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Time-driven activity-based costing of a novel form of CT-guided HDR brachytherapy intraoperative radiation therapy compared to conventional breast intraoperative radiation therapy for early stage breast cancer

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Abstract

Introduction: Intraoperative radiation therapy is an emerging option for adjuvant therapy for early stage breast cancer, although it is not currently considered standard of care in the United States. We applied time-driven activity-based costing to compare two alternative methods of breast intraoperative radiation therapy, including treatment similar to the techniques employed in the TARGIT-A clinical trial and a novel version with CT-guidance and high-dose-rate brachytherapy.

Methods and Materials: Process maps were created to describe the steps required to deliver intraoperative radiation therapy for early stage breast cancer at each institution. The components of intraoperative radiation therapy included personnel, equipment, and consumable supplies. The capacity cost rate was determined for each resource. Based on this, the delivery costs were calculated for each regimen. For comparison across centers, we did not account for indirect facilities costs and interinstitutional differences in personnel salaries.

Results: The CT-guided, high dose-rate form of intraoperative radiation therapy costs more to deliver (\$4,126.21) than the conventional method studied in the TARGIT-A trial (\$1,070.45). The

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cost of the brachytherapy balloon applicator (\$2,750) was the primary driver of the estimated differences in costs. Consumable supplies were the largest contributor to the brachytherapy-based approach, while personnel costs were the largest contributor to costs of the standard form of intraoperative radiation therapy.

Conclusions: When compared to the more established method of intraoperative radiation therapy using a portable superficial photon unit, the delivery of treatment with CT guidance and high dose-rate brachytherapy is associated with substantially higher costs. The excess costs are driven primarily by the cost of the disposable brachytherapy balloon applicator and, to a lesser extent, additional personnel costs. Future work should include evaluation of a less expensive brachytherapy applicator in order to increase the anticipated value of brachytherapy-based intraoperative radiation therapy.

Keywords

intraoperative radiation therapy; breast cancer; time-driven activity-based costing; brachytherapy; high dose-rate

Introduction

In the United States, rising costs in cancer care in general, and radiation oncology in particular, have prompted attention to the importance of value within the specialty of radiation oncology.^{1,2} Mariotto and colleagues projected that costs for cancer care in the United States will increase from \$124.57 billion in 2010 to \$157.7–173 billion in 2020, with a 32% increase expected in annual costs for breast cancer care.³ Porter has defined value as the measure of outcomes achieved for a patient per dollar expended, thus placing patient care and outcomes at the focus of value.^{4,5} In order to estimate costs of health care delivery to inform value considerations, Kaplan and colleagues described a bottom-up analysis technique called time-driven activity-based costing (TDABC) as a method to effectively evaluate the cost of a given medical treatment. TDABC follows a formalized, step-by-step process to track the personnel, equipment, and facilities costs associated with a treatment to estimate overall costs.^{6,7} Within radiation oncology, TDABC has been used to evaluate the costs associated with various radiation therapy options for prostate, cervical, endometrial and breast cancers.^{8–12}

In this report, we apply TDABC to compare two alternative methods of breast intraoperative radiation therapy (IORT). Breast IORT is an emerging adjuvant radiation therapy option for early stage breast cancer that involves the use of a single fraction of radiation therapy at the time of breast conserving surgery (BCS) in order to directly expose the highest-risk areas of the tumor bed to radiation before wound closure.¹³ Patient enthusiasm for the convenience of breast IORT has driven substantial interest in this treatment approach.^{14,15} The largest prospective trial of breast IORT to date is the TARGIT-A trial, which randomized patients to IORT versus whole breast irradiation (WBI).^{16,17} Results from the TARGIT-A trial revealed 5-year breast cancer recurrence rates of 3.3% after conventional breast IORT (CB-IORT), compared to 1.3% after WBI. The observed difference in recurrence rates satisfied the TARGIT-A trial's pre-specified statistical definition of equivalence for IORT and WBI,^{16,17} but elicited concerns and controversy among physicians.¹⁸ The TARGIT-A trial and the

available commercial systems for IORT employ portable IORT units that can be used in an unshielded, standard operating room to deliver treatment with low-energy photons. This form of treatment, which we refer to as CB-IORT, is capable of delivering approximately 20 Gy to the lumpectomy cavity surface and 5–7 Gy at 1 cm depth.^{19,20} There are concerns with CB-IORT in its current form, particularly in regard to the lack of intraoperative imaging of the tumor bed available during the procedure, as well as the poor dosimetry outcomes resulting from the physical limitations of low-energy photons.^{19,21,22}

