

aiming to establish that a false negative rate of 5% can reliably be achieved (confidence interval = 0–10%) would need at least 300 patients and of 3 studies identified with over 300 patients, 2 had a false negative rate of over 10%. Several well quoted 'validating' studies have 95% confidence intervals of 88–99%, translating to a possible 12% risk of a false negative result.

We have prospectively assessed SLNB within a 4-node sample in 200 patients with breast cancer. As a single blinded study we employed isotope only. Four node sampling was carried out and the most active node identified ex-vivo. The axilla was then probed and any remaining active node(s) removed.

SLN(s) was identified in 96%. It was contained in 80% of the 4-node samples. In lymph node positive patients, 8 had a false negative SLN but only 1, a false negative 4-node sample. Two randomized trials and a large case review have shown 4NAS to be a very reliable staging procedure associated with significantly less morbidity than ANC overall with 4NAS itself having only minimal morbidity. SNB provides a potential alternative to 4NAS and may have a role as an adjunct to 4NAS or vice versa. However, our study suggests that SNB has little to offer those who perform 4NAS and we can provide no evidence to suggest that their current practice should change.

#### **O-69. FACTORS INFLUENCING THE DETECTION RATE AND THE FALSE NEGATIVE RATE IN SENTINEL NODE BIOPSY IN BREAST CANCER**

J. Frisell, L. Bergkvist, G. Liljegren, M. Thörn. *Huddinge University Hospital, Central Hospital Västerås, Örebro Hospital and Uppsala University Hospital, Sweden*

**Background:** The development of sentinel node (SN) biopsy in breast cancer has been very rapid, and many hospitals and surgeons have started to do the procedure, after varying level of training. The false negative rate in different studies vary between 0 and 15%. For the method to be useful it is essential that this rate is kept low.

**The aim** of this study was to evaluate factors influencing the detection rate, and the false negative rate during the learning phase of the SN technique.

**Material and Method:** All cases from the very first of each surgeon were collected and analysed, 498 cases in all from 17 hospitals and 28 surgeons. The protocol stipulated use of both radioactive isotope and vital blue. After SN had been identified, a formal axillary clearance level I and II was performed.

**Results:** SN was found in 450 cases (90.4%), and preoperative scintigraphy visualised 82% of the SN. In 66% the SN was detected by both isotope and dye, in 26% with only isotope and in 8% with only dye. Significantly higher detection rate was noted for the same day injection of the isotope compare to the day before (96 vs. 86%). There was a large difference in detection rate between hospitals and single surgeons, from 61–100%. The overall false negative rate was 10.9%. The hospital that performed the operation, the S-phase and tumour multifocality modified the risk of a false negative SN, in an univariate analysis,

and in the multivariate analysis high S-phase and multifocality of the tumour was related to a significantly higher false negative rate of the SN.

**Conclusion:** The results from this study point out that the individual surgeon, the hospital, the combined technique with isotope and dye, the same day injection of the isotope are essential for the detection rate. Factors related to tumour characteristics rather than operation technique seem to be primarily responsible for the false negatives, but this has to be further explored.

#### **O-70. OCCULT AXILLARY LYMPH NODE METASTASES ARE OF NO PROGNOSTIC SIGNIFICANCE IN BREAST CANCER**

R.R. Millis, R. Springall, A.H.S. Lee, K. Ryder, E.R.C Rytina. *Guy's Hospital, London, UK*

The significance of occult metastases in axillary lymph nodes in patients with carcinoma of the breast is controversial. Two groups were studied. The first consisted of 477 women with invasive carcinoma of the breast, who had no metastases seen on initial assessment of haematoxylin and eosin (H&E) sections of axillary lymph nodes (median follow up 19 years, 153 breast cancer related deaths). The second group was 202 patients who had one involved axillary node on H&E sections (median follow up 13 years, 111 breast cancer related deaths). The node negative group had further sections of axillary lymph nodes stained using immunohistochemistry with CAM5.2 and HMFG2, and with H&E. The size of nodal metastases was assessed in both groups.

60 patients (13%) in the node negative group had occult metastases, but there was no difference in survival. Multivariate analysis showed tumour size and histological grade were predictors of survival in the node negative group. There was a significant survival difference between the node negative and the single node positive groups. The size of axillary nodal metastases was not related to survival.

Occult metastases had no effect on survival in this study. Although some studies have found a worse prognosis associated with occult metastases on univariate analysis, there is little evidence that it is an independent prognostic factor on multivariate analysis. The current evidence does not support the routine use of serial sections or immunohistochemistry for the detection of occult metastases in the management of lymph node negative patients, but tumour size and grade are useful.

#### **O-71. DISCUSSION PAPER – SENTINEL NODE BIOPSY: HOPE OR HYPE?**

R.W. Blamey. *Nottingham City Hospital, UK*

The breast surgical world is at present obsessed with sentinel lymph node biopsy (SLNB) and many papers have been submitted to this meeting. SLNB on current data appears to offer little over clearance for prognostic discrimination. SLNB offers an

alternative method for samplers; however one recent study failed to show advantage over 4 node sampling<sup>(1)</sup> and another suggested overlap between SLNB and sampling<sup>(2)</sup>.

