Group 1 – Nucleotyping
Group 2 – DNA ploidy
CCR – correct classification rate

This study is still ongoing and our early data suggest large scale genomic instability studies may provide an accurate method of prognosticating patients.

O-121. End of 4 node sampling? Comparative morbidy versus sentinel lymph node biopsy in the ALMANAC trial

Monypenny IJ, Dixon JM, Kissin M, Newcombe RG, Goyal A, Mansel RE *on behalf of the ALMANAC Trialists Group*

Background: This randomised trial compares the postoperative morbidity of sentinel lymph node biopsy (SLNB) with four node sampling (FNS) in patients with early stage breast cancer.

Methods: Patients with clinically node-negative invasive breast cancer, planned to undergo four node sampling were randomised to SLNB or four node sampling in this multicentre trial. The primary outcome measure was axillary morbidity. From November 1999 to October 2003, 229 patients were randomized to undergo SLNB (120) or FNS (109). The sentinel lymph node was identified using a combined technique involving Patent Blue V and 99mTc-albumin colloid injected peritumorally. Patients with axillary nodal metastases proceeded to axillary clearance or received axillary radiotherapy (non-randomised). The intention to treat analyses of data to 6 months are presented in this paper.

Results: The failed localisation rate for SLNB was 2%. Axillary metastases were similar in both SLNB and FNS arms (24.2% vs. 16.5%, $p = 0.152$). Sensory loss and lymphedema at 6 months were significantly worse after FNS ($p = 0.005$, $p = 0.021$). Axillary operative time, drain usage, hospital stay and time to resume normal day-to-day activities were similar in the two groups.

Conclusions: Sentinel node biopsy is associated with reduced arm morbidity compared to four node sampling and should now be considered standard of care in early breast cancer.

O-122. Age related quality of life (QoL) benefits: results from the Almanac Trial with 18 months follow-up

Fallowfield LJ, Fleissig A, Langridge CL, Newcombe RG, Mansel RE *on behalf of the ALMANAC Trialists*

The ALMANAC trial is a UK based multi-centre RCT of patients with clinically node negative breast cancer in which sentinel node biopsy (SNB) is compared with standard axillary surgery (level I-III axillary lymph node dissection or 4 node sampling). Previous reports in the literature regarding the consequences of axillary treatment on QoL in patients of different ages have been inconsistent. In our study 829 patients completed 2 standardised questionnaires; the FACT-B+4 to assess QOL and the STAI to assess anxiety. Questionnaires were given prior to randomisation at baseline and at 1, 3, 6, 12 & 18 months post-surgery. Patients were categorised into 3 age groups-: under 50 years ($n = 154$), 50 to 64 years ($n = 494$) and 65 years and older ($n = 181$). The primary endpoint was the Trial Outcome Index (TOI), a summation of physical and functional well-being and breast cancer concerns, including 5 items on arm functioning. Change in TOI from baseline to each of the follow-ups examined the effects of treatment group (standard or SNB) and age. This revealed a significant main effect of treatment in favour of the SNB group (1 month $p < 0.001$, 3 months $p = 0.027$, 6 months $p = 0.017$, 12 months $p = 0.011$, 18 months $p = 0.006$) and a significant main effect of age in favour of older patients for 6 months post-surgery ($p < 0.001$). Changes in arm functioning from baseline to each follow-up showed a significant main effect of treatment in favour of the SNB group ($p < 0.001$) and a significant main effect of age in favour of older patients ($p < 0.003$). Changes in anxiety throughout he trial were unrelated to treatment group, but there was a significant main effect of age for 6 months post surgery, in favour of older patients (1 month $p < 0.001$, 3 months $p = 0.01$, 6 months $p = 0.007$). The impact of breast cancer diagnosis, primary surgery and adjuvant therapy may also affect QoL differently depending on a patient's age.

O-123. Axillary relapse following axillary surgery

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The aim of this study was to assess axillary recurrence in patients treated by axillary sampling alone (ANS), axillary sampling with radiotherapy (ANS+RT) or axillary clearance (ANC). 1816 patients were treated between 1981 to 1998 by breast conserving surgery plus radiotherapy to the breast. Some patients were randomised in an ANS v ANC trial but generally patients with clinically involved nodes or larger tumours (>2 cm) had ANC, those witlh clinically negative nodes and smaller tumours (≤2 cm) were treated by ANS with radiotherapy to the axilla for all node positive patients except for 18 patients who took part in the Scottish Conservation Trial. These and 4 patients who received radiotherapy after an axillary clearance were excluded from this analysis. The minimum follow up of this group is 5 years. The results are as follows:

	5 yr recurrence	5 yr survival	10 yr survival
Node −ve			
ANC	0.5%	90.5%	86.5%
ANS + RT	1.4% $p = 0.008$	92.9%	88.2%
ANS	2.3%	95.6%	93.0%
Node +ve			
ANC	5.1%	77.8%	67.4%
ANS + RT	8.2% NS	85.5%	71.5%

Although the recurrence rate in node −ve patients is higher after ANS, overall survival is not compromised and in node +ve cases recurrence rates after ANS + RT and ANC are not significantly different suggesting that ANS + RT is an alternative to ANC in these cases. Similar results might be expected with node positive sentinel node biopsy followed by radiotherapy.