Outcomes of postoperative radiation therapy for breast cancer in older women according to age and comorbidity status: An observational retrospective study in 752 patients

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ARTICLE INFO

Article history:
Received 19 September 2017
Received in revised form 27 December 2017
Accepted 23 February 2018
Available online xxxx

Keywords:
Breast cancer
Age
Older women
Radiation therapy
Toxicities

ABSTRACT

Objectives: The aim of this study was to assess efficacy, tolerability, and the impact of comorbidities on outcomes in older women treated by radiation therapy (RT) for non-metastatic breast cancer.

Materials and Methods: Women aged ≥70 years at diagnosis who received postoperative RT for primary non-metastatic BC between 2003 and 2009 were retrieved from the Institut Curie registry. We calculated the Charlson Comorbidity Index (CCI) for each patient. We analyzed overall survival (OS), progression free survival (PFS), and acute and late toxicities according to the Common Terminology Criteria for Adverse Events (CTCAE) v3.0.

Results: A total of 752 patients were included in this study. Median age at diagnosis was 75 years [70–93.3], With a median follow-up of 7.3 years [0.4–12.9], OS and PFS at 5 years were 87.2% CI [84.8–89.8] and 85.7% CI [83.1–88.3], respectively. OS at 5 years was statistically different according to the CCI: 90.7% CI [87.6–93.9] for a CCI of 0, 85.8% CI [81.8–90.1] for a CCI of 1, and 79.1% CI [71.1–87.9] for a CCI ≥ 2 (p < 0.01, log-rank test), respectively. Similar results were found for PFS (p < 0.05, log-rank test). Most (23.3%) of the patients had no toxicities; of those who experienced side-effects, the majority were grade I or II (96.9%).

Conclusion: Postoperative RT for non-metastatic BC in older women is effective and well-tolerated. Outcome is impacted by age and comorbidities, which are clear independent prognostic factors.

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1. Introduction

Breast cancer (BC) incidence increases with age and is considered a public health issue, especially in the older population. BC management requires an individual approach based on estimated benefits and risks [1]. Postoperative radiation therapy (RT) in the framework of breast conserving therapy is a standard approach for most patients with BC [2,3], but its benefit remains a subject of debate in older patients. Two phase III randomised trials (CALGB 9343 and PRIME II) have demonstrated a lower risk of local recurrence in patients treated with postoperative RT compared to patients without postoperative RT for low-risk early-stage BC (Estrogen Receptor positive ER+ T1 N0 for patients ≥70 years in the CALGB 9343 study, and Hormone Receptor positive HR+ T1-T2 N0 for patients ≥65 years in the PRIME II study, respectively). However his result did not impact overall survival [4,5].

However, older patients are a heterogeneous group and efforts have been made to better identify which subgroup would benefit most from postoperative RT. In fact, omission of RT may be relevant only for some subgroups of the CALGB 9343 and PRIME II studies. Two recent studies based on large cohorts of patients ≥70 years from the Surveillance, Epidemiology, and End Results (SEER) database showed that postoperative RT improved breast cancer specific survival in older patients with ER+ Human Epidermal growth factor Receptor 2 HER2- and ER- HER2- early stage BC, especially in case of poorly-differentiated or high-grade disease [6,7]. This relative benefit may be counteracted by potential RT side-effects, which can impact quality of life (QoL). Moreover, a clear need for information exists among patients aged ≥65 years with early-stage BC for comprehensive information on toxicities as well as benefits to assist their own decision-making process before postoperative RT [8]. They most often requested information about benefits of RT, side-effects, and impact on QoL. Only a few toxicity data points were reported in the CALGB 9343 and PRIME II studies [4,5].