If advantage is shown it remains to be demonstrated that it lies in the technique of SLNB and not in the number of sections and staining procedures, which if used for sampling would also raise the detection rate; furthermore micrometastases in LN's may not be of prognostic significance.

Assessments of the value of SLNB in improving discrimination of long-term outcomes are a long way from being produced. SLNB may improve estimation of LN status but LN status by itself is not as strong a prognostic factor as often imagined, at 10 years 35% of negatives have died, whilst 40% of positives are alive.

For accurate prognostic discrimination LN status has to be used in combination with other factors (eg) grade, size, hormone receptor. Even if it improves estimation of LN status SLNB can at best offer only a small advance in overall prognostic discrimination and may offer none.

## References

- [1] Macmillan, RD, Barbera, D, Hadjiminas, DJ, Rampaul, RS, Lee, AHS, Pinder, SE, Ellis, IO, Blamey, RW, Geraghty, JG. Sentinel node biopsy for breast cancer may have little to offer four-node samplers: results of comparison study. EJC 2001; in press
- [2] G Cserni. Estimating the overlap between sentinel lymph nodes and axillary node samples in breast cancer. Pathology Oncology Research 1999; 5: No 2: 129–133

## O-72. RANDOMIZED CONTROLLED TRIAL COMPARING 14 G CORE BIOPSY WITH MINIMALLY INVASIVE BREAST BIOPSY (MIBB) IN PRE-OPERATIVE DIAGNOSIS OF MAMMOGRAPHICALLY DETECTED BREAST LESIONS

E. Hurley, S. Reaney, N. Bundred. *South Manchester University Hospital, UK*

Conventional stereotatic 14 g core biopsy and 8 g minimally invasive breast biopsy were compared for diagnosis of mammographically detected breast lesions. Associated technical difficulties and complications were evaluated.

One hundred patients requiring needle biopsy for assessment of lesions detectable only by mammography, were randomized to either conventional 14 g stereotatic upright core biopsy (Siemens Mammomat or IGE 600T; Bard biopsy device) or 8 g prone core histology proceeded to diagnostic or therapeutic surgery. Those with normal or benign histology were discharged or followed up unless radiological appearances were suspicious. Calcium retrieval from lesions was greater with MIBB (84%) than with core biopsy (58%  $p = 0.008$ ).

There was greater polarization of histological findings into benign and malignant categories with MIBB than for conventional core biopsy (76% vs 58%). Pre-operative diagnosis of malignancy was 92% for MIBB vs 83% for conventional core biopsy.

Where malignancy was diagnosed pre-operatively, there was underestimation of an invasive component in both groups: 12.5% for MIBB AND 14% for conventional core biopsy. Pre-existing medical conditions did not preclude either technique. Technical problems related mainly to equipment failure for MIBB and to difficult positioning for core biopsy. Both techniques produced mainly mild bruising and the majority of patients did not require post biopsy analgesia.

(B1, B3 and B4)	Benign	Malignant	Other
Core Biopsy	28% (14)	28% (14)	44% (22)
MIBB	54% (27)	22% (11)	24% (12)

$p = 0.024$

8 g MIBB was well tolerated and more accurate in biopsy of microcalcifications. Further data is required to determine whether this additional outlay on MIBB is cost-effective in reducing the need for repeat diagnostic and therapeutic procedures.

## O-73. MINIMALLY INVASIVE BREAST SURGERY: EXPERIENCE WITH THE MAMMOTOME

M. Schuijtvlot, A.K. Sahu, N. Ibrahim, S.J. Cawthorn. *Frenchay Hospital, Bristol, UK*

The mammotome is a diagnostic vacuum assisted large bore core biopsy gun placed and controlled under ultra sound (U/S) guidance, which takes repeated large cores of tissue without removal of the core needle in between each core. The skin incision is minimal, the dissection track is minimal and the amount of tissue removed depends on the size of the lump. Little surrounding tissue is removed. This is an out patient procedure under local anaesthetic with minimal complications. We present the technique and the outcome of our first 2 years experience.

A total of 115 patients underwent the diagnostic U/S guided mammotome procedure. Of these 78 were lumps, 18 nipple discharge, 11 thickening and 8 gynecomastia. The age varied between 17 and 80. Histological groups were 43 fibroadenomas, 28 fibrocystic change, 14 duct ectasia/periductal inflammation, 8 gynecomastia, 7 fibro-adenosis, 7 duct papillomas, 3 adipose tissue, 2 granulomatous change due to cyst/duct rupture, 2 tubular adenomas, 2 duct carcinomas, 1 phylloides tumour and 1 Atypical Lobular Hyperplasia. Dual pathology was seen in 3 patients (fibrocystic disease and duct papilloma). The size of the samples varied between  $10 \times 5 \times 3$  mm to  $80 \times 30 \times 3$  mm. One procedure had to be abandoned due to discomfort, 6 procedures caused haematomas that were managed conservatively and one milk fistula occurred that dried within 2 weeks.

This is a safe technique for diagnosis and treatment of benign breast conditions. But longer term follow up is awaited.