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## Review article

# Omission of axillary staging in elderly patients with early stage breast cancer impacts regional control but not survival: A systematic review and meta-analysis

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## ABSTRACT

**Introduction:** Management of early breast cancer in the elderly population is challenging due to different breast cancer biology and limited tolerance to aggressive treatments. The aim of this study is to evaluate whether the omission of axillary staging impacts breast cancer outcomes in elderly patients.

**Patients and Methods:** A systematic review and meta-analysis was carried out following the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines. The electronic databases were searched in August 2014 using the following inclusion criteria:

**Population** Elderly patients ( $\geq 70$  years) with early stage (T1/T2, N0) breast cancer.

**Intervention** Axillary staging with a sentinel node biopsy, axillary sampling or axillary node dissection.

**Control** No axillary surgery.

**Outcomes** Local-regional recurrence, disease-free survival, overall survival.

**Study design** RCTs.

**Results:** Two RCTs met the eligibility criteria and were included. A meta-analysis of the included RCTs of 692 patients found that axillary staging reduced the risk of axillary recurrence compared to no axillary staging (RR 0.24, 95% CI: 0.06 to 0.95,  $I^2 = 0\%$ ,  $p = 0.04$ ). There were no differences observed in in-breast recurrence or distant recurrence (RR 1.20, 95% CI: 0.55 to 2.64,  $I^2 = 62\%$ ,  $p = 0.65$ , RR 1.17, 95% CI: 0.75 to 1.82,  $I^2 = 0\%$ ,  $p = 0.48$ , respectively). There were no differences observed in overall or breast-cancer specific mortality (RR 0.99, 95% CI: 0.79 to 1.24,  $I^2 = 0\%$ ,  $p = 0.92$ , RR 1.07, 95% CI: 0.72 to 1.57,  $I^2 = 0\%$ ,  $p = 0.75$ , respectively).

**Discussion:** Omission of axillary staging in elderly patients with clinically negative axillae results in increased regional recurrence but does not appear to impact survival.

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## 1. Introduction

Women above the age of 65 make up approximately 40% of new breast cancer diagnoses [1]. With an aging population, management of breast cancer in the elderly is a growing problem that general and specialized breast surgeons are increasingly facing. Management of breast cancer in this growing patient population is challenging as breast cancer biology differs in some respects in older patients, treatment tolerance varies, and there are substantial competing risks of mortality [2,3]. Without definitive data demonstrating better survival with axillary lymph node dissection, the National Comprehensive Cancer Network (NCCN) recommends that axillary lymph node dissection *may be considered optional* in patients for whom the decision regarding adjuvant therapy is not affected by the results of the axillary dissection such as in the elderly [4].

Currently there is significant variability in managing elderly patients with breast cancer. A recently published study using the American Commission on Cancer's National Cancer Data Base, which captures approximately 80% of all newly diagnosed breast cancers, demonstrated significant variation in the use of axillary staging in T1N0 breast cancers in the elderly across the United States. Patients treated at academic facilities were 18.5% less likely to undergo axillary staging compared to community practices (OR 0.81, 95% CI 0.76–0.87) and there were also variations by geographic region [5]. Similarly, a study comparing breast cancer treatment in the elderly between the Netherlands and Ireland demonstrated variations in receipt of axillary surgery and concomitant variations in survival stage for stage [6].

Given the volume of breast cancer diagnoses and the non-centralized nature of its treatment, determination and dissemination of evidence-based practices are critical to avoid both the overtreatment and the under-treatment of elderly patients. Thus we undertook a systematic review and meta-analysis of randomized controlled trials in elderly women with early stage breast cancer to evaluate whether the omission of axillary staging impacts breast cancer outcomes.

## 2. Materials and Methods

### 2.1. Protocol

A systematic review protocol was developed using the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines for protocols (PRISMA-P) [7]. The protocol was registered on the PROSPERO register (Prospective Register Of Systematic Reviews) with registration number CRD42014010750.

### 2.2. Eligibility Criteria

The following criteria were used to select studies for inclusion:

**Patients:** Elderly ( $\geq 70$  years of age) patients with early stage breast cancer (T1/T2, N0). Studies including a population with at least

50% of the patients over 70 years of age were included. Studies evaluating in-situ breast cancer or more advanced disease (T3/T4, clinically or biopsy proven positive nodes) were excluded.

**Intervention:** Axillary staging with a sentinel node biopsy, axillary sampling or axillary lymph node dissection.

**Control:** No axillary surgery. Studies comparing sentinel lymph node biopsy to axillary lymph node dissection or evaluating completion axillary dissection following a positive sentinel lymph node biopsy were excluded. Studies comparing axillary staging to axillary radiation were excluded.

**Outcomes:** Local, regional, and distant recurrence; breast cancer specific mortality and overall mortality.

**Study design:** Randomized controlled trials (RCTs).

**Other:** No other limitations were used (e.g. language of publication, publication status).

### 2.3. Information Sources

The electronic databases MEDLINE, Embase, and Cochrane Register of Controlled Trials were searched from inception until August, 2014. The MESH terms breast cancer and lymph node excision were used along with a validated filter for RCTs. The MEDLINE strategy was compiled by an expert librarian and peer reviewed by another using the Peer Review of Electronic Search Strategies (PRESS) checklist as a guide [8]. The final search strategies for MEDLINE and Embase can be found in Appendix 1. The reference lists of the eligible studies were searched. In order to ensure literature saturation, a PubMed Related Article search was conducted for the studies that were deemed relevant and included.

### 2.4. Study Selection

After pilot-testing the eligibility criteria, two independent reviewers assessed the relevance of the literature search results. This was conducted for level 1 screening of titles and abstracts and level 2 screening of potentially relevant full-text articles. Conflicts were resolved by discussion.

### 2.5. Data Collection Process

After a pilot-test of the data abstraction form, data was abstracted from the RCTs by two independent reviewers. Conflicts were resolved by discussion. Authors were contacted for data clarifications, as necessary.

### 2.6. Risk of Bias Appraisal

The risk of bias was assessed using the Cochrane Risk of Bias tool [9] by two reviewers, independently. Conflicts were resolved by discussion.

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