However, individual assessment of benefit-risk balance of postoperative RT for BC in older women may be difficult as it requires estimation...
of life-expectancy. This depends on health status, age, with 80 years as an important turning point, and co-morbidities, which impact therapeutic decision-making [19-20]. Although many publications report on the relation between age and outcome for patients with BC treated with postoperative RT, little is known on the relation between co-morbidity and outcome in this population. Previous studies have shown that competitive causes of mortality, such as cardiovascular diseases, could negatively impact survival of older women with early-stage BC [11,12]. Few specified the impact of co-morbidities on outcomes in a wider population of older patients with BC, specifically treated by postoperative RT. The aim of this study was therefore to assess efficacy, acute and long-term radiation-induced toxicities, and impact of age and co-morbidities on outcomes in older women treated with RT for non-metastatic breast cancer.

2. Materials and Methods

2.1. Patient Selection

All women aged 70 years or older consecutively treated at Institut Curie (Paris) by surgery and postoperative RT between 2003 and 2009 for newly diagnosed primary breast cancer were included in this retrospective study. Breast surgery included breast-conserving or mastectomy, with axillary dissection or sentinel node biopsy. All treatment decisions were reviewed and validated in multidisciplinary meetings. Patients with history of prior malignancy, bilateral BC, or metastases at diagnosis were excluded. Clinical data, histopathological features, and technical details of RT were collected from electronic medical records. Clinical data included age, mode of detection, co-morbidities, stage at diagnosis, and molecular subtype. This project was approved by the Institut Curie Breast Cancer Study Group.

2.2. Comorbidity Measurement

Status of comorbidities was assessed using a modified Charlson Comorbidity Index (CCI) (Supplementary Data Table SD1), excluding some irrelevant co-morbidities (solid tumor, metastases), and including cardiovascular risk factors. The CCI, widely used in geriatric oncology studies, is based on a simple scoring system. It is a reproducible tool, which is useful for retrospective studies [13]. Cardiovascular risk factors complementary to age included: hypertension, dyslipidemia, smoking status (active or discontinued), and overweight/obesity (defined as a Body-Mass Index ≥ 30). Medical history was retrieved from the initial consultation at Institut Curie and the preoperative consultation with the anaesthetist recorded in the electronic health record.

2.3. Treatment Modalities

Indication of postoperative RT was validated in a multidisciplinary meeting according to the regional guidelines. Time between initial breast surgery and RT was 6–8 weeks. All patients were reviewed by a specific RT staff member in order to confirm target volumes (whole-breast/chest wall ± boost to the tumor bed ± lymph nodes (LN)), RT fractionation, and the preferred RT technique (conformational 3-dimensional in dorsal decubitus position, lateral decubitus (LD) position, or helical tomotherapy). Decision-making criteria between these techniques were previous history of cardio-pulmonary disease and the breast size. Whole-breast RT (WBRT) using LD, allowing improved dose-homogeneity and minimal dose to the heart and lungs [14], was preferred in case of cardio-pulmonary disease. Conventionally fractionated RT dose was 50 Gray (Gy) in 2 Gy fractions to the breast or the chest wall, with a boost of 16 Gy in 2 Gy fractions if indicated. Hypofractionated WBRT was prescribed at the physician’s discretion among the following schedules: 32.5 Gy in 5 fractions of 6.5 Gy in 5 weeks [15], 40.05 Gy in 15 fractions of 2.67 Gy in 3 weeks [16], or 41.6 Gy in 13 fractions of 3.2 Gy in 5 weeks [17]. In case of chest wall irradiation with or without LN, conventionally fractionated RT was used as previously reported [18]. Patients with aggressive disease (inflammatory cancers before surgery or bad responders after neoadjuvant treatment, followed by surgery with residual breast and/or lymph node residual disease) received chemotherapy concomitantly to RT. The chemotherapy regimen used was 5 Fluorouracil Day 1–5500 mg/m² and vinorelbine 25 mg/m² on Day 1 and Day 6. Adjuvant endocrine therapy (aromatase-inhibitors or tamoxifen) was prescribed for 5 years for patients with HR+ BC.