Our institution developed *Precision* Breast IORT (PB-IORT) to improve upon the technical aspects of CB-IORT, allowing for an increase in the delivered dose beyond the lumpectomy cavity, and to potentially narrow the difference in recurrence rates between IORT and WBI with this novel approach (compared to CB-IORT).^{23,24} PB-IORT applies high dose-rate (HDR) brachytherapy techniques to deliver a form of IORT with computed tomography (CT) image guidance, customized CT-based treatment planning, and the use of an Iridium-192 HDR source to deliver a higher, more conformal radiation dose (12.5 Gy to 1 cm depth) than in CB-IORT (5–7 Gy to 1 cm depth).^{23,24} We have shown that CT imaging leads to actionable findings in one-quarter of PB-IORT cases, leading to applicator repositioning, sculpting dose off of uninvolved normal tissue, or other clinical actions prior to radiation treatment, suggesting that image-guidance would also significantly benefit CB-IORT delivery.²¹ PB-IORT delivers a substantially higher biological equivalent dose than CB-IORT, but less than standard adjuvant therapy options like WBI and accelerated partial breast irradiation (APBI).²⁴ PB-IORT is currently being studied in a Phase II, multicenter trial with a primary endpoint of local breast tumor recurrence ([NCT02400658](#); R01CA214594–02).

While PB-IORT seems promising, the ultimate value of this novel approach to breast IORT will depend upon the costs of delivery as well as the observed outcomes. We conducted this study to compare delivery costs of PB-IORT and CB-IORT. This is a two-institution study of TDABC for CB-IORT in a regular operating room at one center and PB-IORT in a brachytherapy suite with an integrated CT-on-rails unit at a second center. The current TDABC analysis focuses on IORT delivery costs at each institution, but not account for differences in reimbursement or cost-effectiveness between the IORT methods or in comparison with other adjuvant radiation therapy approaches.

Methods and Materials

Clinical management (PB-IORT)

The currently open clinical trial of PB-IORT ([NCT02400658](#)) enrolls patients who have opted for BCS treatment for early stage breast cancer and have met the following criteria: age < 45 years, invasive cancer or ductal carcinoma in situ (DCIS), tumor size < 3 cm and node negative disease. Exclusion criteria include: history of ipsilateral breast cancer treated with RT, *BRCA* gene mutation, and receipt of neoadjuvant chemotherapy. These clinical trial selection criteria were designed to be similar to partial breast brachytherapy guidelines from the American Brachytherapy Society.²⁵ All patients complete informed consent for the trial prior to treatment, and the study is approved by the University of Virginia (UVA) Institutional Review Board for Health Sciences Research. A more complete overview of the

treatment protocol has been previously published,²³ but a brief review of the way the procedure is performed at UVA is provided here. After BCS is performed, a multi-lumen balloon brachytherapy applicator (Contura®; Hologic, Inc., Bedford, MA) is placed on the lumpectomy bed by the breast surgeon, and a CT scan is immediately acquired using the CT-on-rails unit available in the brachytherapy suite (Siemens Somatom®, Siemens Healthcare; Erlangen, Germany). Following confirmation of correct applicator placement on CT, commercial software (BrachyVision © V. 11.0; Varian Medical Systems; CA, USA) is used to contour and plan treatment. The treatment plan and written directive are signed and safety checks completed prior to treatment delivery. Through the entire course of PB-IORT, the patient is under anesthesia and stationary, and the applicator is immobilized. Once all necessary precursor steps have been performed, HDR brachytherapy treatment is delivered in a single, 12.5 Gy fraction to the planning target volume (PTV) via an HDR afterloader (Varian Varisource® iX HDR afterloader; Varian Medical Systems; CA, USA). The radiation oncologist is present for contouring, parts of radiation treatment planning, and during delivery of HDR brachytherapy. All steps of care occur within the brachytherapy suite. An initial Phase I clinical trial of 28 patients showed that PB-IORT was both safe and feasible. PB-IORT was delivered in 90 minutes in 93% of patients (time from CT scan to completion of PB-IORT delivery), with median treatment time of 67.2 minutes.²³

