



ST. JOHN HEALTH BREAST CARE PROGRAM

STANDARD 2.1 POST-MASTECTOMY RADIATION THERAPY

Standard of Care:

Patients who meet the following criteria should receive post mastectomy radiation therapy (PMRT) unless determined unable to tolerate treatment:

- 4 or more positive axillary lymph nodes;
- Positive margins.

Patients for whom the following criteria apply should be strongly considered for PMRT:

- T3N0
- T1 or T2 tumors with 1-3 positive axillary lymph nodes;
- Tumors with margins < 1 mm

Special precautions with respect to PMRT:

- Full axillary radiation therapy should not be given routinely to patients undergoing complete or level I/II axillary dissection.

Standard of Practice:

- In patients with 4 or more positive axillary lymph nodes, PMRT should be given to the chest wall and supraclavicular area with consideration of radiation therapy to internal mammary nodes.
- In patients with T1 or T2 tumors with 1-3 positive axillary lymph nodes, PMRT should be strongly considered to the chest wall and supraclavicular area with consideration of radiation therapy to internal mammary nodes.
- In patients with T3 tumors with positive axillary nodes, PMRT should be given to the chest wall and supraclavicular area with consideration of radiation therapy to internal mammary nodes.
- In patients with T3N0 or positive margins, PMRT should be given to the chest wall.
- In patients with margins < 1 mm, PMRT should be considered to the chest wall.
- In patients receiving preoperative systemic therapy, PMRT should be given on the basis of pre-chemotherapy tumor characteristics, irrespective of tumor response to preoperative chemotherapy.
- In patients receiving post chemotherapy radiation therapy, adequately treating the chest wall is mandatory. Recommended radiation is 45-50 Gy in fractions of 1.8-2.0 Gy to the ipsilateral chest wall, mastectomy scar, and drain sites making sure that adequate dose is given to the skin. This will usually require using a bolus. Additional "boost" dose of radiation can be delivered. Radiation dose to regional lymph nodes is 45-50 Gy given using 1.8-2.0 Gy fraction size. Total dose,

fraction size, the use of bolus and the use of scar boosts are to be at the discretion of the treating physician.

- Internal mammary nodal irradiation to be at the discretion of the treating physician for any patient subgroup indicated above.
- Sequencing of chemotherapy, hormonal therapy and post mastectomy radiation therapy are to be at the discretion of the treating physician; however, doxorubicin should not be administered concurrently with PMRT.
- Patients should be monitored for the potential of increased risk of toxicities (e.g., lymphedema, brachial plexopathy, radiation pneumonitis, rib fractures, cardiac toxicity, and radiation-induced second neoplasms).
- The integration of PMRT and reconstructive surgery are to be at the discretion of the treating physician(s).

Potential Benefits of Procedure:

- Reduction in the risk of local-regional failure;
- Reduction in distant recurrence;
- Improvement in overall survival.

References:

Randomized clinical trials clearly show that post mastectomy radiation therapy substantially reduces the risk of local regional failure in patients with involved axillary nodes undergoing modified radical mastectomy who receive systemic therapy. They also show, though not as uniformly, that post mastectomy radiation therapy improves disease-free and overall survival rates. For the population of node positive patients taken as a whole, the magnitude of these improvements is sufficient that they substantially outweigh the potential long-term risks of life-threatening complications from post mastectomy radiation therapy performed using modern radiotherapy techniques. (Guidelines of the American Society of Clinical Oncology: Post Mastectomy Radiotherapy, 12/22/2000)

Three randomized clinical trials have shown that a disease free and overall survival advantage is conferred by the addition of chest wall and regional lymph node irradiation in women with positive axillary lymph nodes after mastectomy and axillary lymph node dissection. In these trials, not only the ipsilateral chest wall but also the ipsilateral local-regional lymph nodes were irradiated. These studies contrast, however, with a number of other studies, including a randomized trial from an NCCN institution that failed to show a survival advantage with post mastectomy chest wall and regional node irradiation. However, on the basis of the studies demonstrating a survival advantage with post mastectomy chest wall and regional lymph node irradiation in node positive breast cancer, the current guidelines call for post mastectomy irradiation in women with 4 or more positive axillary lymph nodes and strong consideration of post mastectomy irradiation in women with 1-3 positive axillary lymph nodes. Two retrospective analyses have provided some evidence for benefit of radiation therapy for only selected patients receiving preoperative chemotherapy prior to mastectomy. However, the Panel recommends that decisions related to administration of radiation therapy for patients receiving neoadjuvant chemotherapy should be made on the basis of pre-chemotherapy tumor characteristics, irrespective of tumor response to preoperative chemotherapy (i.e.,

