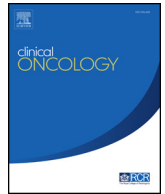




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Original Article

Omission of Breast Radiotherapy in Low-risk Luminal A Breast Cancer: Impact on Health Care Costs

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Abstract

Aims: The economic burden of cancer care is substantial, including steep increases in costs for breast cancer management. There is mounting evidence that women age ≥ 60 years with grade I/II T1N0 luminal A (ER/PR+, HER2– and Ki67 $\leq 13\%$) breast cancer have such low local recurrence rates that adjuvant breast radiotherapy might offer limited value. We aimed to determine the total savings to a publicly funded health care system should omission of radiotherapy become standard of care for these patients.

Materials and methods: The number of women aged ≥ 60 years who received adjuvant radiotherapy for T1N0 ER+ HER2– breast cancer in Ontario was obtained from the provincial cancer agency. The cost of adjuvant breast radiotherapy was estimated through activity-based costing from a public payer perspective. The total saving was calculated by multiplying the estimated number of luminal A cases that received radiotherapy by the cost of radiotherapy minus Ki-67 testing.

Results: In 2010, 748 women age ≥ 60 years underwent surgery for pT1N0 ER+ HER2– breast cancer; 539 (72%) underwent adjuvant radiotherapy, of whom 329 were estimated to be grade I/II luminal A subtype. The cost of adjuvant breast radiotherapy per case was estimated at \$6135.85; the cost of Ki-67 at \$114.71. This translated into an annual saving of about \$2.0million if radiotherapy was omitted for all low-risk luminal A breast cancer patients in Ontario and \$5.1million across Canada.

Conclusion: There will be significant savings to the health care system should omission of radiotherapy become standard practice for women with low-risk luminal A breast cancer.

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Key words: Breast cancer; cost savings; Ki-67; luminal A; omission; radiotherapy

Introduction

The economic burden of cancer care is substantial [1]. Breast cancer is the most common malignancy affecting women worldwide [2]. The financial resources required for

breast cancer management have been soaring, primarily due to the increasing utilisation and costs of chemotherapy and radiotherapy [3].

Adjuvant breast radiotherapy after breast-conserving surgery (BCS) reduces local recurrence, resulting in long-term survival similar to that of mastectomy [4]. Currently, most women with early stage breast cancer are treated with radiotherapy after BCS; however, the majority will not recur even without radiotherapy [5]. Breast radiotherapy causes inconvenience for the patient, requiring daily treatments, is

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not without side-effects and has an associated cost of delivery.

Previous randomised studies failed to identify women at very low risk of local recurrence after BCS alone (without radiotherapy) based on clinicopathologic factors, although older women with smaller oestrogen receptor-positive (ER+) tumours experienced a lower risk of local recurrence [6–8]. The most recent UK PRIME II trial that randomised women age ≥ 65 years with hormone receptor-positive, node-negative breast cancer (≤ 3 cm) after BCS and endocrine treatment to radiotherapy versus observation concluded that adjuvant endocrine treatment alone is a reasonable therapeutic option for some women, based on the low local recurrence risks of the overall study population (4.1% no radiotherapy versus 1.3% radiotherapy) [9]. These trials included all patients with early stage breast cancer independent of molecular subtyping, which only became evident after the era of gene expression and next-generation sequencing studies [10]. The distinct molecular subtypes with varying prognosis and treatment response can also be estimated using immunohistochemical (IHC) surrogates: ER, progesterone receptor (PR), HER2, CK5/6, EGFR and Ki-67 [11,12]. The favourable biology of luminal A subtype has been well established [13], but its potential predictive value for radiotherapy response has never been explored until recently. Tumours from the Toronto/British Columbia trial [7], a randomised trial of tamoxifen \pm radiotherapy in node-negative breast cancer patients age ≥ 50 years were recently subtyped using IHC. This study showed that patients with luminal A tumours (ER/PR+, HER2– and Ki-67 $\leq 13\%$) [11] had the lowest local recurrence rate [14]. When molecular subtyping was combined with clinicopathological features, women over age 60 years with T1 grade I/II luminal A tumours experienced a 10 year local recurrence rate of 1.3% with tamoxifen alone versus 5.0% with tamoxifen plus radiotherapy ($P = 0.3$) [14]. Thus, these patients had such a favourable prognosis that they could be spared the inconvenience and side-effects of radiotherapy. This observation is being validated in a prospective cohort study evaluating the risk of local recurrence after BCS and endocrine therapy in women age ≥ 60 years with T1 grade I/II luminal A breast cancer (LUMINA NCT01791829).

