Group (RTOG) 0413 protocol guidelines, the planning target volume for evaluation (PTV_EVAL) = clinical target volume = PTV. The PTV_EVAL was delineated as the breast tissue volume bounded by the uniform expansion of the balloon radius in all dimensions by 10 mm less than the balloon volume and was limited to 5 mm from the skin surface and by the posterior breast tissue extent (the chest wall and pectoralis muscles were not to be included).

Contura MLB placement and treatment planning

The Contura MLB was placed with a closed cavity placement technique in all patients. Radioactive source location, number of lumens, number of positions, and dwell times were at the discretion of the treating physician and were determined by high-dose rate CT-based three-dimensional (3D) treatment planning using BrachyVision (Varian Brachytherapy, Charlottesville, VA) to produce the optimal conformal plan in accordance with volume definition and dose requirements. The treatment plan used for each patient was based on an analysis of the volumetric dose including dose–volume histogram analyses of the PTV_EVAL and critical normal tissues.

Determination of appropriateness for treatment

Appropriateness for treatment was based on the ability to achieve idealized dosimetric goals. Once achieved, treatment was typically initiated within 1–5 days from the acquisition of the planning CT. The balloon remained inflated throughout the treatment course and patient positioning, balloon inflation, and proper balloon rotation was confirmed before each treatment delivery. A total of 34 Gy was prescribed to the PTV_EVAL such that the dosimetric requirements of target coverage, dose homogeneity, and reduced skin dose were satisfied. Two fractions per day, each of 3.4 Gy, separated by at least 6 h, were given in 5 consecutive working days.

Quality assurance of dose distribution

Dose–volume histogram analyses of target coverage were performed in each case to confirm that a minimum of 90% or more of the prescribed dose (PD) covered 90% or more of the PTV_EVAL (per NSABP B-39/RTOG 0413 criteria). The maximum skin dose was reduced to as low as achievable while satisfying all dose parameters and not exceeding 145% of the PD. The maximum rib dose was reduced to as low as achievable while satisfying all dose parameters to not exceed 200% of the PD (if possible). The volume of breast tissue receiving 150% (V_{150}) of the PD was reduced to as low as achievable while satisfying all dose parameters but was not to exceed 50 cc. The volume of breast tissue receiving 200% (V_{200}) of the PD