an important part of the trial design. SN biopsies are performed by the combined technique using preoperative lymphoscintigraphy by injection of Technetium-99m nanocolloid, immediate pre-operative injection of Patent Blue dye, and SN 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 SN procedure is witnessed.
Results: As of 25 May 2005, 1795/3485 (52%) patients were included by 23 institutes from Europe and Israel. SN biopsy results demonstrated 34% positive and 64% negative sentinel nodes leading to an overall identification rate of 98%. Last interim quality control analysis revealed one axillary recurrence in the SN negative group resulting in a 5-year axillary recurrence estimate of 1% (95%CI: 0–3%) in the SN negative group. Other preliminary results showed that adjuvant systemic treatment was given to 56% (95%CI: 43–69%) of patients randomised for ALND and to 58% (95%CI: 47–70%) of patients randomised to RT of the axilla.
Conclusions: Accrual status of the AMAROS trial has reached halfway. A strict quality control protocol resulted in a SN identification rate of 98%. Information of the complete axillary lymph node status did not show a difference in distribution of adjuvant systemic treatment between the two treatment arms. Finally, the small number of axillary recurrences developed after a SN negative procedure supports the accuracy of this new promising staging technique in early breast cancer.

330 POSTER

A prospective evaluation of a new technique using aponeurosis padding without vacuum drainage to reduce morbidity in patients undergoing axillary node dissection for localized breast cancer (LBC)

J.-R. Garbay[1], A. Thoury[2], E. Moinon[1], O. Picone[1], A. Rey[1], M. Di Palma[1]. [1]*Institut Gustave Roussy, Surgery-Medicine, Villejuif, France;* [2]*Hopital Bichat, Surgery, Paris, France*

Objective: Despite the use of sentinel node biopsy, many patients with LBC require axillary lymphadenectomy. Axillary aponeurosis padding appeared to be a valuable alternative technique as it avoids vacuum drainage and its risks. After reporting our first experience with muscular padding [1], we report here the results with axillary aponeurosis padding.
Patients and methods: Aponeurosis padding was prospectively performed in patients with LBC. Level I and II axillary lymphadenectomy was performed through a horizontal skin incision close to the hairline. The aponeurosis was incised at the same level and dissection started underneath. Padding consisted of suturing the edges of the axillary aponeurosis to the underlying muscle with 3 separate stitches, without drainage. A surgeon, a pain clinician and a physiotherapist, respectively evaluated surgical complications (i.e. infection, seroma, ...), pain after surgery and at 6 weeks, mobility of the shoulder and arm.
Results: From 01/2004 to 03/2005, 114 patients were treated. The mean number of excised nodes was 14 (5–36). The mean hospital stay was 2 days. There was no clinical seroma in 91% of the patients and aspiration was required in only 4%. There was no pain at 6 weeks in 71% of the patients. This compares very favourably with a previous cohort of patients operated on by the same team using vacuum drainage: mean hospital stay was 4 days, incidence of seroma and upper arm mobility were similar, and pain at 6 weeks was present for almost 50% of the patients.
Discussion and conclusion: Aponeurosis padding without drainage is easy to learn and effectively reduces morbidity after axillary node dissection in patients with LBC. A longer follow-up is required but this new technique appears to be very promising.

References

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331 POSTER

The number of recovered axillary lymph nodes affects lymph node recurrence but not specific survival in node-negative breast cancer

A. Courdi[1], J.-M. Ferrero[2], R. Largillier[2], C. Ortholan[1], I. Raoust[3], I. Birtwisle-Peyrottes[4], J.-M. Hannoun-Lévi[1], J.-C. Machiavello[3], M. Lallement[3], A. Sudaka[4]. [1]*Centre Antoine-Lacassagne, Radiotherapy, Nice, France;* [2]*Centre Antoine-Lacasagne, Medical Oncology, Nice, France;* [3]*Centre Antoine-Lacasagne, Surgery, Nice, France;* [4]*Centre Antoine-Lacasagne, Pathology, Nice, France*