Given that women age ≥ 60 years with T1N0, grade I/II luminal A tumours have such a favourable prognosis, and breast radiotherapy might offer minimal benefit, omission of radiotherapy would spare these women side-effects and achieve significant cost savings. The main objective of this current study was to estimate the total savings to a publicly funded health care system should omission of radiotherapy in these patients become standard of care.

Materials and Methods

This study received approval from the Review Ethics Board at University Health Network. The main cost analysis was conducted from the perspective of a public payer, the Ontario Ministry of Health and Long-Term Care. The estimated cost savings from the omission of radiotherapy in

luminal A breast cancers was calculated using the following equation:

$$\text{\$ totalsavings} = n \times (\text{\$ radiotherapycost} - \text{\$ Ki-67cost})$$

where n = estimated number of patients age ≥ 60 years with low-risk luminal A breast cancer being treated with adjuvant radiotherapy; radiotherapy cost = estimated cost of adjuvant radiotherapy; and Ki-67 cost = estimated cost of routine Ki-67 IHC testing.

Estimated Number of Patients with Low-risk Luminal A Breast Cancer (n)

The number of patients with luminal A breast cancer was calculated using data collected by Cancer Care Ontario (CCO), the provincial cancer agency. Patients with newly diagnosed breast cancer in 2010 and 2011 were identified from the Ontario Cancer Registry [15], the population-based registry for Canada's largest province. The number of patients age ≥ 60 years with pT1N0, ER+ and HER2– breast cancer was determined from collaborative staging data [16]. The proportion of patients who underwent radiotherapy, as reported by the cancer centres to CCO was ascertained. We estimated that 61% of these patients would have had grade I/II luminal A tumour, based on data from the Toronto/British Columbia trial [14], where 157 of 258 pT1N0, ER+ HER2– tumours in women age ≥ 60 years were of grade I/II luminal A subtype.

Costs

All costs were expressed in 2014 Canadian dollars. Costs obtained from earlier years were adjusted using the health and personal care component in the Canadian Consumer Price Index. The cost of adjuvant radiotherapy for breast cancer was estimated using an updated activity-based costing model for radiotherapy (Supplementary Table S1) [17]. In this model, the costs of equipment (capital, specialised construction, maintenance), personnel and immobilisation costs were allocated to five major activities of radiotherapy: consultation; computed tomography simulation; dosimetry; physics quality assurance; treatment preparation and delivery. In the base case analysis, the cost of a course of standard 16-fraction adjuvant breast cancer radiotherapy regimen [18] was estimated for the Princess Margaret Cancer Centre, one of the largest single-institution radiotherapy programmes in Canada, delivering more than 10 000 radiotherapy courses each year. As all adjuvant breast radiotherapy cases at the Princess Margaret Cancer Centre were treated with intensity-modulated radiotherapy (IMRT), the costing for this technique was used.

Costs and the expected lifespan of equipment were obtained from the Capital Planning Department at CCO; operating cost estimates were supplemented by financial information from the Radiation Medicine Program at the Princess Margaret Cancer Centre. Maintenance costs were assumed to be 10% of the acquisition cost. The equipment cost per activity was estimated using cost per unit time or per patient, based on operating hours and the total number

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