Clinical management (CB-IORT)

The CB-IORT treatment method, performed at Medstar Georgetown University Hospital, has been described in-depth previously.²⁶ A brief overview, however, is provided here. Eligible patients were identified by the treating surgeon and/or radiation oncologist during evaluation prior to surgery. Clinical selection criteria include: patient age > 50 years, infiltrating ductal carcinoma, tumor size ≤ 3cm, estrogen receptor and progesterone receptor positivity, node-negative, grades 1 or 2, and no lymphovascular invasion. On days when IORT will be performed, a medical physicist performs quality assurance for the IORT unit (INTRABEAM™ radiotherapy system; Carl Zeiss, Oberkochen, Germany). In the operating room immediately following BCS, the IORT unit is located next to the patient and the chosen applicator is inserted into the lumpectomy cavity. Dose calculations are verified and the treatment is delivered. The radiation oncologist is present during applicator placement into the lumpectomy cavity and treatment delivery. CB-IORT delivery time has been measured to be a mean of 22.3 minutes (range, 17.5 to 45.3 minutes).²⁶

Time-driven activity-based costing

Process maps were created for each institution to represent all treatment steps involved in delivering CB-IORT (Figure 1) and PB-IORT (Figure 2). For each step, the specific resources involved were determined based upon input from staff members and by observation before and during treatment delivery. Capacity cost rates (CCR) for each resource were calculated by dividing the annual costs by total annual capacity for the resource. Annual personnel costs were determined from institutional salary and fringe benefit data from one institution, to allow comparison of dollar amounts without adjusting for interinstitutional salary variations. Equipment and facility costs were determined by the administrative department with a 10-year time horizon for equipment (and annual service contract included) for PB-IORT; for CB-IORT, we applied cost estimates from a 2018 cost

analysis.²⁷ Additional general institutional overhead factors were not applied to equipment costs for either procedure. The amount of time spent at each step was estimated through interview of staff members and corroborated with observations. Because treatment time varies among procedures, the personnel time estimates represent an approximate average per case. We endeavored to include personnel time attributable to IORT and to exclude time spent performing BCS or participating in other care activities as the time and personnel associated with these steps is equivalent between IORT methods. Some personnel (e.g., anesthesia staff) are captive in a single space in an off-site location during PB-IORT, rather than covering additional OR spaces, and the additional time required of these individuals was included in the cost analysis. The costs of anesthesia equipment and medications were not included in the analysis, as these do not impact the radiation center and are not likely to be altered significantly by IORT delivery. We assumed capacity for 4 IORT cases per day, based on the capacity of personnel, equipment and facilities (irrespective of actual patient volumes). The total cost of care was then calculated by multiplying the CCR by the time estimate for the process step and adding any additional costs of consumable products.

Results

PB-IORT costs more to deliver (\$4,126.21) than CB-IORT (\$1,070.45), driven in large part by substantial difference in consumable supplies between cases, \$2,750 per multi-lumen balloon applicator used during PB-IORT (Table 1). Consumable supplies were the largest contributor to PB-IORT costs, while personnel costs were the largest contributor to CB-IORT costs. Personnel costs were higher for PB-IORT than CB-IORT (Table 1), with similar attending radiation oncologist expenses for the two options (Table 2). Overall costs for personnel, equipment supplies for CB-IORT vs PB-IORT are summarized in Table 1 and selected personnel costs are shown in Table 2.

