The role of a second tracer injection in the success rate of SN identification in patients with non-visualisation of axillary SNs was also studied.

Methods: Patient group I consisted of 356 breast cancer patients who underwent LS and SN biopsy after intratumoural injection of 99Tcm—labelled albumin colloid (Nanocol®) with a median dose of 92 (range 50–119) MBq. In the patient group II (178 patients) the dose of the tracer was adjusted according to BMI: 113 patients with BMI < 26 received 80 MBq, those 41 with BMI 26–30 received 100 MBq and those 24 with BMI > 30 received 140 MBq. Anterior and lateral scintigraphic imaging was performed approximately four hours after the injection and SN biopsy was performed within 26 hours. A second tracer injection, intratumoural or subdermal, was given in 39 of the 81 patients without axillary hot spots in LS

Results: Non-visualisation rate of axillary sentinel nodes was 49/356 (14%)in group I and 31/178 (17%) in group II (table 1). The parasternal sentinel nodes were visualised in 68 (19%) patients in group I and 21 (12%) patients in group II.

Table 1. Non-visualisation of axillary sentinel nodes

Patient group	BMI<26	BMI 26-30	BMI>30
I	21/217	19/90	9/49
II	13/113	13/41	5/24

The intraoperative SN identification failed in 3 patients with and 3 without axillary metastases in 39 patients receiving a second injection. 22 patients (3 with and 19 without axillary metastases) of the 42 without a second injection underwent axillary clearance because of non-identification of SNs.

Conclusions: Adjusting the dose of the radioactive tracer according to BMI did not lead to optimised SN visualisation in LS. The failure rate in intraoperative SN identification is minimised using a second tracer injection in patients without axillary hot spots in LS.

93 POSTER

The number of resected axillary lymph nodes (ALN) influences the risk for axillary recurrences in node-positive, but not in node-negative patients

W. Janni, B. Gerber, B. Rack, B. Strobl, W. Thieleke, H. Sommer, K. Friese. *LMU Munich, I. UFK, Munich, Germany*

Background: Based on broad evidence, the International Consensus Conference, 'Primary Therapy of Early Breast Cancer' St. Gallen 2003 established sentinel lymph node excision as sufficient surgical procedure in the axilla of node-negative breast cancer patients. However, there is little data available, whether the excision of a low number of ALN increases the risk for axillary recurrences, compared to systematic axillary dissection.

Material and Methods: By multivariate analysis of 3800 pts. treated for early breast cancer UICC stage I–III, we investigated the prognostic relevance of the number of resected ALN for axillary recurrences in patients with and without evidence of axillary lymph node metastases. Pts. with carcinoma in situ, distant metastases at time of presentation, primary systemic therapy, unknown hormone receptor status or histopathological grading were excluded. Data were contemporaneously collected and pts. were followed for a mean of 72 months.

Results: Axillary recurrences as sole manifestation site of recurrence occurred in 67 pts (1.7%). In node negative patients (n=2667), multivariate analysis, allowing for number of removed ALN, histopathological grading, tumor size and hormone receptor status, revealed only grading (P=.04, RR 2.7, 95%CI 7.1–1.1) and tumor size (P=.03, RR 2.8, 95%CI 7.1–1.1), but not the number of removed ALN (P≈.42) as predictor for axillary recurrence. In contrast, in node positive pts. (n=1133), multivariate analysis demonstrated the number of removed ALN as independent significant predictor for axillary recurrences (P=.002, RR 9.9, 95%CI 2.7–35.3), next to tumorous fixation of ALN (P=.005, RR 3.6, 95%CI 1.5–8.3).

Discussion: There is no evidence that a low number of removed ALN increases the risk for axillary recurrences in node negative pts. However, evidence suggest that complete axillary dissection should be maintained in node positive pts.

