



Clinical implementation of a novel Double-Balloon single-entry breast brachytherapy applicator

Bethany M. Anderson^{1,*}, Charles R. Wallace², Anna-Maria A. De Costa¹, Rupak K. Das¹

¹Department of Human Oncology, University of Wisconsin, Madison, WI

²Department of Medical Physics, University of Wisconsin, Madison, WI

ABSTRACT

PURPOSE: The purpose of the study was to describe the clinical utilization of a novel Double-Balloon applicator for accelerated partial breast irradiation (APBI).

METHODS AND MATERIALS: The Double-Balloon single-entry breast applicator contains a single central treatment catheter, as well as four peripheral catheters that can be differentially loaded to customize radiation dose coverage. An inner balloon is filled with up to 7–30 cm³ of saline to increase separation between the peripheral catheters, and an outer balloon is filled with up to 37–115 cm³ of saline to displace breast tissue from the peripheral catheters. Treatment planning objectives include coverage of the breast planning target volume to a minimum of $V_{90} > 90\%$, limiting dose heterogeneity such that $V_{200} < 10 \text{ cm}^3$ and $V_{150} < 50 \text{ cm}^3$, and limiting maximum dose to skin (<100% of prescription dose) and ribs (<145% of prescription dose).

RESULTS: High-dose-rate APBI was delivered to 11 women using this device (34 Gy in 10 twice daily fractions). The mean V_{90} was 98.2% (range 94.2–99.4%). The mean skin D_{max} with the Double-Balloon applicator was 83.3% (range 75.6–99.5%). The mean breast V_{200} was 5.8 cm³ (range 2.3–10.2 cm³), and the mean breast V_{150} was 32.9 cm³ (range 25.0–41.7 cm³). Pretreatment quality assurance was performed using CT prior to each morning fraction and ultrasound prior to each afternoon fraction.

CONCLUSIONS: The Double-Balloon applicator can be easily introduced into a previously existing brachytherapy program. APBI plans created with this applicator achieve excellent planning target volume coverage, while limiting skin dose and maintaining breast $V_{200} < 10 \text{ cm}^3$. © 2017 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords: Breast cancer; Brachytherapy; Accelerated partial breast irradiation

Introduction

Accelerated partial breast irradiation (APBI) is an adjuvant radiotherapy option that is desirable for many women, given that it allows radiation to be targeted directly to the tumor bed and completed over approximately 1 week. Two randomized trials have demonstrated that multicatheter APBI produces the same local control rates as whole breast irradiation for women with low-risk breast cancers

(1, 2). While multicatheter APBI is the only breast brachytherapy method supported by mature phase III data, this treatment method is currently only available at select institutions with specially trained brachytherapy teams. Single-entry applicators are easier to incorporate into a breast cancer treatment program, as evidenced by the rapid increase in APBI cases treated per year after the Food and Drug Administration (FDA) approved the first MammoSite applicator (Proxima Therapeutics Inc, Alpharetta, GA) in May 2002 (3). Therefore, single-entry applicators have the capacity to improve access to breast brachytherapy to women who live remotely from centers that offer multicatheter APBI.

Since 2002, much has been learned about optimizing APBI techniques, and several advances have been made in single-entry breast brachytherapy applicators (4). The original MammoSite (now Hologic Inc, Bedford, MA) has been revised, and additional applicators have been

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* Corresponding author. Department of Human Oncology, University of Wisconsin, 600 Highland Ave, K4/B100, Madison, WI 53792. Tel.: +1 608-263-8500; fax: +1 608-263-9167.

E-mail address: anderson@humonc.wisc.edu (B.M. Anderson).

developed to improve radiation dose distribution, including Contura (Hologic Inc, Bedford, MA) and strut-adjusted volumetric implant (SAVI; Cianna Medical, Aliso Viejo, CA). Important treatment planning goals include limiting radiation dose to skin and chest wall, as well as avoiding dose heterogeneity within the breast tissue (5–8). Most recently, a novel Double-Balloon applicator has been developed, with the hypothesis that an ideal balance between dose heterogeneity and sculpting capability could be achieved by displacing the peripheral treatment catheters from the center, while keeping them from directly contacting breast tissue. Following FDA approval of the Double-Balloon breast brachytherapy applicator (Best Medical International, Springfield, VA), this device was incorporated into our clinic in 2015 as a part of standard-of-care treatment for women receiving high-dose-rate APBI. The purpose of this work is to describe the implementation of the Double-Balloon applicator into a previously existing brachytherapy program, highlighting practical aspects such as catheter placement and quality assurance methods.

