

sentinel lymph node (SLN) did not show any difference in terms of overall and disease-free survival between the two study groups. These data question the concept of the SLN which appears to lose part of its role and meaning.

Materials and Methods: The SOLE (Senologia Oncologica Lombarda di Eccellenza) group designed a prospective multicentric randomized controlled trial in which patients of any age with small breast cancer ($T \leq 2$ cm), candidates to breast conserving surgery, and a negative preoperative assessment of the axilla (ultra-sound with FNAC in presence of one doubtful lymph node) will be randomized into two treatment arms: (1) SLNB \pm axillary dissection vs (2) No axillary surgical staging. In the arm 1, SLNB will be completed by axillary dissection when 3 or more positive nodes will be found or in presence of extra-nodal invasion. In case of either micrometastases or macrometastases in 1 or 2 SLNs no axillary dissection will be performed.

The study, which has been approved by the Ethical Committee of the European Institute of Oncology (IEO S637/311) will start in January 2012.

Overall, 1560 women (780 per arm) will be enrolled to decide whether the group without treatment of the axilla is no worse than the reference group (trial of non-inferiority), given a margin D of non-inferiority of 2.5% (maximum tolerable 5-years DDFS = 94% given a 5-years DDFS of 96.5% in the reference group). Statistical power and one-sided type I error are set to 80% and 5%, respectively.

After 3 years from the start of accrual an interim safety analysis will be performed.

The primary endpoint of the study is distant-disease free survival. Secondary endpoints will be the cumulative incidence of distant recurrences, the cumulative incidence of axillary recurrences, the disease free survival and the overall survival. Other secondary endpoints are quality of life and evaluation of type of adjuvant treatment administered.

Results: No results available at the moment.

Conclusions: No conclusions available at the moment.

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Predictive Factors for Non Sentinel Nodes Metastasis in Patient with Positive Sentinel Nodes

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Background: Recent results from the ACOSOG Z0011 showed that the role of axillary dissection for sentinel node positive breast cancer patients is questionable. We studied the predictive factors for non sentinel nodes metastasis in patient with positive sentinel nodes of breast cancer.

Material and Methods: Between January 2003 and May 2011, we performed 652 cases of sentinel node biopsy, and 168 cases had sentinel node metastasis by pathologic result. However, we excluded more three SLNs showed positive tumor cell because these patients are high risk for recurrence. Therefore, total 158 cases were included. We divided into two groups according to non-sentinel lymph node (NSLN) metastases and reviewed their medical record retrospectively. We compared clinicopathologic factors including age, operation method, histologic grade, multiplicity of tumor, preoperative radiologic finding of axillary node metastases, number of positive sentinel nodes, total harvested nodes, total harvested NSLN and biologic markers such as estrogen receptor (ER), progesterone receptor (PR), C-erbB-2 status between NSLN positive group and NSLN negative group.

Results: Out of 168 patients, 71 (44.9%) patients had NSLN metastases and 87 (55.1%) patients did not. Between two groups, univariate analysis showed that patients who had breast conserving procedure (BCP), negative lymphovascular invasion and negative finding at preoperative axillary imaging found to be associated with less likelihood of NSLN metastases. Multivariate analysis showed same results with statistical significance.

Conclusions: The rate of negative NSLN in patient with positive sentinel node is 55.1%. We suggest that the patient without any sign of axillary node metastasis and negative lymphovascular invasion of tumor during preoperative period will not undertake axillary node dissection despite of positive sentinel node.

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FDG-PET/CT Follow-up of Patients with Sentinel Node-Positive Breast Cancer After Axillary Nodal Irradiation Without Completion Axillary Dissection

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Purpose: The Hungarian National Institute of Oncology has just closed a randomized clinical phase III study. The OTOASOR (Optimal Treatment of the Axilla – Surgery or Radiotherapy) trial compared the result of the completion axillary lymph node dissection (ALND) and axillary nodal irradiation (ANI) without ALND in early-stage breast cancer patients after positive sentinel lymph node biopsy (SLNB). In the investigational arm of the trial patients received postoperative 50 Gy ANI without ALND. Actually we had information only about the sentinel lymph node (SLN) status, but the further nodal involvement remained unknown. Positron emission tomography combined with computed tomography (PET/CT) has been receiving increasing attention recently for restaging and follow-up of breast cancer. The aims of this study were to evaluate the therapeutic effect of the axillary nodal irradiation and to detect early axillary recurrences or residual diseases.

Patients and Methods: In year 2009, forty-five T1-2 SLNB positive patients were retrospectively selected from the investigational arm of the OTOASOR trial. All patients underwent surgery (breast-conserving or mastectomy) and SLNB, the SLN(s) were found positive and the patients received 50 Gy ANI instead of completion ALND. Six months after the end of the radiotherapy, patients underwent 18F-FDG PET/CT and mammography with breast and axillary ultrasound or breast MRI simultaneously. The findings of PET/CT and mammography or breast MRI were compared.

Results: Only 5 out of 45 patients had suspicious findings in the axillary tail on mammography with breast and axillary ultrasound. In those five patients PET/CT suggested locoregional residual disease in only one patient, and it was confirmed by core biopsy. In the remaining four cases both the PET/CT and the biopsy showed no evidence of malignancy.

Conclusions: Our results demonstrate the benefit of 18F-FDG PET/CT in the follow-up of breast cancer patients with a high or unknown risk of recurrence.

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Report on Results Following Single Institution Routine Usage of Margin Assessment Device in Lumpectomy Procedures

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Background: Breast cancer is a common disease which affects 1 in 9 women worldwide. Approximately 15–30 percent of patients who undergo lumpectomy (excision of breast primary tumor) require re-operation because of tumor involvement at the edges of the removed tissue (tumor positive margins). Lumpectomy, even with radiation, is less likely to be successful in controlling breast cancer when even small amounts of tumor cells are left at the margin compared to complete tumor removal. Return to surgery carries the risk of surgical complications, infections, morbidity and delay of adjuvant chemotherapy.

Materials and Methods: The intraoperative real-time margin assessment device (MarginProbe® – Dune Medical Devices) measures the electrical properties of tissue within the immediate vicinity of the probe tip. By comparing a measurement to the electric properties of known tissue types, the system classifies a reading as either normal or malignant. Criteria for use were: patient's age over 18, pre-diagnosed with carcinoma of the breast and undergoing a breast lumpectomy procedure. The device was not used if patient had implants in the operated breast, received neoadjuvant systemic therapy, or had a prior surgical procedure in the operated breast. Device was used routinely at the Barzilai Medical Center. Measurements were performed on the main specimen.

Results: Results are reported for 49 patients. Age range was 30–70 years old. From these, 26 were with Invasive Carcinoma (IDC, ILC), 13 with DCIS and LCIS, and 10 patients with a combination of Invasive Carcinoma and Carcinoma In Situ. In 20 of the 49 cases (40.8%), an extension of the excision was made during the surgery due to a positive device signal, and in 8 of those cases (40%) neoproliferative cells were