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BRACHYTHERAPY

Frequency of whole breast radiation therapy after intraoperative radiation therapy due to criteria identified by lumpectomy

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ABSTRACT

PURPOSE: For selected early breast cancers, intraoperative radiation therapy (IORT) at the time of lumpectomy can be an efficient alternative to fractionated whole breast radiation therapy (WBRT). However, some patients are later recommended WBRT after IORT due to surgical pathologic findings. To understand risk factor identification rates triggering WBRT recommendation, we analyzed adverse prognostic features based on multiple international criteria for suitability for accelerated partial breast irradiation.

METHODS AND MATERIALS: We performed a single-institution retrospective review of all 200 nonrecurrent invasive breast carcinomas that received IORT in 20 Gy to the tumor cavity using a 50 kV photon applicator between January 2011 and December 2015. IORT eligibility was based on the 2009 accelerated partial breast irradiation Consensus Statement from the American Society for Radiation Oncology (ASTRO). IORT was offered as the sole radiation modality to patients meeting 0−1 ''cautionary'' and no ''unsuitable'' criteria before lumpectomy. WBRT was recommended after IORT when 2+ cautionary and/or 1+ unsuitable criteria were met after accounting for resection pathology. We recalculated WBRT recommendation rates using initial and reresection margins for ASTRO consensus, Groupe Européen de Curiethérapie−European Society for Therapeutic Radiology and Oncology recommendations, and TARGeted Intraoperative radioTherapy vs. Postoperative Radiotherapy trial ''prepathology'' stratum protocol.

RESULTS: Depending on the selection criteria chosen, rates of WBRT recommendation can vary from 4.5% to 33%.

CONCLUSIONS: WBRT recommendation rates of 30−33% after lumpectomy and IORT are observed when the WBRT indication is a single ASTRO cautionary/unsuitable, Groupe Européen de Curiethérapie−European Society for Therapeutic Radiology and Oncology intermediate/high-risk criterion, or TARGeted Intraoperative radioTherapy vs. postoperative radiotherapy trial protocol recommendation. Alternatively, allowing for re-excision to clear margins and accepting one ASTRO cautionary factor lowered the rate of WBRT recommendation to 9.5%. © 2016 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords: Radiotherapy; Breast neoplasms; Intraoperative procedures

Introduction

Breast-conserving surgery (lumpectomy) followed by whole breast radiation therapy (WBRT) remains a standard of care for early breast cancer resulting in improved local control and overall survival (1). Because ~90% of early recurrences occur in the area surrounding the lumpectomy cavity, multiple techniques for accelerated partial breast irradiation (APBI) have emerged as an alternative to WBRT (2−4).

Continued debate surrounds appropriate APBI patient selection. Several risk factors likely portend increased risk of

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in-breast tumor recurrence (IBTR) from residual microscopic cancer untreated by APBI fields. These risk factors were independently compiled and reviewed to guide patient selection in the American Society for Radiation Oncology (ASTRO) consensus statement and The Groupe Européen de Curiethérapie - European Society for Therapeutic Radiology and Oncology (GEC-ESTRO) recommendations (5,6).

There are multiple APBI delivery techniques including intraoperative radiation therapy (IORT) by 50 kV photons (5). Compared to other APBI techniques, patient selection for IORT is uniquely challenging because complete pathologic assessment cannot be performed before treatment. Some risk factors are identifiable before lumpectomy based on patient characteristics and core needle biopsy (patient age, estrogen receptor positivity, etc.), whereas others are revealed by lumpectomy pathology (pathologic size, surgical margins, etc.).

A similar technique using intraoperative electron radiation therapy (IOERT) was tested in the ELIOT trial of 1305 patients randomized to IOERT or WBRT (7). The 5-year IBTR of 4.4% for IOERT was greater compared to 0.4% for WBRT ($p = 0.0001$). Nevertheless, it was recently demonstrated that risk factors from the ASTRO consensus criteria correlated with IBTR for 1822 IOERT patients, suggesting that proper patient selection for intraoperative techniques is crucial (8). In that series, 5-year IBTR rate was lowest for patients with all ASTRO suitable criteria (1.5%), intermediate for patients meeting suitable and cautionary criteria (4.4%), and highest for patients with any unsuitable criteria (8.8%).