94 POSTER

Long-term follow-up of sentinel node negative breast cancer patients: a quality control

I. Burgmans, A.N. van Geel, M. Menke-Pluymers. Erasmus Medical Centre, surgical oncology, Rotterdam, The Netherlands

Sentinel node biopsy (SNB) in breast cancer accurately predicts axillary status and is generally adopted for disease staging. To evaluate the feasibility of this technique it is important to determine the frequency and impact of local axillary failure after negative SNB. The purpose of this study

was to evaluate the axillary recurrence rate in our institute and to determine if axillary control is lost in case of recurrence. From November 1998 to November 2001, 330 consecutive patients with T1-2 breast cancer without clinical or sonographic signs of lymph node involvement, underwent SNB. 190 patients who had a negative sentinel node biopsy without additional axillary dissection were studied prospectively in order to identify tumour recurrence. After a median follow-up of 42 months (24-60) four patients (2%) developed overt axillary disease. The recurrences were treated with axillary node dissection, chemotherapy and radiotherapy in case of involvement of four or more lymph nodes. During follow-up no more axillary recurrences occurred. Reassessment of the SNB procedures revealed two doubtful procedures. In one patient the axillary 'recurrence' was due to a new primary carcinoma. This study provides reassurance that SNB is safe. In case of recurrence, the axilla can be treated successful without losing locally control. It also emphasise that conventional axillary dissection should be performed in case of doubt of the SNB procedure.

95 POSTEF Patients needs and preferences in routine follow-up after treatment for breast cancer

J. Bonnema¹, G.H. de Bock, R. Zwaan, C.J.H. van de Velde, J. Kievit, A. Stiggelbout. ¹Department of Surgery, Leiden University Medical Center, Leiden; ²Department of Medical Decision Making, Leiden University Medical Center, Leiden

Background: After primary care for breast cancer patients participate in routine follow-up care. Informational needs of patients may change over time. In this study we focussed on a patient's needs and preferences in a routine follow-up programme 2–4 years after treatment for primary breast cancer. These needs include information and preferences regarding additional investigations and organisation of follow-up care.

Methods: A cross-sectional survey was performed using a postal questionnaire among women without any sign of relapse during the routine follow-up period. The questionnaire was sent 2–4 years after primary surgical treatment.

Results: Most important to patients was information on long-term effects of treatment and prognosis, discussion of prevention of breast cancer and hereditary factors and changes in the untreated breast. Patients preferred additional investigations (such as X-ray and blood tests) to be part of routine follow-up visits. More than half of the patients preferred lifetime follow-up, performed by a hospital doctor. Less satisfaction with interpersonal aspects and higher scores on the HADS-anxiety scale were related to higher informational needs. Higher scores on the HADS-anxiety and depression scale were related to stronger preferences for additional investigations. Receiving adjuvant hormonal or radiotherapy was related to a preference for a more intensive follow-up schedule. There were no significant differences between patients treated with mastectomy compared to those treated with breast conserving therapy. During routine follow-up after a diagnosis of breast cancer, not all patients needed all types of information.

Conclusion: When introducing alternative follow-up schedules, individual patients' information needs and preferences should be identified early and incorporated into the follow-up routine care, to target resources and maximise the likelihood that positive patient outcomes will result.

96 POSTER Detection of sentinel lymph node in breast cancer: blue dye technique versus combined blue dye—radioactive tracer technique

Z. Radovanovic¹, A. Plzak¹, A. Golubovic¹, B. Stojiljkovic², D. Radovanovic³. ¹Institute of Oncology Sremska Kamenica, Department of Surgical Oncology, Sr.Kamenica, Serbia; ²Institute of Oncology Sremska Kamenica, Department of Pathology, Sr.Kamenica, Serbia; ³Institute of Oncology Sremska Kamenica, Department of anesthesiology and intensive care, Sr.Kamenica, Serbia

Background: Sentinel lymph node biopsy in breast cancer can be used to select patients in which axillary lymph node dissection could be avoided. In this study we compared the value of two methods for identification of sentinel node (SN) using either only blue dye or combination of blue dye and radioactive tracer.

Material and methods: All patients were women with clinically $T_{1-2}N_0M_0$ breast cancer. They were randomized into two groups. Group A: In 50 patients SN marking was performed only with blue dye with visual intraoperative identification of SNs. Group B: In 100 patients combined SN marking was performed (blue dye and radiotracer) with intraoperative visual and gamma probe (Gammed IV 0 -Capintec) identification of SNs. We used 2 ml of blue dye Patentblau V 0 (Byk Gulden). Radiotracer was Antimony sulfide marked with Tc 99 m and of 0.3 mCy (9.6 MBq) activity. Application method of both contrasts was peritumoral. Radiotracer

application time was approximately 16 hours preoperatively, while the blue dye was applied 10–15 min. before operation. After SN biopsy all patients underwent mastectomy or conservative surgery with axillary lymph node dissection of level I and II.

