Both procedures were performed under stereotaxis or ultrasound. Correct positioning of the wire tip or isotope was confirmed with check mammography. Analysis of results included accuracy, duration and degree of difficulty (1–10), lesion concentricity, rate of immediate re-excision and second therapeutic operation. QOL questionnaires were administered to patients following each procedure to evaluate patient perceptions.

To date 62 patients have been entered, 32 randomised to ROLL and 30 to wire-guidance. Of the 32 who had ROLL, 1 had a failed technique.

Accurate marking was 99% for ROLL and 93% for wire. Mean time for imaging was 17 minutes for ROLL and 21 minutes for the wire group. ROLL scored a median of 2 for degree of difficulty compared to 3 for wire.

Specimen x-ray analysis showed centrality of the lesion in 90% for ROLL and 83% for wire. Re-excision was higher in ROLL (13 vs 9) but the need for a second therapeutic operation was lower (23% vs 28%). Duration of operation was longer in those undergoing wire placement (37 vs 31 minutes). The median for degree of difficulty for surgery was 2 for ROLL and 4 for wire. QOL assessments showed a greater preference for ROLL over wire.

ROLL appears to be acceptable to patients quicker and easier to perform for both radiologists and surgeons compared with wire guidance. Success rates are similar.

O-7. SCINTIMAMMOGRAPHY: DOES SIZE MATTER?

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One of the major factors which determine the accuracy of breast imaging is the size of the detected lesion. This may be a particular issue in those women with dense breast in whom a small lesion may be difficult to see on mammography. The aim of this study was to review the results of Tc-99m MIBI scintimammography and x-ray mammography and compare these results with lesion size. Comparisons in accuracy were performed by comparison of area under ROC curve analysis.

Data from 273 women were reviewed were a lesion had been identified by imaging and biopsied. The mean age of the women studied was 52 with a range of 26–84 years. All patients underwent x-ray mammography, Tc-99m MIBI Scintimammography. Results of the imaging were then compared to the final histology in three size groups. Firstly in the 74 lesions of less than 2 cm the sensitivity of mammography was 51% and scintimammography 70%. In the 104 lesions sized 2–4 cm the sensitivity of mammography was 70% and scintimammography 87%. In the 52 lesions greater than 4 cm mammography found 88% of cancers and scintimammography all cancers.

Both methods have an improved sensitivity with increasing lesion size. Scintimammography was always more sensitive than mammography, however the biggest difference was in tumours of less than 2 cm when the sensitivity of scintimammography was significantly better than mammography ($p < 0.05$, Wilcoxon matched pairs). Therefore scintimammography may be of help in all women with breast cancer irrespective of tumour size but offers the biggest advantage in the smallest cancers.

O-8. UK EXPANDED ACCESS PROGRAMME (EAP): HERCEPTIN® (TRASTUZUMAB) TREATMENT FOR WOMEN WITH HER2 POSITIVE METASTATIC BREAST CANCER (MBC)

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Herceptin is a humanised monoclonal antibody against the HER2 receptor. Between 15–20% of breast cancers over-express HER2 at high levels and these patients appear to benefit most from Herceptin.

This open, non-randomised study aimed to evaluate the safety of Herceptin (H) given alone or in combination with Docetaxel (Doc.) or Paclitaxel (Pac.) in patients with HER2 positive tumours. Herceptin treatment was continued for as long as patients showed clinical benefit. Response to treatment was not formally assessed but duration of therapy was considered to be a surrogate for time to disease progression/treatment failure. All patients were ECOG PS 0-2 and could receive H as 2nd or 3rd line as single agent or 1st, 2nd or 3rd line in combination with Doc. or Pac..

From Jan to Sept 2000, 32 UK centres recruited 168 patients of whom 85 received H + Doc., 4 received H + Pac. and 79 received H alone. At end March 2001 median duration of Herceptin therapy was 5.9 months. 61 patients were still ongoing of whom 21 had received more than 9 months treatment and 7 had received more than 12 months Herceptin treatment.

Of 33 drug related SAEs reported, 8 occurred with H alone, 24 with H + Doc. and 1 with H + Pac. 4 SAEs were due to cardiac toxicity; AF on H + Doc. (2), SVT on H alone (1) and clinically significant reduced EF on H alone (1). 17 cases of myelosuppression occurred with H + Doc. One patient had a severe infusion related reaction with hypotension. In this EAP study Herceptin was generally well tolerated. Recruitment has completed and patients continue to be followed up in the study.

O-9. CORRELATION BETWEEN IMMUNOHISTOCHEMICAL AND FISH ANALYSIS FOR HER-2 IN 441 BREAST CARCINOMAS FROM MULTIPLE HOSPITALS

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The monoclonal antibody Herceptin is clinically effective in metastatic breast cancer strongly over-expressing the HER-2 oncogene. Rigorous testing procedures are required for accurate diagnosis and appropriate usage of Herceptin. Substantial controversy has surrounded the relative value of IHC and FISH for diagnosis. In particular fixation techniques and subjective scor-