Alternatively, IORT can be delivered in a ''risk-adapted'' fashion as per the TARGeted Intraoperative radioTherapy vs. Postoperative Radiotherapy (TARGIT-A) noninferiority trial of 3451 early breast cancer patients randomized to IORT vs. WBRT (9). Overall, the TARGIT-A trial demonstrated higher IBTR in the IORT arm (3.3% vs. 1.3% 5-year IBTR, $p = 0.042$). However, in the ''prepathology'' stratum, 2298 patients were selected for IORT, and those found to have selected recurrence risk factors on final pathology received WBRT with IORT being considered an up-front boost. Subset analysis of the prepathology stratum identified that IORT met noninferiority criteria compared to WBRT in that subset (2.1% vs. 1.1% 5-year IBTR, respectively) (10).

One difficulty in implementing the risk-adapted IORT model is that the TARGIT-A trial protocol allowed sites to customize their eligibility criteria and only recommended but did not mandate, criteria for WBRT after IORT. Our institution had previously selected the ASTRO consensus criteria for patient selection for multiple APBI techniques. Thus, although the ASTRO and GEC-ESTRO criteria were not intended to be used with IORT (being developed for postoperative APBI techniques), we applied the ASTRO criteria to risk-adapted IORT in the absence of clear risk factors to specifically guide IORT patient selection. At our institution, patients with up to one ''cautionary'' and no ''unsuitable'' consensus criteria have been eligible for APBI. We hypothesized that the presence of only one cautionary criterion would expand eligibility for APBI techniques and would not increase IBTR rate. Therefore, patients meeting these criteria were eligible to receive IORT, despite the incomplete information at the time of surgery. For patients found after final pathology to have 2+ cautionary or any unsuitable criteria, WBRT was then recommended without additional boost.

Using this approach, we examined the identified ASTRO consensus risk factors to counsel future patients regarding WBRT recommendation rates after IORT. To aid decision-making for those considering risk-adapted radiotherapy using other established criteria, we also analyzed rates of WBRT using criteria suggested by the GEC-ESTRO APBI recommendations and TARGIT-A trial protocol.

Methods and materials

With institutional review board approval, we retrospectively identified 200 consecutive primary invasive breast cancers treated with lumpectomy and IORT at the time of surgery at our institution from January 2011 to December 2015. Patients eligible for IORT were at least age 50 years and had preoperative core needle biopsy confirmation of a unicentric, AJCC seventh edition stage cT1−T2 (<3 cm) N0 M0 breast carcinoma. These patients did not receive neoadjuvant therapy, had no suspected or known breast cancer susceptibility gene 1/2 mutations, and no history of cancer in the same breast. Per our institutional pathway, patients had no unsuitable and at most one ASTRO APBI consensus cautionary criterion before lumpectomy based on patient characteristics and biopsy pathology (5). Patients with pure ductal carcinoma in situ (DCIS) on biopsy were excluded due to concerns about the possibility of extensive intraductal component and underestimation of tumor size (11).

Needle localized lumpectomy of the breast carcinoma and sentinel lymph node biopsy was performed. Touch prep cytology of all sentinel nodes was performed intraoperatively. Positive sentinel lymph node biopsy did not alter the decision to offer IORT but triggered either WBRT after axillary lymph node dissection or WBRT without axillary lymph node dissection if criteria were met for the ACOSOG Z0011 trial (12). Patients were not included in this study if IORT was aborted (about 14% of cases overall), which was typically due to skin-to-applicator distance < 1.0 cm (about 71% of aborted cases) or altered wire localization findings precluding IORT (about 19% of aborted cases) (13). Gross evaluation of the lumpectomy specimen was performed intraoperatively to identify any gross margin <5 mm, for which re-excision of the close margins was required before intracavitary placement of the radiation applicator.

The Zeiss INTRABEAM System applicator delivered a single dose of 20 Gy to the lumpectomy cavity. Final

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