Results: In Group A mean patient age was 59.1 years (range 27–83 years). A mean of 1.68 SNs were identified (median 1.00, range 1–4). In three patients (6%) the SN was false-negative for metastasis. False-negative rate in this group was 17.64% with sensitivity of 82.3% and negative-predictive value of 86.95%.

In Group B mean patient age was 55.3 years (range 30–78 years). The mean number of SNs excised per case was 1.62 (median 1.00, range 1–5). Two cases (2%) were false-negative while false-negative rate was 4.54%. Sensitivity was 95.45% and negative-predictive value 95.34%.

Conclusions: The detection of SNs with combined technique has significantly better sensitivity and lower false-negative rate than marking of SN with blue dye alone and therefore should be preferred.

97 POSTER Sentinel node and ductal carcinoma in situ of the breast

C. Tunon de Lara¹, M. Baron², J. Classe³. ¹Bergonie, surgery, Bordeaux, France; ²Becquerel, surgery, Rouen, France

Background: Axillary lymph node dissection in patients with ductal carcinoma in situ (DCIS) of the breast is not warranted because DCIS has no metastatic potential. However the risk of micro invasive carcinoma exists in large DCIS, which was not totally examined as in case of a mastectomy.

Material and methods: The aim of this series is to evaluate, feasibility of sentinel node procedure in DCIS.

We analysed retrospectively patients treated in 3 French cancer centres for pure DCIS or DCIS with micro invasive carcinoma. Surgical procedures were lumpectomy or mastectomy associated with an axillary sentinel node procedure alone.

Results: We included 32 patients suffering from pure DCIS (26/32, 81%) or micro invasive carcinoma (6/32, 19%). Mean age was 56 years (33–77). Seventeen tumours were non palpable (53%). 13 breast conservative procedures were performed and 19 mastectomies. Sentinel node procedure was performed using blue (10/32), technetium (8/32) or both (14/32). The detection rate was (29/32) 90% and no patient had axillary lymph node sampling.

Conclusion: Whatever the size, subtype, grade of the tumour or patient age no sentinel node was found positive. Sentinel Node in DCIS is an interesting procedure but not necessary for all patients. We need to focus on the subgroup with a risk of occult micro invasive carcinoma: a young patient, DCIS diagnosed by micro biopsy, high grade and large tumour size.

98 POSTER Sentinel lymph node biopsy in male breast cancer patients

A. Goyal, R.E. Mansel. University of Wales College of Medicine, Surgery, Cardiff. UK

Background: The concept of sentinel node biopsy has been validated for female breast cancer patients whereas, ALND remains the standard of care for male breast cancer patients with similar tumours. We evaluated the results of SLN biopsy in male breast cancer patients with clinically negative axillae.

Methods: This study included all male breast cancer patients who underwent SLN biopsy between February 1998 and October 2003. All patients had negative axillae on clinical examination. All patients underwent preoperative lymphoscintigraphy. SLN biopsy was performed using a combination of Patent blue V and ^{99m}Tc-radiolabelled colloidal albumin injected peritumourally.

Results: Nine patients, 26–79 years of age, were included in the study. Pre-operative lymphoscinitgraphy identified SLNs in all patients. Intraoperatively, SLNs were successfully localised in all patients. The mean number of SLNs encountered was 2.4. Five patients had a positive SLN, 4 a negative SLN. Five patients (1 with a negative SLN, 4 with a positive SLN) had been elected preoperatively to undergo ALND regardless of findings on SLN biopsy. ALND confirmed the SLN to be negative in 1 patient (false-negative rate: 0%) and 3 of the 4 patients with positive SLN(s) had additional positive nodes in the axilla. SLN biopsy accurately predicted axillary lymph node status in these 5 patients.

Conclusion: These findings compare favourably with findings reported in the literature regarding SLN biopsy in female breast cancer patients. SLN biopsy accurately staged the axilla in male breast cancer patients and should be considered for axillary staging in male breast cancer patients with clinically negative axillae.