Equipment costs were substantially higher for PB-IORT than CB-IORT (Table 1 and Supplementary Table 3), with the CT-on-rails unit and the HDR brachytherapy afterloader unit contributing most of the costs. Attending surgeon time and costs were higher for CB-IORT than PB-IORT, since the surgical team must spend time waiting for IORT delivery rather than completing other clinical tasks (as done during PB-IORT). Full details for personnel time and costs, equipment and supplies are included in the Supplementary Materials.

Discussion

We applied TDABC methods to compare the costs of two forms of IORT for early stage breast cancer, and found that an HDR brachytherapy-based form of IORT (PB-IORT) is substantially more expensive to deliver than CB-IORT. The higher costs of PB-IORT were driven largely by the cost of a disposable brachytherapy balloon applicator, but the costs of nurses, physicists and other personnel also contributed to the increased cost of delivery. This comparative study provides useful information for centers considering implementation of a breast IORT program and highlights potential areas to for cost reduction to reduce the gap in delivery costs between CB-IORT and PB-IORT. Based on this analysis, the most promising area to cut costs from PB-IORT is the category of consumable supplies.

The ultimate value of PB-IORT will be determined by patient outcomes as well as costs,^{4,5} so the value of PB-IORT will depend on how clinical outcomes, such as recurrence rates and cosmesis, compare to CB-IORT. Although PB-IORT offers potential advantages related to CT-based applicator position evaluation and customized planning, with a higher dose of radiation therapy delivered to 1 cm beyond the lumpectomy cavity (12.5 Gy) compared to CB-IORT (~5–7 Gy), long-term results from clinical trials of PB-IORT are not yet available. In the future, the outcomes of PB-IORT will need to be weighed against the additional costs associated with this delivery method. Additionally, the current findings may influence future reimbursement policy for PB-IORT if this technology becomes widely disseminated. Currently, the higher cost of PB-IORT compared to CB-IORT, in the absence of evidence to show improved outcomes with PB-IORT, raises concerns about the value of PB-IORT and highlights a need for more data. The current study does not compare reimbursement rates between CB-IORT and PB-IORT, since PB-IORT is currently investigational and does not qualify for the reimbursement codes applied in CB-IORT. However, reimbursement rates would impact institutional decisions regarding PB-IORT at other centers.

Limitations of this study include calculations based on a single institution per modality, which may not adequately represent costs in other settings. For example, when PB-IORT is performed in a facility without an integrated brachytherapy suite, there may be different personnel and equipment costs compared to the current study, especially if a CT-on-rails is not available in the brachytherapy suite. In the current TDABC analysis, we assumed capacity for 4 cases per day to reflect overall capacity, although this exceeds typical patient volumes. Differences among institutions with respect to personnel, facilities, workflows and institutional regulations may impact cost estimates significantly and limit the external validity of our study to other centers. Specific considerations of our cost analysis that may be unique to our centers include: the involvement of resident physicians in PB-IORT (reducing attending physician time); the involvement of a radiation oncology nurse throughout the entire process of PB-IORT (serving as a circulating nurse); and the presence of the surgeon during the CB-IORT delivery. The TDABC focused on practice at two institutions, but these factors and others may impact estimates at other centers. Furthermore, institutions considering implementing PB-IORT or CB-IORT must also consider the opportunity costs of this clinical activity, since personnel may otherwise be engaged in other work such as outpatient consultations or supervision of external beam radiation therapy. Our ongoing Phase II trial includes two sites with different workflow and technological environments, without an integrated brachytherapy suite, so we expect to gain further insights on this subject in the future.