2.4. Outcomes Assessment and Follow-up

Overall survival (OS), progression-free survival (PFS), and breast cancer specific survival (BCS) were calculated from the start of RT to death from any cause, to the date of any documented disease progression, and to death from BC, respectively. Loco-regional recurrence was defined as any relapse in the ipsilateral breast or regional lymph nodes. After RT, patients were seen twice per year with a physical examination and with an annual bilateral mammography. After 5 years, they were monitored on a yearly basis.

2.5. Toxicity Assessment

In accordance with National Cancer Institute (NCI), acute and long-term toxicities were defined before and after 90 days, using Common Terminology Criteria for Adverse Events (CTCAE) version 3 and Late Effects Normal Tissue Task Force-Subjective, Objective, Management and Analytic (LENT-SOMA) scale, respectively. Assessed acute toxicities were dermatitis, breast pain, breast edema, and dysphagia. Recorded long-term events associated with breast cancer RT included breast pain, lymphedema, skin fibrosis, cardiac toxicity, lung toxicity, and secondary malignancies. Cosmetic results were assessed clinically and reported by the radiation oncologist and the surgeon at each follow-up consultation.

2.6. Statistical Analysis

The Kaplan-Meier method was performed for survival analysis, and survival curves were compared with the log-rank test. Patients were divided into two subgroups (<80 years or ≥80 years) in order to assess the impact of age on survival and toxicities, and into three subgroups (CCI = zero, CCI = one, and CCI = two) to assess impact of comorbidities on survival. Univariate and multivariate Cox regression models were applied to estimate the impact of age and comorbidities on survival and the risk of developing toxicities. Hazards-ratio (HR) associated with each prognostic factor were calculated and expressed with their confidence intervals (CI95%). Statistical analyses were carried out using R software version 3.2.2 (R CoreTeam (2015). R: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. https://www.R-project.org/).

3. Results

3.1. Population

Of the 752 patients included in this study, median age at diagnosis was 75 years [70–93.3], with 155 patients (20.6%) being 80 years or older. Baseline characteristics are shown in Table 1. Most women (86.6%) had a modified CCI of zero or one. The most frequent comorbidities were rheumatism, chronic pulmonary disease, and diabetes without end organ damage (Table SD2). Hypertension was the most frequent cardiovascular risk factor (50.9%). Breast cancer was mainly discovered by mammography (n = 412, 54.8%), breast self-examination (n = 142, 18.9%), or medical examination by a family physician or gynecologist (n = 101, 13.4%). Most patients had HR+ HER2- breast cancer (83.9%), and the majority had stage I disease (53.4%). Eighty-six percent of patients had a lumpectomy and 14% a mastectomy. Approximately half
Table 1

Patients’ characteristics.

<table>
<thead>
<tr>
<th>Age at diagnosis (years)</th>
<th>n (%) (N = 752)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [range]</td>
<td>75 [70–93.3]</td>
</tr>
<tr>
<td>70–79</td>
<td>597 (79.4%)</td>
</tr>
<tr>
<td>≥ 80</td>
<td>155 (20.6%)</td>
</tr>
<tr>
<td>Charlson comorbidity index</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>355 (47.2%)</td>
</tr>
<tr>
<td>1</td>
<td>296 (39.4%)</td>
</tr>
<tr>
<td>2</td>
<td>73 (9.7%)</td>
</tr>
<tr>
<td>≥3</td>
<td>28 (3.7%)</td>
</tr>
</tbody>
</table>

Breast cancer side

<table>
<thead>
<tr>
<th>Follow-up of previous benign breast disease</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>60 (8%)</td>
</tr>
</tbody>
</table>

Breast cancer mode of detection

<table>
<thead>
<tr>
<th>Screening mammography</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>412 (54.8%)</td>
<td></td>
</tr>
</tbody>
</table>

Breast-cancer specific survival at 5 years was 94.6% CI95% [92.9–96.4] (Fig. SD1). Five-year local and loco-regional recurrence rates were 1.9% and 2.5%, respectively. Five-year metastatic recurrence rate was 8.8%. At the latest update, 610 patients (81.1%) were still alive and 15.7% of patients were lost to follow-up.

