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 ($T \leqslant 2$ 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 therapuetic effect of the axillary nodal irradiation and to detect early axillary recurrences or residual diseases.

Patients and Methods: In year 2009, fourty-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 complection 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 malignity.

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

found in the additional excised tissue. The additional extensions did not negatively affect the outcome. Only 6% (3/49) patients were summoned to an additional breast preserving surgery due to positive margins. Only one of these 3 patients had a false negative result (of the main specimen which was measured by the device).A total mastectomy was performed in two other patients due to extent of disease.

Conclusion: The use of the intraoperative real-time margin assessment device (MarginProbe®) prevents repeat operations and opens a new era in breast surgery. The usage of the device was smooth, except two cases of faulty hand-held probes. Intraoperative use of the device in order to recognize positive excisional margins in breast preserving surgeries is safe and effective, and decreases the repeat operations rate.

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Axillary Node Preservation on Sentinel Node-metastasized Patients Can Be Justified by Second Nodes Biopsy Guided by 3D-CT Lymphography

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Background: To avoid the axillary node dissection on the sentinel node (SN)-positive patients, the number of positive nodes should be one or two, according to the results of ACOSG Z0011. However, the average sampled number of SN biopsy is almost around two. We cannot deny the possibility of more than two node metastasis only by SN biopsy. 3D-CT mammary lymphography (LG) can show the detailed lymphatic system from the whole breast tissue to SN and to deep axillary nodes. By using 3D-CT LG, we can perform precise SN biopsy and can sample the second and the third nodes after SN. The endoscopic biopsy of SN and the second node will help to avoid the axillary node dissection, with low-invasive and better cosmetic procedure.

Materials and Methods: 3D-CT LG was performed to mark SN on the skin before surgery. Above the tumor and near the areola, 2 ml of Iopamidol 300 was injected subcutaneously. Images of CT scan were taken at 1 and 3 min after injection to produce 3D images of lymph ducts and nodes. For the lymphoscintigraphy, 99mTc phytate 74mBq was injected, and SPECT was taken after 2 hours. We fused it with 3D-CT LG. SN biopsy was performed by dye and RI method. 2 ml of 1% indocyanin green or indigocarmine was injected subcutaneously and, 20 minutes later, a 1-cm skin incision was made along wrinkles in the axilla at the position marked by 3D-CT LG. The endoscopic view was made through the optical trocar Visiport and showed stained lymph ducts and SNs, which can be navigated by the RI detector probe. The second nodes were removed by mapping of 3D-CT LG in relation to the RI-positive nodes. We dissected the axillary nodes on SN-positive patients by endoscopic technique.

Results: The endoscopic SN biopsy was performed on 260 patients. We can recognize the passage of lymph flow from SN into the venous angle. Even in the multiple SN case, the lymph ducts were converging into the second node. The lymph nodes after SN were detected in more than two thirds patients in SN biopsy assisted by 3D-CT LG. The average sampled number of SN was 2.2. The patients with metastasized nodes were 52. Only SN metastasis was 22. The second node involvement was 8. The third node involvement was 7. All patients without metastasis in the second and the third nodes had metastasis only in SN. Therefore, they can be candidates to evade the axillary node dissection. There was no false negative study. The endoscopic SN biopsy did not need any useless detachment around axillary nodes. The spatial projection of RI with the 3D-CT LG mapping on the body helped us to find SN and the second and the third nodes easily. They were low-invasive manipulation and made better cosmetic results.

Conclusions: 3D-CT LG can detect the precise lymphatic system, and can help the endoscopic biopsy of the second and the third nodes beyond SN. It should be needed to preserve the axillary node on SN-positive patients.

