

Evaluating Radiotherapy Options in Breast Cancer: Does Intraoperative Radiotherapy Represent the Most Cost-Efficacious Option?

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Abstract

Increasingly intraoperative radiation therapy is being utilized in the management of early stage breast cancer despite a lack of data supporting its efficacy based in part on potential cost savings with the technique. While cost minimization demonstrates a reduction in cost with intraoperative therapy, this is misleading. When factoring additional medical and non-medical costs whole breast irradiation and accelerated partial breast irradiation represent cost effective modalities with more quality data supporting their safety and efficacy.

Introduction: This study analyzed the cost-efficacy of intraoperative radiation therapy (IORT) compared with whole-breast irradiation (WBI) and accelerated partial-breast irradiation (APBI) for early-stage breast cancer.

Materials and Methods: Data for this analysis came from 2 phase III trials: the TARGIT (Targeted Intraoperative Radiotherapy) trial and the ELIOT (Electron Intraoperative Radiotherapy) trial. Cost analyses included a cost-minimization analysis and an incremental cost-effectiveness ratio analysis including a quality-adjusted life-year (QALY) analysis. Cost analyses were performed comparing IORT with WBI delivered using 3-dimensional conformal radiotherapy (3D-CRT), APBI 3D-CRT, APBI delivered with intensity-modulated radiotherapy (IMRT), APBI single-lumen (SL), APBI multilumen (ML), and APBI interstitial (I). **Results:** Per 1000 patients treated, the cost savings with IORT were \$3.6-\$4.3 million, \$1.6-\$2.4 million, \$3.6-\$4.4 million, \$7.5-\$8.2 million, and \$2.8-\$3.6 million compared with WBI 3D-CRT, APBI IMRT, APBI SL, APBI ML, and APBI I, respectively, with a cost decrement of \$1.6-\$2.4 million compared with APBI 3D-CRT based on data from the TARGIT trial. The costs per QALY for WBI 3D-CRT, APBI IMRT, APBI SL, APBI ML, and APBI I compared with IORT were \$47,990-\$60,002; \$17,335-\$29,347; \$49,019-\$61,031; \$108,162-\$120,173; and \$36,129-\$48,141, respectively, based on data from the ELIOT trial. These results are consistent with APBI and WBI being cost-effective compared with IORT. **Conclusion:** Based on cost-minimization analyses, IORT represents a potential cost savings in the management of early-stage breast cancer. However, absolute reimbursement is misleading, because when additional medical and nonmedical costs associated with IORT are factored in, WBI and APBI represent cost-effective modalities based on cost-per-QALY analyses. They remain the standard of care.

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Introduction

Breast-conserving therapy continues to be the standard of care in the management of early-stage breast cancer. Traditionally, adjuvant

radiation therapy is delivered after breast-conserving surgery and entails 5 to 6^{1/2} weeks of treatment with whole-breast irradiation (WBI) with or without a boost. Unfortunately, owing to the

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IORT Cost Efficacy

treatment duration of WBI, studies have found that up to 50% of women do not receive the radiotherapy component of their breast-conserving therapy.¹ More recently, accelerated partial-breast irradiation (APBI) has emerged as a technique that allows for the treatment of the lumpectomy cavity with a margin in 1 week or less; recent studies (including a matched-pair analysis with 12-year outcomes and 10-year results from a randomized trial) have found equivalent outcomes between APBI and WBI.^{2,3} Intraoperative radiation therapy (IORT) represents an alternative to WBI or APBI and allows for delivery of radiation therapy at the time of surgery or in a single session after pathology review, eliminating adjuvant treatment for more than 80% of patients; IORT can be delivered using low-energy x-rays or electrons, and both techniques have been evaluated in randomized studies.⁴⁻⁶ Given the nature of the technique, IORT has been suggested as a modality that could reduce costs associated with breast cancer, but limited data have emerged regarding this hypothesis.⁷

When evaluating new radiation therapy techniques such as IORT, the focus is often on absolute differences in reimbursement rather than on evaluating reimbursement in light of differences in outcomes, toxicity profiles, or both.⁷ More recently, radiation therapy techniques for breast cancer have been evaluated using multiple cost-effectiveness modalities including incremental cost-effectiveness ratios (ICER) and the associated cost per quality-adjusted life-year (QALY); these techniques are able to provide a more meaningful understanding of the costs associated with novel radiation therapy techniques compared with traditional modalities, and they incorporate differences in outcomes, toxicity, and quality of life.^{8,9} Therefore, the purpose of this study was to evaluate the cost-efficacy of IORT via a cost-minimization analysis, an ICER analysis, and a cost-per-QALY analysis based on local recurrence data from 2 recently updated randomized trials comparing IORT with WBI.