3.2. Survival Outcomes

Median follow-up was 7.3 years [0.4–12.9]. Five-year overall survival and five-year progression-free survival were 87.2% CI95% [84.8–89.8] and 85.7% CI95% [83.1–88.3], respectively. Breast-cancer specific survival at 5 years was 94.6% CI95% [92.9–96.4] (Fig. SD1). Five-year local and loco-regional recurrence rates were 1.9% and 2.5%, respectively. Five-year metastatic recurrence rate was 8.8%. At the latest update, 610 patients (81.1%) were still alive and 15.7% of patients were lost to follow-up.

3.2.1. Impact of Age on Survival

OS and PFS were significantly better in patients <80 years compared to patients aged ≥80 years (HR = 3.04, CI95% [2.14–4.32], p < 0.001 and HR = 2.82, CI95% [2.02–3.92], p < 0.001, respectively). BCS was also significantly better in patients <80 years compared to older patients (HR = 3.31, CI95% [1.96–5.59], p < 0.001) (Fig. 1). There was no significant difference according to age for local recurrence-free survival and loco-regional recurrence-free survival, BC metastasis-free survival was significantly different according to age < or ≥80 years old (HR 2.93, CI95% [1.91–4.49], p < 0.001) (Fig. SD2).

3.2.2. Impact of Comorbidities on Survival

Five-year OS was statistically different (90.7% CI95% [87.6–93.9], 85.8% CI95% [81.8–90.1], and 79.1% CI95% [71.1–87.9]) for CCI 0, 1, and ≥2, respectively (p < 0.001). Five-year PFS was also statistically different (89.5% CI95% [86.2–92.9], 83.3% CI95% [79–87.8], and 79.1% CI95% [71.1–88]) for CCI 0, 1, and ≥2, respectively (p < 0.001) (Fig. 2). Causes of death are described in Table SD3.

3.3. Toxicity

All patients were assessable for tolerability. For 23.3% of patients, no acute or chronic toxicities were observed. Of those who experienced acute or chronic toxicity, most were limited to grade I or II (96.9%).

3.3.1. Acute Toxicities

Breast dermatitis was by far the most frequent acute toxicity (52.7%). 2.9% of patients had transient breast pain. Detailed results are displayed in Tables 2 and in SD4. In the group of 15 patients with pace-makers, only one presented dysfunction after completion of RT. RT was discontinued in 7 patients (0.9%). Of four patients who discontinued RT definitively (0.5%), one patient treated by RT with concurrent chemotherapy died from febrile bone marrow aplasia with infectious pneumonitis (Table SD5).

3.3.2. Long-term Toxicities

The most frequent radiation-induced side-effects were breast deformation (24.2%), skin fibrosis (16.9%) and telangiectasia (13.2%) (Table 2). Median timeline of development was 24.7 months, 37.1 months and 35.8 months, respectively. Only four cases of lung toxicities were reported (0.5%): 3 cases of lung fibrosis (two of which had dyspnea were treated by 3D conformational RT in supine position and 42.7% using the LD technique. Hypofractionated RT was delivered in 57% of cases.

Notes to Table 1:

ER = Estrogen Receptor; PR = Progesterone Receptor; HER2 = Human Epidermal growth factor Receptor 2.

\( \text{Gy/\text{fr}} = \text{Gray per fraction.} \)

\( \text{WB} = \text{Whole-Breast LD} \)

\( \text{LD} = \text{Lateral Decubitus RT} = \text{Radiation Therapy.} \)

\( ^a \text{n = 742/752, 96.7.} \)

\( ^b \text{n = 651/752, 86.6%.} \)

\( ^c \text{n = 739/752, 98.2%.} \)

\( ^d \text{n = 629, 83.6%.} \)
grade I), and 1 case of pneumonitis with grade I cough (history of asthma). One patient with cardiovascular history (coronary heart disease with stent implants, obesity, hypertension, dyslipidemia) died of myocardial ischemia 24 months after the end of RT for a left-sided breast cancer with node involvement. 31 patients (4.1%) developed contralateral breast cancer. 32 patients (4.2%) developed a new non-breast cancer over the period of follow-up. No case of radiation-induced second malignancy was reported.

