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A dosimetric comparison of the Contura multilumen balloon breast brachytherapy catheter vs. the single-lumen MammoSite balloon device in patients treated with accelerated partial breast irradiation at a single institution

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ABSTRACT

PURPOSE: A comparison of dosimetric findings in 33 patients treated with the Contura multilumen balloon (SenoRx Inc., Irvine, CA) (C-MLB) breast brachytherapy catheter vs. 33 patients treated with the MammoSite (Hologic Inc., Bedford, MA) (MS) at a single institution to deliver accelerated partial breast irradiation (APBI) was performed.

METHODS AND MATERIALS: CT-based 3-dimensional planning with dose optimization was completed. APBI treatment of 34 Gy in 3.4 Gy fractions was delivered. Endpoints analyzed included: (*1*) The percentage of the prescribed dose (PD) covering the planning target volume (PTV), (*2*) the maximum skin dose as a percentage of the PD, (*3*) the maximum rib dose as a percentage of the PD, and (*4*) the V150 and V200.

RESULTS: The C-MLB was placed more frequently in patients with closer skin spacing (<7 mm) and rib spacing (<7 mm) than in MS patients (45.5% vs. 12.1%, $p = 0.0057$ and 57.6 vs. 33.3, $p = 0.0131$, respectively). Despite closer skin spacing, the overall median skin dose was significantly lower in C-MLB patients (112% of the PD vs. 134%, $p = 0.0282$). No statistically significant differences in the V150 or V200 were observed. In patients with very limited rib spacing (<4 mm), the C-MLB delivered significantly lower rib doses than the MS (144% of the PD vs. 191%, $p = 0.0107$). In all clinical scenarios, coverage of the PTV with the C-MLB was either equal to or significantly better than with the MS ($p = 0.0024$).

CONCLUSION: The C-MLB catheter produced clinically significant improvements in dosimetric endpoints (e.g., reduced skin and rib doses and improved PTV coverage) in most clinical scenarios.

Keywords: Breast conserving therapy; Balloon brachytherapy; Contura; Partial breast irradiation; Breast cancer

Introduction

Accelerated partial breast irradiation (APBI) has been investigated as an option to deliver adjuvant irradiation after lumpectomy in selected patients treated with breast conserving therapy (1). Most retrospective trials (and more recently some Phase III data) have demonstrated acceptable 5- and 10-year rates of local control and cosmesis using this treatment approach (2–4). Studies using catheter-based interstitial brachytherapy (IB) as the APBI technique continue to provide the largest group of patients with the longest followup. However, a potential limitation of IB as a technique to deliver APBI includes its complexity and reproducibility (from patient to patient). In recognition of this, the MammoSite (MS) applicator (Hologic Inc., Bedford, MA) was developed to provide a much more user-friendly implant with increased reproducibility compared with IB.

In the first Phase I or II clinical trial with the MS balloon catheter, 43 patients were treated with APBI (5) and

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experienced only mild to moderate side effects. Five-year cosmetic results were good-to-excellent in 83% of the women treated in this study and no local recurrences have been observed (median followup of 66 months) (6). Multiple single-institution experiences have also demonstrated acceptable early local control and cosmesis (with minimal toxicities) (7). More recent data on the use of the MS to deliver APBI by the American Society of Breast Surgeons have shown a 5-year ipsilateral breast local recurrence rate of only 3.18% in the first 400 patients treated on this registry trial (median followup of 59 months) with 93% of these patients having good or excellent cosmesis (American Society for Radiation Oncology abstract).

With increased treatment experiences using both IB and the MS balloon device, several dosimetric parameters have been identified as treatment planning goals to reduce potential acute and chronic toxicities and to optimize target volume coverage. Many of the original dosimetric parameters that were used to judge the appropriateness for treatment were based on the limited dosimetric performance of the single-lumen MS device. The dosimetric capabilities of this device are highly dependent on (*1*) The location of balloon placement within the breast, (*2*) the symmetry of the balloon, and/or (*3*) the fit of the inflated balloon within the lumpectomy cavity (e.g., conformance). Often, to reduce the number of abandoned cases, a physician may be forced to compromise on certain of these dosimetric parameters and potentially reduce target volume coverage and/or risk toxicity. Ideally, dosimetric parameters to optimize target coverage and reduce toxicity should not be compromised to avoid aborting cases.

The new Contura multilumen balloon (SenoRx Inc., Irvine, CA) (C-MLB) catheter was developed to address the dosimetric shortcomings of current balloon-based brachytherapy and to provide the radiation oncologist with additional options to better conform the radiation dose to the target tissue. Through the addition of four offset lumens, significant dose shaping (e.g., improved dosimetric flexibility) is possible. This offers the ability (in many cases) to potentially overcome present geometric restrictions of balloon brachytherapy, which include (*1*) limited skin thickness, (*2*) close rib proximity, (*3*) balloon asymmetry, and (*4*) inadequate conformance.

To evaluate the potential dosimetric advantages of this new device, a dosimetric comparison of actual cases treated with the C-MLB vs. the MS catheter at a single institution was performed.

Methods and materials

The primary goal of this study was to compare dosimetric findings in patients treated with the C-MLB catheter vs. those treated with the single-lumen MS device at the WellStar Kennestone Hospital by the same two surgeons and four radiation oncologists. Each cohort (C-MLB and MS) comprising 33 cases were treated consecutively (from a given start date to a given completion date) to achieve a uniform unselected group of patients treated with APBI using balloon-based brachytherapy. For the MS cohort, the study period was from October 23, 2006 to July 23, 2008 and for the C-MLB cohort, the study period was September 23, 2007 to January 30, 2009. This retrospective dosimetric study was approved by the Western Institutional Review Board' s (WIRB' s) Regulatory Affairs Department and granted an exemption determination under 45 Code of Federal Regulations g46. 101(b) (4).

Inclusion/exclusion criteria

All 66 patients were treated with APBI after lumpectomy with negative surgical margins. Ductal carcinoma in situ and/or invasive breast carcinoma was allowed and all invasive cancer patients had an axillary staging procedure (either sentinel lymph node biopsy alone or axillary dissection). Typical characteristics of patients treated with balloon-based brachytherapy at the WellStar Kennestone Hospital can be found in a previous publication (8).

Brachytherapy treatment procedure

In all cases, the balloon catheters were placed into the lumpectomy cavity and inflated in a separate procedure after surgery using ultrasound guidance. The details of both the surgical and radiation therapy planning goals of balloon placement have been previously reported (8). Balloons remained inflated throughout the duration of the radiation. Standard treatment planning guidelines for APBI were used and CT scan imaging was mandatory for treatment planning (CT-based 3-dimensional brachytherapy treatment planning was conducted.)

The total prescribed dose (PD) was 34 Gy delivered to the planning target volume for evaluation (PTV_EVAL) divided in 10 fractions over 5 consecutive working days. The treatment fractions were delivered twice a day with at least 6 h separating each fraction. Before each fraction, the patient's position and balloon inflation volume were confirmed. Additionally, the rotational orientation of the catheter was confirmed to be identical to that at the time of initial planning CT. This meant that a visual inspection was conducted to be certain that the line on the shaft of the device was in alignment with a skin mark drawn at the time of the initial planning CT. If necessary, the rotational orientation was adjusted. All treatments were completed using a high-dose rate remote afterloader and ^{192}Ir radioactive source. After completion of treatment delivery, the balloon was deflated and the applicator was removed.

Dosimetric guidelines and quality assurance criteria

At the time of CT acquisition for planning, appropriateness of balloon placement was assessed, adjustments made (e.g., balloon volume adjustment, improved orientation