POSTER

Population-based sentinel lymph node biopsy (SLNB) in early invasive breast cancer (EIBC)

P. Fenaroli¹, M. Merson², A. Bonasegale³, G. Virotta⁴, S. Pericotti⁵, M. Valentini⁶, P. Poletti⁷, R. Labianca⁸, A. Personeni⁹, <u>C. Tondini¹⁰</u>. ¹Ospedali Riuniti, Senology, Bergamo, Italy; ²Ospedali Riuniti, Senology, Bergamo, Italy; ⁴Ospedali Riuniti, Senology, Bergamo, Italy; ⁴Ospedali Riuniti, Nuclear Medicine, Bergamo, Italy; ⁵Ospedali Riuniti, Pathology, Bergamo, Italy; ⁶Istituto Mario Negri Sud, Biostatistics, Chieti, Italy; ⁷Ospedali Riuniti, Medical oncology, Bergamo, Italy; ⁸Ospedali Riuniti, Medical oncology, Bergamo, Italy; ⁹Ospedali Riuniti, Radiotherapy, Bergamo, Italy; ¹⁰Ospedali Riuniti, Medical oncology, Bergamo, Italy

SLNB has been proposed as a reliable method for staging of EIBC. The aim of SLNB is to identify women who are likely to be pNo, avoiding the side effects of AD. In the present study we analyse the impact of this procedure when systematically applied to all unselected women of a community-based Breast Cancer Unit (BCU). The BCU at the Ospedali Riuniti of Bergamo comprises a diagnostic and surgical service for a general population of approximately 500.000 people. A team of dedicated surgeons, specifically trained both in the diagnostic and surgical procedures of breast cancer treatment, is serving full-time in the BCU. In particular, all team members, before performing SLNB in routine clinical practice, were specifically trained in the radiocolloid sentinel node localisation (RCSNL) and sampling of SLN according to current recommendations.

All consecutive women with unifocal cT1–1 (≤3 cm) cNo EIBC diagnosed at our BCU were considered for RCSNL and biopsy. Only 387 (71%) of all 542 patients met eligibility criteria for SLNB. Reasons for ineligibility included tumour size, palpable axillary nodes, plurifocality and/or multicentricity, and refusal to undergo the procedure. Successful SLNB was performed in 362 patients (94% of those eligible), but in 108 of these axillary dissection (AD) had to be performed anyway, mainly because of SLN-positivity. Therefore, a total of 286 patients (53% of all patients with EIBC) ultimately underwent AD. Systematic application of the SLNB procedure allowed sparing AD in 256 patients, corresponding to 71% of patients eligible for SLNB and to 47% of all consecutive patients. SLNB procedure was well tolerated and resulted in no major complication. A single patient developed axillary recurrence 18 months after surgery during adjuvant tamoxifen treatment.

In conclusion, our study shows that the systematic application of SLNB by highly qualified surgical teams can have a relevant impact in terms of reduction of unnecessary AD on a population scale, with consequent improvement in patients' quality of life. In absolute terms, in the EU this could result in approximately 100,000 unnecessary AD avoided each year. We believe that radiocolloid-guided SLNB, when appropriately applied in the context of a population-based service, can help sparing unnecessary AD and related costs and morbidity in many women presenting with EIBC, and that such a strategy should be more widely and appropriately adopted for all eligible patients with EIBC.

100 POSTER

The prevalence of axillary lymph node metastases in pure tubular carcinoma of the breast

J. Leikola¹, P. Heikkilä², L. Krogerus³, K. von Smitten⁴, M. Leidenius⁵.

¹Helsinki University Central Hospital, Breast Surgery Unit, Helsinki,
Finland; ²Heslinki University Central Hospital, Dept. of Pathology,
Helsinki, Finland; ³Helsinki University Central Hospital, Dept. of
Pathology, Helsinki, Finland; ⁴Helsinki University Central Hospital, Breast
Surgery Unit, Helsinki, Finland; ⁵Helsinki University Central Hospital,
Breast Surgery Unit, Helsinki, Finland

Background and Objectives: Pure tubular carcinoma (PTC, > 90% tubular component) is a rare, well-differentiated histologic subtype of invasive breast cancer. The existing data regarding the prevalence of lymph node metastases and necessity of lymph node staging and axillary treatment in PTC is controversial. We aimed to study the prevalence of lymph node metastases in PTC.

Methods: Altogether 26 patients with primary tumours classified as PTC underwent sentinel node biopsy (SNB) between March 2001 and August 2003 and were entered in the study. Histological re-evaluation of the tumours were performed by an experienced pathologist specialized in breast pathology. A level I/II axillary clearance (AC) was carried out in all patients with tumour positive sentinel nodes (SNs).

Results: Seven of twenty-six (27%) patients had SN metastases, five of them micrometastases only. In six cases SNs were the only tumour positive lymph nodes.

According to the pathological review by the expert pathologist, five patients, three with tumour positive SNs, did not have PTC. In addition, no histological specimens were available for re-evaluation in two patients.