Median follow-up for cosmetic assessment was 4.6 years [0.2–11.7]. Of the 541 evaluated patients (71.8%), most had good results (90.9%).

3.3.3. Impact of Age on Toxicities
In univariate analysis, women aged ≥80 years were less likely to have dermatitis (HR = 0.7, CI95% [0.54–0.91], p = 0.007) and long-term breast pain (HR = 0.46, CI95% [0.23–0.92], p = 0.02) compared to patients younger than 80 years. These results were confirmed in multivariate analysis (Table 3). We found no association between age and the risk of breast deformation, skin fibrosis, or telangiectasia.

3.3.4. Impact of Comorbidities on Toxicities
In univariate analysis, obesity was significantly associated with an increased risk of dermatitis (HR = 1.31, CI95% [1.01–1.7], p = 0.038), lymphedema (HR = 2.55, CI95% [1.3–5.02], p = 0.005) and telangiectasia (HR = 1.77, CI95% [1.09–2.88], p = 0.019). These results were confirmed in multivariate analysis (Table 3). There was no association found between smoking and radio-induced toxicity, but this may be the consequence of insufficient registration of smoking habits.

4. Discussion
Our study shows that RT for non-metastatic breast cancer in older women is well-tolerated, with excellent outcomes. Survival results are encouraging, especially given the proportion of patients with stage II–III disease in our population (36.4%). With a median follow-up of 7.3 years, five-year local recurrence rate was 1.9% in our study, which is close to the results of the Early Breast Cancer Trials’ Collaborative Group (EBCTCG) meta-analysis (2.6% in node-negative disease in the subgroup of patients aged ≥70 years treated with breast-conserving surgery and RT) [19]. Thus, older women with non-metastatic BC, including those with node-positive disease as in our study, should not have optimal treatment with postoperative RT withheld.

The survival results obtained are, however, clearly impacted by age and comorbidities. We have demonstrated a negative impact of age ≥80 years on PFS and on BC metastasis-free survival, which reflected into overall survival. This impact of age was also observed for BCS. Competitive causes of death alone cannot thus explain the significant difference in OS between the patients aged <80 years compared to the patients aged ≥80 years, as specific mortality was higher in the
Table 2

Acute and long-term toxicities according to CTCAE v.3.

<table>
<thead>
<tr>
<th></th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade III</th>
<th>Total (n %)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute toxicities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermatitis</td>
<td>268</td>
<td>116</td>
<td>12</td>
<td>396 (52.7%)</td>
</tr>
<tr>
<td>Breast pain</td>
<td>19</td>
<td>3</td>
<td>0</td>
<td>22 (2.9%)</td>
</tr>
<tr>
<td>Breast edema</td>
<td>9</td>
<td>1</td>
<td>0</td>
<td>10 (1.3%)</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3 (0.4%)</td>
</tr>
<tr>
<td><strong>Long-term toxicities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast deformation</td>
<td>160</td>
<td>21</td>
<td>1</td>
<td>182 (24.2%)</td>
</tr>
<tr>
<td>Skin fibrosis</td>
<td>104</td>
<td>22</td>
<td>1</td>
<td>127 (16.9%)</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>67</td>
<td>29</td>
<td>3</td>
<td>99 (13.2%)</td>
</tr>
<tr>
<td>Breast pain</td>
<td>74</td>
<td>5</td>
<td>0</td>
<td>79 (10.5%)</td>
</tr>
<tr>
<td>Arm lymphedema</td>
<td>30</td>
<td>8</td>
<td>1</td>
<td>39 (5.2%)</td>
</tr>
<tr>
<td>Pulmonary fibrosis</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3 (0.4%)</td>
</tr>
<tr>
<td>Pneumonitis</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1 (0.1%)</td>
</tr>
</tbody>
</table>

Table 3

Univariate and multivariate analysis of age and cardiovascular comorbidities associated with radiation-induced toxicities.