The use of a less expensive brachytherapy applicator may reduce costs of PB-IORT significantly. This finding mirrors the results of a separate TDABC reported by Schutzer and colleagues, which found that the brachytherapy balloon applicator contributed to substantial consumable materials costs during APBI.⁸ By choosing a different single-entry balloon applicator, we estimate that the costs of consumable supplies during PB-IORT could be reduced by up to 30%. Recently reports of favorable outcomes after single-fraction interstitial breast brachytherapy also suggest that HDR brachytherapy with interstitial catheters may be a promising strategy to deliver conformal brachytherapy at a low cost of supplies.^{28,29} It is important to note that our methodological approach should not be viewed

as a strategy to estimate appropriate reimbursement for PB-IORT or CB-IORT, since our analysis does not include indirect costs and overhead that would be needed to calculate appropriate reimbursement rates. The present analytical framework does not address relative reimbursement or cost-effectiveness CB-IORT or PB-IORT, nor does it compare these approaches to WBI or APBI. The decision to compare PB-IORT directly to CB-IORT in the current report stemmed from our program's overarching goal of improving upon the technical aspects of IORT. The time and cost estimates in our study provide information helpful for considering value of PB-IORT relative to CB-IORT.

Conclusions

In conclusion, we performed TDABC at two institutions to compare delivery costs of CB-IORT using a mobile unit in a standard operating room to a novel form of HDR brachytherapy-based IORT (PB-IORT) in a brachytherapy suite with in-room CT imaging. We found that PB-IORT was associated with substantially higher delivery costs than CB-IORT, driven primarily by the cost of the brachytherapy balloon applicator and, to a lesser extent, additional personnel costs. Future work, including consideration of a less expensive brachytherapy applicator, is warranted to evaluate potential areas of cost reduction for PB-IORT and to estimate the value of PB-IORT in regards to measured differences in clinical outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Process Maps for IORT at Georgetown

- Radiation Oncologist
- Surgeon
- Nurse
- Physicist

Each step in the process map is color-coded based upon the primary personnel utilized for that component of care. In most instances, multiple other personnel members are involved. The time for each personnel at each step is shown in supplementary tables.

IORT at Georgetown

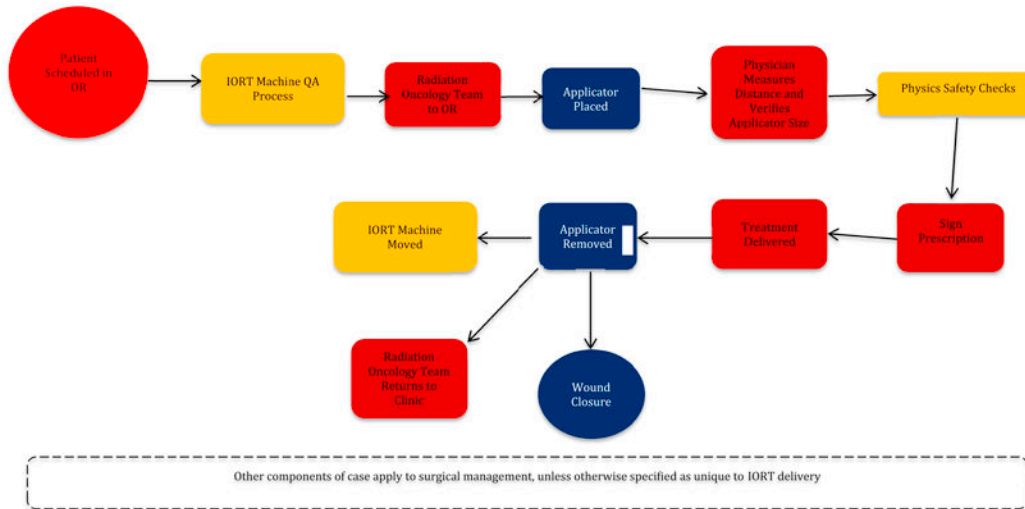


Figure 1. Process map for delivery of conventional intraoperative radiation therapy for early stage breast cancer in an operating room at a single institution. IORT = intraoperative radiation therapy; OR = operating room; QA = quality assurance

Process Maps for Breast Radiation Therapy at the University of Virginia

- Radiation Oncologist
- Surgeon
- Nurse
- Dosimetrist/Physicist
- Anesthesiology Staff
- Administrative/office staff
- Radiation Therapist
- Patient/waiting

Each step in the process map is color-coded based upon the primary personnel utilized for that component of care. In most instances, multiple other personnel members are involved. The time for each personnel at each step is shown in supplementary tables.