Methods and materials

Double-Balloon breast brachytherapy applicator

The Double-Balloon applicator has five total available treatment catheters: one fixed central catheter and four moveable peripheral catheters. Three different applicator sizes are available, to accommodate lumpectomy cavities

measuring from 4.5 to 6.5 cm along the long axis of the applicator (Fig. 1, Table 1). At our institution, very small lumpectomy cavities measuring <4 cm in maximum dimension are treated with multicatheter APBI. Depending on the size of the applicator, the inner balloon is filled with up to 7–30 cm³ of sterile saline, to variably displace the peripheral catheters depending on the degree of dose sculpting that is desired. The outer balloon is then filled with up to 37–115 cm³ of saline to fully occupy the lumpectomy cavity and displace the peripheral catheters from the breast tissue. The maximum filling volume for the outer balloon, including the contents of the inner balloon, is a total of 40 cm³ for the small applicator (model #1994), 100 cm³ for the standard size applicator (model #1922), and 130 cm³ for the large applicator (model #1994). This corresponds to maximum balloon diameters of 3.8 cm, 5.2 cm, and 6.5 cm, respectively. For example, if a standard-sized applicator is being used and the inner balloon is filled with 15 cm³, then no more than 85 cm³ should be placed into the outer balloon, achieving a combined total filling volume of 100 cm³. A vacuum port is also included with this device, to remove any seroma or air trapped between the outer balloon and the lumpectomy cavity after insertion and prior to delivery of each treatment.

Patient selection and applicator placement

At our institution, the process of selecting patients for APBI starts by reviewing clinical and pathologic features

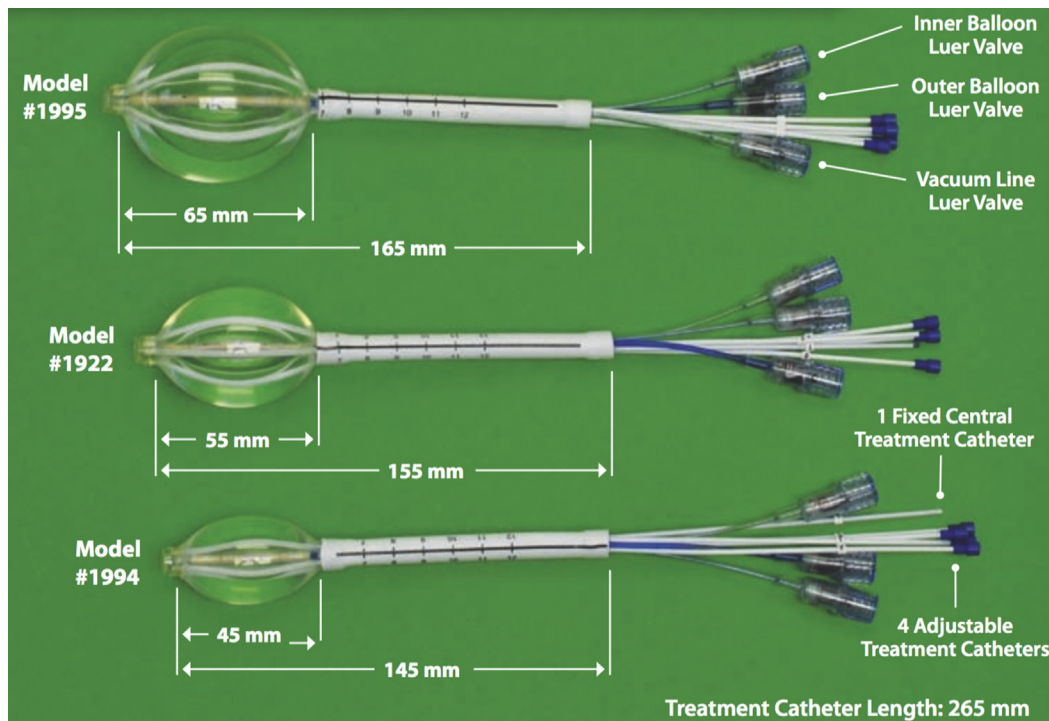


Fig. 1. The Double-Balloon applicator consists of a fixed central treatment catheter surrounded by four moveable peripheral catheters. The applicator comes in three different sizes to better accommodate lumpectomy cavities of variable dimensions. Image courtesy of Best Medical.

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