

Axillary RT and lymph node surgery yielded comparable outcomes for patients with breast cancer

6 December 2018

Patients with early-stage breast cancer who had cancer detected in a sentinel lymph node biopsy had comparable 10-year recurrence and survival rates following either axillary radiotherapy or axillary lymph node dissection, according to data from the randomized, phase III AMAROS clinical trial presented at the 2018 San Antonio Breast Cancer Symposium, held Dec. 4-8.

"Patients with early-stage invasive breast cancer who have no clinical evidence of local spread of disease to axillary (armpit) lymph nodes, meaning that palpation or ultrasound shows no sign of disease spread, undergo a sentinel lymph node biopsy," said Emiel J. T. Rutgers, MD, Ph.D., the principal investigator of the AMAROS clinical trial and a surgical oncologist at the Netherlands Cancer Institute in Amsterdam. "Traditionally, those patients who had cancer detected in a sentinel lymph node biopsy underwent axillary lymph node dissection, which is an effective but invasive surgical procedure that is associated with adverse side effects such as lymphedema and difficulties moving the arm."

Rutgers; Mila Donker, MD, Ph.D., a <u>radiation</u> <u>oncologist</u> at the Netherlands Cancer Institute; and colleagues from the EORTC and ALMANAC breast cancer research organizations, conducted the AMAROS clinical trial to test whether axillary radiotherapy could yield comparable outcomes to axillary lymph node dissection with fewer <u>adverse</u> side effects.

"Our new 10-year data show that axillary radiotherapy and axillary lymph node dissection provide excellent and comparable overall survival, distant-metastasis-free survival, and locoregional control," said Donker. "Given that we previously published five-year follow-up data from the trial showing that lymphedema occurred significantly

more often after axillary lymph node dissection than after axillary radiotherapy, we believe that axillary radiotherapy should be considered a good option for patients who have a positive sentinel lymph node biopsy instead of complete surgical clearance of the axillary lymph nodes."

Updated five-year follow-up information on quality of life and morbidity show again that radiotherapy is associated with significantly less lymphedema as compared to surgery.

Of the 4,806 patients with early-stage, clinically node-negative breast cancer who the researchers enrolled in the trial, 1,425 went on to have a positive sentinel ymph node biopsy; 744 of these patients had been randomly assigned to the axillary lymph node dissection group and 681 to the axillary radiotherapy group.

After 10 years, 1.82 percent (11 out 681 patients) of those assigned to axillary radiotherapy had axillary recurrence, compared with 0.93 percent (7 out of 744 patients) of those assigned to axillary lymph node dissection. In addition, neither distant metastasis-free survival nor overall survival were significantly different between the two treatment arms. Distant metastasis-free survival was 78.2 percent among those assigned to axillary radiotherapy and 81.7 percent among those assigned to axillary lymph node dissection; overall survival in the two arms was 81.4 percent and 84.6 percent, respectively.

A significantly greater proportion of patients assigned to axillary radiotherapy went on to develop a second primary cancer than did patients assigned to axillary lymph node dissection, 11.0 percent versus 7.7 percent. Donker explained that this difference was mainly due to a higher incidence of contralateral breast <u>cancer</u> in the patients treated



with axillary radiotherapy. She also noted that since the radiation technique of that time was performed with the use of two tangential fields, the "extra" radiation to the contralateral breast by including an axillary, or periclavicular field is negligible.

"We have found no indication that the increased incidence of second primary cancers is induced by the radiotherapy," said Donker. "Therefore, we strongly believe that axillary radiotherapy is a good alternative to axillary lymph node dissection in this group of patients."

"Data from another recent clinical trial suggested that there may be some patients who do not need axillary treatment even if they have a positive sentinel lymph node biopsy," added Rutgers. "Moving forward, we need to better tailor treatment for each individual patient. Some will still need axillary treatment, and our data indicate that axillary radiotherapy is a good option here."

According to the researchers, the main limitation of the study is that the size of the radiation field was greater than what is currently deemed necessary, which caused some morbidity that may now be avoided. There was also an imbalance in the number of patients who had a sentinel lymph node biopsy in the two arms and the number of recurrences was by far lower than expected, reducing the statistical power of the study. However, the researchers noted that these limitations do not adversely affect the conclusion from the trial data that axillary radiotherapy is not inferior to axillary lymph node dissections in terms of locoregional control.

Provided by American Association for Cancer Research

APA citation: Axillary RT and lymph node surgery yielded comparable outcomes for patients with breast cancer (2018, December 6) retrieved 10 June 2021 from https://medicalxpress.com/news/2018-12-axillary-rt-lymph-node-surgery.html

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