IORT at UVA

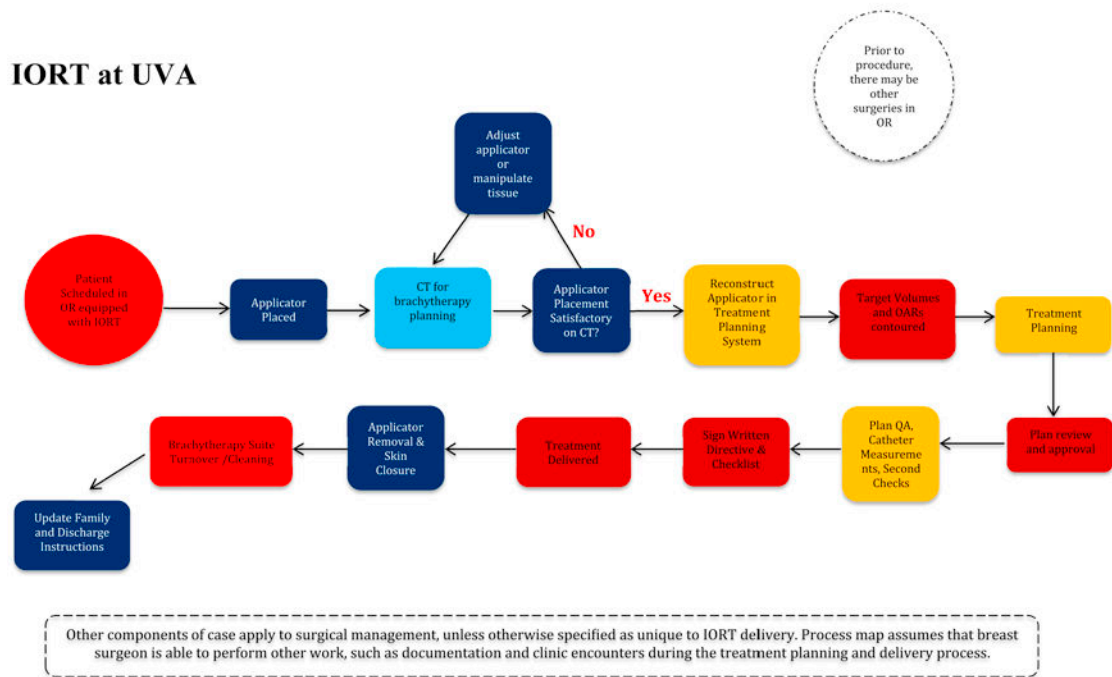


Figure 2. Process map for delivery of Precision Breast Intraoperative Radiation Therapy for early stage breast cancer in a brachytherapy suite with in-room CT-on-rails. CT = computed tomography; IORT = intraoperative radiation therapy; OAR = organ-at-risk; QA = quality assurance

Total personnel, equipment, and consumable supply cost by treatment modality for a breast intraoperative radiation therapy. Costs are expressed in 2019 US dollars. CB-IORT = conventional breast intraoperative radiation therapy (using superficial photon unit); PB-IORT = Precision Breast intraoperative radiation therapy (HDR brachytherapy-based treatment)

Table 1:

Treatment modality	Personnel	Equipment	Consumable	Total Costs
PB-IORT (\$)	1,158.81	217.40	2750	4,126.21
CB-IORT (\$)	958.81	111.64	0	1,070.45

Contribution of personnel costs associated with selected professional categories to the total personnel costs of two types of breast intraoperative radiation therapy. Costs are expressed in 2019 US dollars. CB-IORT = conventional breast intraoperative radiation therapy (using superficial photon unit); PB-IORT = Precision Breast intraoperative radiation therapy (HDR brachytherapy-based treatment)

Table 2.

Treatment modality	Attending Radiation Oncologist	Physicist	Nursing	Other Staff	Total Costs
PB-IORT (\$)	227.97	348.40	247.17	335.27	1,158.81
CB-IORT (\$)	259.26	226.20	62.06	411.29	958.81