Materials and Methods

Randomized Trials

Local recurrence data were extracted from 2 randomized trials comparing outcomes between IORT and WBI.⁴⁻⁶ The first randomized trial was the TARGIT (Targeted Intraoperative

Radiotherapy) trial, which was an international, multicenter, prospective, noninferiority trial comparing IORT with WBI among 2232 patients. Eligibility included women aged 45 years or older with early-stage ductal breast cancer, with individual institutions able to add additional inclusion criteria. WBI was delivered with a variety of dose schemes (40 to 56 Gy with or without a boost of 10 to 16 Gy) using tangents. IORT was delivered using a 50-kV x-ray source delivering 20 Gy to the surface and 5 to 7 Gy to 1 cm over a period of 20 to 35 minutes. This trial initially reported 4-year outcomes, with no difference noted in local recurrence between IORT and WBI (1.2% vs. 0.95%)⁵; however, a recent update of this trial noted increased 5-year rates of local recurrence with IORT (3.3% vs. 1.3%; $P = .04$) and increased overall recurrences with IORT (8.2% vs. 5.7%), albeit with a median follow-up of 29 months.⁵

The second randomized trial was the ELIOT (Electron Intraoperative Radiotherapy) trial, which was a single-institution, prospective trial that randomized women to IORT delivered with electrons or to WBI, with a total of 1306 patients enrolled. Eligibility included women older than 45 years with unicentric cancer less than 2.5 cm. No women in the IORT arm received WBI, regardless of margin or nodal status. WBI patients received 50 Gy delivered with tangents, along with a 10-Gy boost, whereas patients receiving IORT received 21 Gy prescribed to the 90% isodose line using electrons with a 1.5- to 3.0-cm expansion around the tumor bed. Recent presentation of this study noted statistically significant increases in the rates of local recurrence with IORT (5.3% vs. 0.7%).⁶

Cost-Effectiveness Analyses

Reimbursement models were generated based on a previous publication from the present authors' group for each treatment technique with the exception of IORT; models for the latter were based on a publication from Grobmyer et al (Table 1).^{7,8} In these models, WBI costs were assessed without boosts owing to the heterogeneity of techniques (and therefore reimbursement); however, indirect costs did incorporate a traditional 6-week schedule with boost. Reimbursement models were calculated in several ways: (1) reimbursement only (professional and facility); (2)

Table 1 Reimbursements by Treatment Technique

Technique	Total Reimbursement	Reimbursement Including Additional Medical Costs ^a	Reimbursement Including Medical and Nonmedical Costs ^a	Reimbursements Including Medical, Nonmedical, and Recurrence Costs ^a (TARGIT)	Reimbursements Including Medical, Nonmedical, and Recurrence Costs ^a (ELIOT)
IORT	\$3094	\$8003-\$8706	\$8192-\$8971	\$9399-\$10179	\$9230-\$10,009
WBI 3D-CRT	\$11,726	\$11,726	\$12,985	\$13,743	\$13,122
APBI 3D-CRT	\$6578	\$6578	\$7028	\$7786	\$7165
APBI IMRT	\$10,547	\$10,547	\$10,997	\$11,755	\$11,134
APBI SL	\$12,602	\$12,602	\$13,052	\$13,810	\$13,189
APBI ML	\$16,439	\$16,439	\$16,889	\$17,646	\$17,025
APBI Interstitial	\$11,765	\$11,765	\$12,215	\$12,974	\$12,353

Abbreviations: 3D-CRT = 3-dimensional conformal radiotherapy; APBI = accelerated partial-breast irradiation; ELIOT = Electron Intraoperative Radiotherapy trial; IMRT = intensity-modulated radiation therapy; IORT = intraoperative radiation therapy; ML = multilumen; SL = single-lumen; TARGIT = Targeted Intraoperative Radiotherapy trial; WBI = whole-breast irradiation.

^aRange based on differences in whole breast irradiation rates (15%-21%).

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