Background: The number of examined axillary lymph nodes (LN) varies among patients and may also be surgeon-dependent. In case of insufficient LN retrieved upon axillary dissection, it has been often recommended to re-operate. Axillary relapse is known to affect prognosis. Sentinel LN biopsy is increasingly been used, where one of a few LN are examined. The purpose of this study is to examine LN recurrence and specific survival (SS) in node-negative breast cancer patients according to the retrieved number of axillary LN.
Materials and Methods: Between 1973 and 2003, 2461 patients presenting with infiltrating breast adenocarcinoma and registered in our database were examined. They were treated with either conservative surgery (57.9%), or mastectomy (42.1%). All patients had axillary LN dissection and were negative for LN involvement. Radiotherapy was given after conservative surgery, and for T3 or T4 tumours after mastectomy. Some patients with central or inner lesions were given radiotherapy to the internal mammary chain. No axillary radiotherapy was delivered. Hormonal therapy and or chemotherapy was given according to the policy at the time the patient was seen. The mean follow-up was 120 months. The 5- and 10-year Kaplan-Meier rate of LN relapse was studied, as well as the specific survival.
Results: The overall 5- and 10-year LN relapse rate was 1.1% and 1.4%. No LN relapse was observed after 8 years of follow-up, with 1369 patients at risk at that time. In the group of patients with less than 8 axillary LN examined, the 5- and 10-year LN relapse rate were 2.1% and 2.8%. For those with 8 or more LN, the respective values were 0.8% and 1.1% ($p = 0.0046$). For the whole population, the 5- and 10-year SS were 95.5% and 88.3%. Patients with less than 8 axillary LN had SS of 94.9% and 89.8% respectively, versus 95.6% and 88.0% for patients with 8 or more examined LN ($p = 0.58$). Similar results were obtained if patients were classified into more than 2 groups according to the number of retrieved axillary LN.
Conclusions: Even though LN relapse increased by a factor of 2.5 in case fewer than 8 LN were recovered at axillary dissection, the long-term SS was not affected by the number of LN, probably because of the rare occurrence of axillary relapse. These findings do not favour re-operation of the axilla, nor performing axillary radiotherapy in case of insufficient LN examined. In addition, these data tend to comfort the sentinel LN biopsy technique.

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Comparison of peritumoral and periareolar injection of Tc-labeled colloid in sentinel lymphnode biopsy (slnb) in patients with clinically node negative breast cancer

B.J. van Wely[1], M.L. Smidt[1], F.B.J.M. Thunnissen[2], L.J.A. Strobbe[1]. [1]*Canisius Wilhelmina Hospital, Surgical Oncology, Nijmegen, The Netherlands;* [2]*Canisius Wilhelmina Hospital, Clinical Pathology, Nijmegen, The Netherlands*

Background: After it's introduction SLNB gained broad exceptance as a minimal invasive alternative for staging the axilla in breast cancer patients. However the optimal site of injection of blue dye and Tc-labeled colloid remain an issue for debate. The aim of this study was to compare two different injection sites of the radioactive tracer, using a deep (peritumoral) and a superficial (periareolar) technique.
Material and Methods: To this purpose a prospective registration of 525 patients, operated on between 1998 and 2004, was analysed. Group A (284 patients) underwent the SLNB after subareolar injection of the radioactive tracer (60 MBq of technetium-99m nanocolloid). In group B (241 patients) the radioactive tracer was injected peritumoral, the blue dye was injected peritumoral in all patients. The Sentinel Lymph Node (SLN) was identified guided by the preoperative lymphoscintigraphy, the blue lymphatic vessels and hand-held gamma probe. Extra-axillairy SLN's were not harvested.
Results: Patient and tumour characteristics were comparable in both groups. A median of 1.0 SLN's were harvested in group A compared to 2.0 SLN's in group B. In Group A 13 extra-axillairy SLN's were visualised on scintigraphy compared to 21 in group B. In group A 30.6% of all patients had tumour postive SLN's, in group B 39.8% had metastatic SLN's ($p = 0.03$). In group A this concerned micrometastases in 47.7%, in group B 41.7% ($p = 0.42$). In group B a false negative rate of 5.2% was seen (non-SLN harvested was tumour positive while SLN was tumour negative), in group A there were no false negatives. Tumour positive SLN's were hot and blue in 83.4%, hot only in 2.3% and blue only in 13.8% of all metastatic patients in group A, compared to 79.1%, 8.8% and 12.1% respectively in group B.