RT is recommended in patients with clinical stage III disease and a pathologic complete response to neoadjuvant chemotherapy).

For women with 1-3 involved axillary lymph nodes, the Panel recommends strong consideration of radiation to the chest wall and supraclavicular area after chemotherapy with consideration also given to the inclusion of the ipsilateral internal mammary nodal field (in selected patients). The recommendation for chest wall and supraclavicular irradiation in women with 1-3 involved axillary lymph nodes generated substantial controversy among Panel members. The use of regional nodal irradiation is supported by a subgroup analysis of studies from the Danish Breast Cancer Collaborative Group. In this analysis, a substantial survival benefit was associated with post mastectomy radiation therapy for women with 1-3 positive axillary lymph nodes. Some Panel members believe chest wall and supraclavicular irradiation should be used routinely after mastectomy and chemotherapy in this subgroup of patients. However, other Panel members believe radiation should be considered in this setting but should not be mandatory given the studies that do not show an advantage. This is an unusual situation in which high-level evidence exists but is contradictory. Women with 1-3 involved axillary lymph nodes and with tumors greater than 5 cm or tumors with positive pathologic margins post mastectomy should receive post chemotherapy radiation therapy to the chest wall and supraclavicular areas with consideration of inclusion of the ipsilateral internal mammary field.

There is considerable disagreement regarding the inclusion of the ipsilateral internal mammary field. Some Panel members believe that irradiation of the internal mammary nodes is unnecessary and produces possible morbidity. Internal mammary node radiation has not been isolated as an independent factor in decreasing recurrence. Others believe internal mammary nodes should be included in the radiation fields, as used in the studies that demonstrated an advantage for post mastectomy, post chemotherapy radiation therapy.

Women with 4 or more positive axillary lymph nodes are at substantially increased risk for locoregional recurrence of disease. The use of post mastectomy, post chemotherapy chest wall and regional lymph node irradiation is recommended. The use of prophylactic chest wall irradiation in this setting substantially reduces the risk of local recurrence. Again, there was substantial disagreement among Panel members regarding the inclusion of the ipsilateral internal mammary field.

Post mastectomy irradiation should be performed using CT-based treatment planning to assure reduced radiation dose to the heart and lungs. The recommended radiation is 50 Gy in fractions of 1.8-2.0 Gy to the ipsilateral chest wall, mastectomy scar and drain sites. Additional "boost" dose of radiation to the mastectomy scar can be delivered (e.g., 2 Gy fractionated in 5 doses, typically with electrons). Radiation dose to regional lymph nodes is 50 Gy given using 1.8-2.0 Gy fraction size.

Features in node-negative tumors that predict a high rate of local recurrence include primary tumors greater than 5 cm and close (less than 1 mm) or positive pathologic

margins. Chest wall irradiation is recommended for these patients. Consideration should be given to radiation to the ipsilateral supraclavicular area and to the ipsilateral internal mammary lymph nodes, especially in patients with inadequate axillary evaluation of extensive lymphovascular invasion. Post mastectomy radiation therapy is not recommended for patients with negative margins, tumors 5 cm or smaller, and no positive axillary lymph nodes. The Panel recommends that decisions related to administration of radiation therapy for patients receiving preoperative chemotherapy should be made on the basis of pre-chemotherapy tumor characteristics irrespective of response to neoadjuvant chemotherapy. (National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer, 2009)

Attested that this standard was reviewed and approved by the St. John Health Breast Care Advisory Board on: 9/16/09.

Cheryl A. Wesen

Dated: 9/24/09

Cheryl A. Wesen, MD, FACS

Medical Director, St. John Health Breast Care Program