Introduction and Objectives

The Single-Lumen Catheter (SLC) MammoSite® brachytherapy applicator was approved by the FDA in May of 2002 and has become an accepted modality for adjuvant radiation therapy, delivering accelerated partial breast irradiation (APBI) in early stage breast cancer patients. [1–3]

Due to concern regarding unwanted increase of radiation dose to the skin or chest wall, 2nd generation devices were developed that allowed for a more tailored treatment plan that could selectively adjust and minimize the radiation dose to adjacent structures. [4] The first MammoSite® Multi-Lumen Catheter (MLC) was cleared by the FDA in May 2008 (Contura® MLB), followed by MammoSite® MLC Catheter in August 2009.[1]

All of the catheters described above, both SLC and MLCs, are now classified as the MammoSite® Radiation Therapy System (Hologic, Inc., Bedford, MA).

At our institution, SLC devices were gradually exchanged to MLC devices beginning in May 2010.

The objective of this study was to assess clinical outcomes in patients who underwent APBI using MammoSite® balloon catheter 5-Day targeted radiation therapy, with a specific focus on loco-regional recurrence (LRR) and adverse events with SLC as compared to MLC devices.

Methods

A retrospective chart review of patients with stage 0-2 breast cancer, who were treated with breast conserving surgery, followed by APBI using the MammoSite® balloon catheter device from 2004-2012 at our institution was conducted.

Clinical outcomes including LRR and adverse events were compared between the MammoSite® SLC and the MammoSite® MLC.

In accordance with the American Society for Radiation Oncology guidelines, comparisons were also made between SLC and MLC for lymphovascular invasion (LVI), tumor size, margins, age, extensive intraductal component (EIC)/high grade DCIS (HGDCIS, defined as Grade 3 DCIS or extent of disease on pathology reports), lymph node status, and estrogen receptor (ER) status.

Categorical data were analyzed using chi-square and Fisher's exact tests and continuous data with Mann-Whitney U and independent samples t-tests.

Results

A total of 103 patients were included in this study with a median follow up of 55 months.

Cancer types included Ductal Carcinoma in Situ (DCIS) 28.2%, Invasive Ductal Carcinoma 67%, and Invasive Lobular Carcinoma 4.8%.

Of the 103 patients who completed APBI using MammoSite® balloon catheter 5-Day targeted radiation therapy, 54% had SLC, and 46% had MLC.

Overall, 28.2% were suitable, 64.1% cautionary, and 7.8% unsuitable patients according to American Society for Radiation Oncology guidelines’ criteria.

Analyses between SLC and MLC revealed:

- There was no significant differences in age (p = 0.65).
- There was no significant differences in tumor size (p = 0.437).
- There were no significant differences for margins (p = 0.113).
- There were no associations between catheter type and LVI (p = 0.094).
- There was no significant difference for EIC/HGDCIS (p = 0.132).
- There was no significant difference for lymph node status (p = 0.623).
- There was no significant difference for ER status (p = 0.241).
- However, there was a significant association between catheter type (SLC/MLC) and cancer recurrence (p < 0.05).

Only 1 patient (1.8%) of the SLC patients experienced recurrence (all distal), while 14.9% of MLC patients experienced recurrence (6 patients or 12.8% for in breast tumor recurrence and 1 patient or 2.1% distal recurrence).

In addition, more than half of the number of patients (59.6%) who used MLC suffered adverse events, while only 37.5% of those with SLC suffered adverse events (p < 0.05).

Discussion

The MammoSite® MLC had a higher proportion of breast tumor recurrence and adverse events than SLC. Further study is warranted regarding the safety and efficacy of utilizing MammoSite® MLC instead of MammoSite® SLC for APBI.

Long term outcomes from use of the MammoSite® MLC are yet to be investigated and are currently under represented in the current literature, including both prospective and retrospective protocols and studies.

The current ASTRO guidelines may not reflect patient and tumor characteristics who are at low risk for IBTR and who are candidates for and would benefit from APBI.

There are limitations to this analysis of the MammoSite® Radiation Therapy system. This was a retrospective study, and the results represent reported data documented within our institution.

Under-reporting of local failures and/or toxicities should be critically considered for APBI. Going forward, a prospective trial regarding SLC vs. MLC would contribute to our knowledge regarding the most appropriate delivery of APBI.

References