Metastatic SLN

	Group A (N = 284)	Group B (n = 241)	*P*-value
Total	30.6%	39.8%	**0.03**
Micrometastases	47.7%	41.7%	0.42
False negative rate	0%	5.2%	**0.03**

Conclusion: When using periareolar injection of radioactive tracer combined with peritumoral injection of blue dye, significantly less patients have tumour positive axillairy lymph nodes when comparing them with patients in whom both tracers are injected peritumoral. This can partly be explained by the fact that for the last two years we perform standard ultrasound examination of the axilla before SLNB, diagnosing metastatic disease in 6–7% of metastatic patients without the use of SLNB.
We conclude that the use of periareolar injection technique is a good and easy alternative to deep techniques, however close follow up is needed to ensure that local recurrence rates are comparable for both groups.

333 POSTER

Are lymphogenic micrometastasis in breast cancer a prelude to macrometastases?

E. Madsen[1], P. Gobardhan[1], p. van Beest[1], V. Bongers[2], J. van Gorp[3], C. Perre[1], T. van Dalen[1]. *[1]Diakonessenhuis, Surgery, Utrecht, The Netherlands; [2]Diakonessenhuis, Nuclear medicine, Utrecht, The Netherlands; [3]Diakonessenhuis, Pathology, Utrecht, The Netherlands*

Background: Since the introduction of the sentinel lymph node biopsy (SNB) in patients with breast cancer, micrometastases are detected in 15–20% of patients. The clinical relevance of these small lymphogenic metastases is unclear. There is a well established correlation between lymph node (macro-) metastasis and tumour size. If micrometastases are merely a prelude to larger lymph node metastases, one would expect a similar relation for micrometastasis. We evaluated the relation between lymphogenic micrometastasis and various primary tumour characteristics.
Patients and methods: Between June 1999 and December 2004, 514 patients cT1/2N0 breast cancer underwent surgery that included SNB as a staging procedure. The presence of lymph node metastasis was evaluated after serial sectioning of the sentinel node(s) with 250 micrometer intervals and staining with H&E and immunohistochemistry staining. Based on the presence of tumour in the sentinel node, patients were categorised in three groups: N0: no metastasis (n = 295) N1micro: micrometastasis <2 mm (n = 83) and N1: metastasis ⩾2 mm (n = 136).
Results: In contrast to the increasing frequency of macrometastasis in relation to tumour size (primary tumour <1 cm, 13%; 1–2 cm, 21%; 2–3 cm, 40%; and >3 cm, 41%; P < 0.001), the frequency of micrometastasis in the sentinel lymph node was not correlated with the size of the primary tumour: 17%, 15%, 19%, 18%, respectively. Bloom and Richardson grade, mitotic activity index, estrogen recptor status, and carcinoma type (ductal/lobular) could not be shown to have an impact on the occurrence of macro- and micrometastasis.
Conclusion: In contrast to the increasing chance of lymfogenic macrometastasis in larger primary breast cancers, the occurrence of micrometastasis was not influenced by tumour size. There appears to be a difference between the chance of micrometastasis and the development of macrometastasis. Micrometastasis merely being a prelude to macrometastasis appears unlikely.

334 POSTER

The consequences of long-time arm morbidity in node-negative breast cancer patients with sentinel node biopsy or axillary clearance

M. Leidenius[1], M. Leivonen[2], J. Vironen[3], K. von Smitten[1]. *[1]Helsinki University Central Hospital, Breast Surgery Unit, Helsinki, Finland; [2]Helsinki University Central Hospital, Peijas Hospital, Vantaa, Finland; [3]Helsinki University Central Hospital, Jorvi Hospital, Espoo, Finland*

Background: Several studies have evaluated long time morbidity after sentinel node biopsy (SNB) and axillary clearance (AC) recording self reported morbidity or measuring arm circumferences or ranges of shoulder motions. Statistically significant differences in favour to SNB have been observed, but the consequences of the reported differences have been addressed in relatively few studies. Our aim was to evaluate long-time morbidity in axillary node negative breast cancer patients three years after sentinel SNB or AC emphasising the consequences of morbidity like work-related events and the need of physiotherapy.
Patients and methods: Morbidity was evaluated in 92 breast cancer patients three years after SNB only and in 47 patients after AC using a questionnaire. The circumferences of the upper extremities and the range of the shoulder movements were also measured.
Results: Two (2%) SNB and eight (17%) AC patients were not able to use the ipsilateral upper extremity to former extent, P < 0.005. One SNB (1%) and one (2%) AC patient were retired or on a long-time sick leave because of arm morbidity, P = NS. Clinically apparent upper extremity lymphoedema was observed in one (1%) SNB patient and in 6 (13%) AC patients, P < 0.005. Two (2%) SNB patients had received manual lymph drainage, one of them because of breast oedema. None of the SNB patients needed a compression sleeve. Seven (15%) patients had received manual lymph drainage after AC, three (6%) of them wore also compression sleeve, P = 0.0009 for manual lymph drainage for arm oedema, P > 0.05 for compression sleeve.
Conclusions: The risk of remarkable long-time arm morbidity after SNB is minimal. Work-related events seem uncommon due to arm morbidity, regardless the extent of axillary surgery.

