

118 **SNOLL technique in 959 patients with non-palpable breast cancer**

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Purpose: Due to the improvement and widespread nature of procedures for breast cancer prevention and screening an increased number of non-palpable breast lesions and clinically occult breast cancer are now diagnosed. The sentinel node biopsy in patients with breast carcinoma accurately predicts the axillary nodal status. A modern approach to diagnosis and surgical treatment of occult breast carcinoma requires both the intraoperative localization of non-palpable lesions and the precise assessment of the lymph node status together.

Methods: From March 1997 to March 2004, a consecutive series of 1046 patients were presented at the European Institute of Oncology with suspected non-palpable breast lesions and programmed for conservative surgery with sentinel lymph node biopsy. In 87 patients an intraoperative histological examination revealed benign lesions and sentinel lymph node biopsy was not performed. All remaining 959 patients with cytologically or histologically proven non-palpable breast carcinoma, underwent the radioguided occult lesion localization (ROLL) procedure, using macroaggregates of human serum albumin labelled with ^{99m}Tc injected under mammographic or US guidance into the lesion (peritumoral or intratumoral site) and subsequent injection of microaggregates of human serum albumin labelled with ^{99m}Tc subdermally for the localization of the axillary sentinel lymph node (SNOLL). All these patients, except one, subsequently underwent breast surgery and sentinel lymph node biopsy.

Results: Breast lesions were correctly localized in 97.9% of cases and sentinel lymph nodes were detected in 99.9% of cases. Intraoperative or definitive histological examination revealed 763 invasive carcinomas 12 microinvasive carcinomas and 179 in situ carcinomas. Sentinel nodes were positive in 151 cases (19.5%) out of 775 invasive and microinvasive cancers and in 2 patients with DCIS. In 91.9% of cases breast lesions were removed radically including negative margins.

Conclusions: SNOLL represents the best approach to localize both non palpable lesions of the breast and axillary sentinel lymph node at the same time. This method allows radical and complete removal of the tumor and offers accurate and exact technique for detection and biopsy of axillary sentinel lymph node.

119 **Multicentric breast cancer as a new indication for sentinel node biopsy – a multiinstitutional validation study**

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Introduction: Multicentric breast cancer has been considered to be a contraindication for Sentinel Node Biopsy (SNB) so far. The purpose of this prospective multiinstitutional trial was to show feasibility and accuracy of the SNB procedure in multicentric breast cancer in 150 patients of the Austrian Sentinel Node Study Group.

Methods: Between 1996 and 2004, 3730 patients with operable, clinically node-negative breast cancer patients underwent SNB at 15 hospitals of the Austrian Sentinel Node Study Group (ASNSG) and patients data were prospectively entered into a multicenter database. 150 patients showed multicentric carcinoma of the breast and underwent SNB. The lymphatic mapping techniques involved either vital blue dye or Tc^{99m}-nanocolloid alone or combinations of both.

Results: Intraoperatively a mean number of 1.7 Sentinel Nodes were excised. The incidence of SN metastases was 57.2%. This was confirmed by axillary lymph node dissection (ALND) of level I and II in 125 patients, since two departments already started to omit routine ALND in negative SNB procedures. 60.8% of the 79 patients with positive SNs showed involvement of Non-SNs as well as 3 patients with negative SNs, indicating a false negative rate of 4.1%. Sensitivity, negative predictive and overall accuracy were 96.0%, 93.3% and 97.4% respectively. 91% of the patients underwent mastectomy while 9% were treated with breast conserving surgery. Adjuvant therapy was administered as followed: hormonal therapy in 71% of patients, chemotherapy in 45%, while 46% received adjuvant

radiation therapy and 3% immunotherapy with trastuzumab. None of the patients showed an axillary recurrence so far.

Conclusion: We estimate multicentric breast cancer as a feasible and accurate new indication for Sentinel Node Biopsy without routine axillary lymph node dissection under compliance with quality control and sophisticated interdisciplinary teamwork of surgical, nuclear medicine and pathology departments.

120 **Second biopsy of axillary sentinel lymph node for reappearing breast cancer after previous sentinel lymph node biopsy**

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Methods: Between January 2000 and October 2005, 34 consecutive female operable breast cancer patients with local relapse previously treated with BCS followed by negative sentinel lymph node biopsy in whom axillary lymph node dissection had not been performed underwent the second SLNB and prospectively followed. The SLN were marked and identified with ^{99m}Tc-labelled colloid.

Results: In all 34 patients (8 with ductal carcinoma in situ and 25 with invasive recurrences), sentinel node preoperative identification rate was 100%, and 1 or more SLNs (an average of 1.3 per patients) were surgically removed. In 3 of 34 patients with negative sentinel lymph node of previous surgery, sentinel lymph node metastases were detected with invasive recurrence followed with complete axillary dissection. All patients with negative SLN were disease-free at the last follow-up control.

Conclusion: The second SLNB procedure after previous SLNB proved to be a reliable method for the evaluation of the axillary nodal status in patients with breast cancer local recurrence. However a larger population and further follow up is required. In the meantime, this method has attained definite value in the surgical therapy of breast cancer patients.

121 **European organisation for research and treatment of cancer (EORTC) 10981-22023 after mapping of the axilla radiotherapy or surgery (AMAROS) trial update**

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Background: The EORTC Breast Cancer Group started the AMAROS trial in February 2001. This phase III randomized non-inferiority trial compares a complete axillary lymph node dissection versus radiotherapy to the axilla in sentinel node positive patients, whereas sentinel node negative patients are followed for the endpoints of the study as well. The main objective of the trial is to prove equivalent local/regional control for patients with proven axillary lymph node metastasis by sentinel lymph node biopsy with reduced morbidity if treated with axillary radiotherapy instead of axillary lymph node dissection.

Patients and Methods: Eligible are patients with an operable invasive breast cancer of over 5mm and less than 30mm, without clinically suspected regional lymph nodes. Surgical and radiotherapy quality control constitutes an important part of the trial design. Sentinel lymph node biopsies are performed by the combined technique using pre-operative lymphoscintigraphy by injection of ^{99m}Tc-nanocolloid, immediate pre-operative injection of Patent Blue dye, and sentinel node retrieval by both discoloration and intra-operative use of a detection probe. A successful learning curve of 30 patients and an approved dummy run protocol are mandatory for participation. During a site visit, prior to participation, original patient files of the learning curve are checked and a sentinel lymph node biopsy is witnessed.

Results: As of 9 November 2005, 37 institutes were subject to surgical and/or radiotherapy quality control approval. This resulted in the rejection of 6 institutes: 4 because of a poor sentinel node identification rate and 2 because the radiation technique did not meet the dummy run protocol criteria. So far, 2114/3485 (61%) patients were included by 31 institutes from Europe and Israel. Sentinel lymph node biopsy results demonstrated 34% positive and 64% negative sentinel nodes leading to an overall identification rate of 98%.