<table>
<thead>
<tr>
<th></th>
<th>Univariate analysis</th>
<th>Multivariate analysis*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazard-ratio [CI95%]</td>
<td>p</td>
</tr>
<tr>
<td><strong>Breast deformation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age ≥ 80 years</td>
<td>0.46 [0.23–0.92]</td>
<td>0.023</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>0.81 [0.49–1.34]</td>
<td>0.134</td>
</tr>
<tr>
<td>HT</td>
<td>0.9 [0.6–1.34]</td>
<td>0.589</td>
</tr>
<tr>
<td>Obesity</td>
<td>1.35 [0.88–2.29]</td>
<td>0.262</td>
</tr>
<tr>
<td>Smoking</td>
<td>1.61 [0.84–3.09]</td>
<td>0.140</td>
</tr>
<tr>
<td><strong>Dermatitis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age ≥ 80 years</td>
<td>0.7 [0.54–0.91]</td>
<td>0.007</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>1.01 [0.81–1.26]</td>
<td>0.893</td>
</tr>
<tr>
<td>HT</td>
<td>1.07 [0.88–1.31]</td>
<td>0.497</td>
</tr>
<tr>
<td>Obesity</td>
<td>1.31 [1.01–1.7]</td>
<td>0.038</td>
</tr>
<tr>
<td>Smoking</td>
<td>1.33 [0.94–1.88]</td>
<td>0.108</td>
</tr>
<tr>
<td><strong>Lymphedema</strong>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age ≥ 80 years</td>
<td>0.97 [0.68–1.4]</td>
<td>0.104</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>0.95 [0.14–0.95]</td>
<td>0.07</td>
</tr>
<tr>
<td>HT</td>
<td>1.1 [0.59–2.04]</td>
<td>0.769</td>
</tr>
<tr>
<td>Obesity</td>
<td>0.90 [0.53–1.52]</td>
<td>0.005</td>
</tr>
<tr>
<td>Smoking</td>
<td>0.62 [0.15–2.64]</td>
<td>0.517</td>
</tr>
<tr>
<td><strong>Skin fibrosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age ≥ 80 years</td>
<td>1.28 [0.77–2.02]</td>
<td>0.283</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>1.24 [0.78–2.04]</td>
<td>0.316</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>0.82 [0.46–1.48]</td>
<td>0.514</td>
</tr>
</tbody>
</table>

CI = Confidence Interval HT = arterial Hypertension.

* Analysis was performed by stratifying patients into the following age groups: 70–79 years (n = 81), 80–89 years (n = 155), and ≥ 90 years (n = 36), and using the Charlson Co-morbidity Index.

CI = Confidence Interval HT = arterial Hypertension.

* Analysis was performed by stratifying patients into the following age groups: 70–79 years (n = 81), 80–89 years (n = 155), and ≥ 90 years (n = 36), and using the Charlson Co-morbidity Index.
Supplementary data to this article can be found online at https://doi.org/10.1016/j.jgo.2018.02.008.

Acknowledgements

We thank M-G. Christophe, F. Campana, R. Dendale, A. Chilles, L. Bazire, F. Rollot, and all our patients for their contribution to the work as presented in this manuscript.

Funding

No grant support received.

Disclosures and Conflict of Interest Statements

The authors have declared no conflicts of interest.

Author Contribution

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Data collection: K.-I. Cao, M-C Falcou, M-G Christophe.
Analysis and interpretation of data: K.-I. Cao, F. Salvat, M. Carton, A. Savignoni.
Manuscript writing and approval: K.-I. Cao, M. Carton, A. Fourquet, Y.M. Kirova, F. Laki, P. Poortmans, F. Salvat

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Please cite this article as: Cao KI, et al. Outcomes of postoperative radiation therapy for breast cancer in older women according to age and comorbidity status: An observational study. J Geriatr Oncol (2018), https://doi.org/10.1016/j.jgo.2018.02.008