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Is sentinel lymph node biopsy (SLNB) necessary in women undergoing contralateral prophylactic mastectomy (CPM)? Magee Womens hospital experience

A. Soran, M. Bonaventura, J. Falk, D. Keenan, J. Kelley, M. Balkan, A. Harlak, R. Johnson. *Magee-Womens Hospital, Surgery, Pittsburgh, USA*

Introduction: SLNB remains controversial with prophylactic mastectomy. This retrospective study was undertaken to determine if SLNB is justified in patients undergoing CPM.
Methods: Between 1999 and 2004 a total 155 patients underwent CPM and 80 of them (51.6%) had SLNB performed. 103 of index tumors were diagnosed as invasive tumor. Multicentricity and/or multifocality were reported in 49.7% of index tumor specimens, and estrogen receptor was positive in 60% of them. Two invasive and 3 DCIS were diagnosed in 155 CPM specimens (n = 5, 3.2%). Both blue dye and gamma detection probe technique were used to identify the SLN in 95% of patients with CPM, and blue dye was used in 4 patients.
Results: Median number of identified SLN is 2 (range 1–6) at CPM site. There was no malignant tumor at CPM specimens of 2 patients (Fibrocystic change, Sclerosing Adenosis), but both of them had positive SLNB for metastatic carcinoma (n = 2/80 = 2.5%). Final treatment decision might be affected in 7 patients in CPM group (4.5%) if all 155 would have underwent SLNB (2 SLNB were positive, 2 invasive tumor were diagnosed at CPM specimens, and 3 DCIS were diagnosed at CPM specimens). There was no evidence of arm lymphedema in patients who had undergone CPM and SLNB at a median follow-up of 24 months.

Table 1: Age, malignant histology, family history, BRCA result and time of CPM surgery in all CPM patients

	Total CPM (n = 155)	CPM+SLNB (n = 80)
Age (min-max) years	47 (26–70)	47.5 (26–70)
Malignant histology	5 (3.2%)	4 (5%)
Family history	81 (52.3%)	37 (46.3%)
BRCA 1 or 2 (+)	11 (7.1%)	5 (6.3%)
Immediate CPM	132 (85.2%)	68 (85%)

Conclusion: Even though SLNB is a minimally invasive method of evaluating the lymphatic basin, this retrospective study dose not support its use in patients undergoing CPM.

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Surgical biopsy for nonpalpable breast lesions: should be abandoned as initial management?

E. Kouskos[1,2], C. Markopoulos[2], D. Mantas[2], K. Revenas[2]. *[1]"Vostanio" Hospital, 2nd Surgical, Mytilene, Greece; [2]"Laiko" Hospital, Breast Unit, 2nd Surgical, Athens, Greece*

Background: In this retrospective clinical study an analysis of the histologic findings of nonpalpable breast lesions, treated by open surgical biopsy in our Breast Unit was performed. Aim of that analysis was to clarify if the surgical biopsy could still be a valuable initial management of nonpalpable breast lesions.
Patients and methods: A series of 750 women underwent 784 preoperative localizations of nonpalpable, mammographically detected, breast lesions during the last 12-year period. Indications for biopsy were; 1) clustered microcalcifications, 2) solid mass, and 3) a radiological parenchymal distortion, that were not classified as benign by BI-RADS. The lesions were localized preoperatively using hook-wire methods, and all biopsies were performed under general anesthesia.
Results: Histology revealed carcinoma in 210 (26.8%) cases; noninvasive in 143 (68.1%) cases and infiltrating in 67 (31.9%) cases. The highest malignancy rate was found in cases with microcalcifications (137 carcinomas out of 380 cases, 36%), while for the remaining 404 cases, 73 (18%) cancers were found. Lymph node invasion was present in 22% of patients with invasive cancers. Frozen section was available for 540 cases (68.9%), and it was in all accurate in terms of positiveness of malignancy. General anesthesia was used in all cases without any side effects.