



Embargoed for Release: 12:30 p.m. CT, Dec. 11, 2013

For a photo of Rajendra Badwe, [click here](#). For other inquiries, contact Jeremy Moore at jeremy.moore@aacr.org or 215-446-7109.

Patients With Metastatic Breast Cancer May Not Benefit From Surgery and Radiation After Chemotherapy

SAN ANTONIO — After a response to initial chemotherapy, treatment with radiotherapy and surgical removal of the breast tumor and nearby lymph nodes do not provide any additional benefit to patients with metastatic breast cancer, according to results of a clinical trial presented here at the [2013 San Antonio Breast Cancer Symposium](#), held Dec. 10–14.

“There is a small percentage, about 5 to 20 percent of breast cancer patients, who present with metastatic breast cancer when they see their doctors for the first time, and across the globe, the thought is that the local tumor in such events does not require any surgery or radiation [known as loco-regional treatment (LRT)] after chemotherapy, unless there is bleeding or ulceration,” said [Rajendra Badwe, M.D.](#), director of the [Tata Memorial Hospital](#) in Mumbai, India. “However, there are conflicting results from retrospective analyses, and hence, there was a need for a randomized trial.

“We found that there was no difference in overall survival between those who received LRT and those who did not receive LRT,” explained Badwe. “Indeed, there was a 7 percent excess death rate in those who received LRT. This finding was not statistically significant; nevertheless, it aligns with previous preclinical findings that suggest surgical removal of the primary tumor bestows a growth advantage on metastases.

“I’m sure a lot of oncologists who believe in conventional wisdom and don’t provide loco-regional treatment will feel a lot more comfortable looking at these results,” said Badwe. “As for those who have changed practice based on the retrospective study history, they would have to rethink.”

Badwe and colleagues conducted a prospective, randomized, controlled trial, to which they recruited 350 women between 2005 and 2013. Eligible patients had metastatic breast cancer and an objective tumor response to six cycles of chemotherapy. Patients were randomized to two arms: 173 women received LRT (LRT arm) and 177 women received no LRT (no-LRT arm). Both arms were matched for age, clinical tumor size, hormone receptor and HER2 receptor status, and status of disease spread.

Patients in the LRT arm underwent partial or complete surgical removal of their breasts and surgical removal of axillary lymph nodes, followed by radiotherapy. Patients in the no-LRT arm did not receive any surgery or radiotherapy. Patients from both arms whose breast cancers were hormone-related received standard hormone therapy. The primary endpoint of the study was overall survival. Nine patients from the LRT arm and three patients from no-LRT arm could not adhere to trial protocol.

During the median follow-up period of 17 months, the investigators recorded 218 deaths, 111 from the LRT arm and 107 from the no-LRT arm.

They found that the median overall survival in the LRT and no-LRT arms were 18.8 months and 20.5 months, respectively. Overall survival after two years of follow-up was 40 percent in the LRT arm and 43.3 percent in the no-LRT arm. No difference in overall survival between the two arms emerged, even after adjusting for age, hormone receptor and HER2 receptor status, site of disease spread, and number of tumors in organs other than the indicated breast.

This clinical trial was funded by Tata Memorial Center and the Department of Atomic Energy Clinical Trial Center in India.

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The mission of the 2013 San Antonio Breast Cancer Symposium is to produce a unique and comprehensive scientific meeting that encompasses the full spectrum of breast cancer research, facilitating the rapid translation of new knowledge into better care for patients with breast cancer. The [Cancer Therapy & Research Center](#) (CTRC) at The University of Texas Health Science Center at San Antonio, the [American Association for Cancer Research](#) (AACR), and [Baylor College of Medicine](#) are joint sponsors of the San Antonio Breast Cancer Symposium. This collaboration utilizes the clinical strengths of the CTCRC and Baylor and the AACR's scientific prestige in basic, translational, and clinical cancer research to expedite the delivery of the latest scientific advances to the clinic. For more information about the symposium, please visit www.sabcs.org.

Publication Number: S2-02

Presenter: Rajendra Badwe, M.D.

Title: Surgical removal of primary tumor and axillary lymph nodes in women with metastatic breast cancer at first presentation: A randomized controlled trial

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Background: The role of loco-regional treatment, in women with metastatic breast cancer (MBC) at first presentation, is debatable. Preclinical evidence suggests that such treatment may facilitate growth of metastatic disease. On the other hand, many retrospective analyses in clinical cohorts have suggested favorable impact of loco-regional treatment in these patients. However, these results are likely to be influenced by selection bias. We conducted a prospective randomized controlled trial to assess the impact of loco-regional treatment on outcome in women with metastatic breast cancer at initial diagnosis. [NCT00193778]

Methods: Women with metastatic breast cancer at initial diagnosis and planned to be treated with anthracycline based chemotherapy (CT) were registered for the study. Those who had objective tumor response after 6 cycles of CT were randomized to one of the following arms: 'LRT' (loco-regional treatment) or 'No-LRT' (no loco-regional treatment). Patients were stratified by endocrine receptor (ER) status, site of metastases (visceral Vs bone Vs both) and number of metastatic lesions (< 3 Vs > 3). Women in LRT arm received surgery (breast conservation or mastectomy plus axillary lymph node dissection) followed by radiation therapy (RT), as per standard adjuvant guidelines. Women in No-LRT arm were followed up without surgery and RT. Both groups received standard endocrine therapy after last cycle of chemotherapy, if indicated. They were regularly followed up with clinical evaluation. Appropriate imaging was performed within 6 months after randomization and thereafter as clinically indicated. The primary endpoint was overall survival (OS).

Results: Between Feb 2005 and Jan 2013, 350 women were randomized, 173 in LRT and 177 in No-LRT arm. The data cutoff was in May 2013. The two arms were balanced with respect to age, clinical tumor size, HER2 receptor status and stratification factors. Eight (5.8%) patients in the LRT arm did not undergo loco-regional therapy while 19 (10.7%) patients in the No-LRT arm underwent surgical removal of primary tumor because of palliative reasons. The median follow-up was 17 months and 218 deaths (LRT=111/173, No-LRT=107/177) had been recorded at data cutoff. The median OS in LRT and No-LRT arms were 18.8 and 20.5 months (HR=1.07, 95% CI=0.82-1.40, p=0.60) and the corresponding 2-year OS were 40.8% and 43.3%, respectively. After adjusting for age, ER status, HER2 receptor status, site of metastases and number of metastatic lesions in a Cox regression model, there was no significant difference in OS between LRT and No-LRT arms (HR=1.00, 95% CI=0.76-1.33, p=0.98). There was no interaction between the effect of LRT and covariates in the model.

Conclusions: Loco-regional treatment of the primary tumor and axillary nodes has no impact on OS in patients diagnosed with MBC at initial presentation, who have responded to frontline chemotherapy. We were unable to identify any subgroups that are likely to benefit from LRT. Such treatment should be reserved for women who need it for palliative reasons. Detailed analysis will be presented at the Symposium.