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Impact of Preoperative Axillary Imaging and Fine-Needle Aspiration to Avoid Unnecessary Sentinel Node Biopsy in Breast Cancer Patients

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Background: Axillary lymph node dissection (ALND) is the gold standard of care for breast cancer patients showing metastases with positive sentinel nodes. In order to avoid unnecessary sentinel node biopsy (SNB), accurate evaluation of the axillary node is important. Axillary ultrasound (AUS), positron emission computed tomography (PET-CT), and magnetic resonance imaging (MRI) are useful for preoperative studies. If these imaging modalities reveal metastasis in the axillary nodes, patients should undergo axillary fine-needle aspiration (FNA). In this study, we evaluated the impact of preoperative axillary imaging and axillary FNA to determine the correct application of SNB.

Materials and Methods: A retrospective chart review was performed on 300 patients, who underwent surgery for breast cancer between August 2008 and October 2011. We assessed the ability of axillary imaging to predict metastases in the axillary nodes and examined whether it was possible to avoid unnecessary SNB using axillary FNA.

Results: The sensitivity and specificity of AUS, PET-CT, and MRI were 59.3%, 93.0%; 61.7%, 96%; and 49.3%, 92.9%, respectively (Table 1). All patients found to have malignancy using axillary FNA were also found to have axillary-node involvement. Forty-nine of 66 patients with suspected metastasis on AUS underwent axillary FNA. Thirty-eight (77.6%) of them had metastasis in the axilla. Nine of 17 patients who refused axillary FNA had metastasis in the axilla. 17.5% patients were sentinel node biopsy positive at their operation. And there are no false positive or false negative for detecting metastasis in the axilla. Only 35 of 234 patients (15.0%) who did not have axillary metastases on AUS had metastases in the axilla. Sixteen of 35 patients were found to have suspected metastases in axilla as per PET-CT or MRI.

Conclusions: There are no significant difference about sensitivity or specificity among AUS, MRI and PET-CT. It is important that SNB is performed in patients selected using axillary FNA with preoperative imaging.

Table 1

	AUS	MRI	PET/CT
Sensitivity	59.3%	49.3%	61.7%
Specificity	93.0%	92.9%	96.0%

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Intra-operative Open-cavity Implant for APBI Using HDR Multi-catheter Brachytherapy for Japanese Breast Cancer Patients − 3 Years of Experience at a Single Institution

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Background: The efficacy of an accelerated partial breast irradiation (APBI) has been investigated compared with whole-breast irradiation (WBI). APBI starting just after surgery might give more benefit by intra-operative insertion of catheters. Although balloon catheter-based APBI is available in the US, it would not be adapted for Japanese women with small breast. When the applicators are implanted during operation for the tumor, APBI can start just after surgery. The aim of this study is an assessment of the efficacy and safety of APBI using Intra-operative Open-cavity Implant (IOCI) technique.

Method: Patients ($\geqslant$40yrs) with invasive breast cancer ($\leqslant$3 cm) were enrolled. Before the lumpectomy, the insertion of applicators and delivery doses were simulated with CT. After the confirmation of the free margin and negative SNs for metastasis using frozen section analysis, applicators were inserted. Dose distribution analysis, using dose-volume histograms, was achieved based on a postoperative CT. APBI was started the same day of the operation. APBI therapy delivered 32 Gy in 8 fractions over 5−6 days with coverage of 2 cm tumor margins. This observation study has been approved by the institutional review board in our hospital.

Results: From October 2008 to November 2011, 135 women (137 lesions) were enrolled (55.0 y/o, <40:10, sn+:22, for patients' request). The mean number of applicators was 6.5 (2−15). The mean PTV was 36.3 cm^3 (6.5–137.1). All toxicities related to radiation therapy were mild. However, 10 patients (7.3%) had wound break due to surgical-site infection. Two patients developed ILBR (1: marginal; 1: elsewhere lesion). Cosmetic outcomes were assessed using Harvard Breast Cosmesis Grading for 94/111 patients (>9 months after surgery), 85 patients (90.4%) could achieve excellent/good cosmetic results.

Conclusions: Although this study is a small number of participants and short follow-up period, this convenient technique should be needed to establish clinical efficacy and safety.