367 ORAL

First clinical experience with a computer aided diagnosis system for the assessment of breast lesions in contrast-enhanced MRI

E.E. Deurloo[1], S.H. Muller[1], L.J. Schultze Kool[1], K.G.A. Gilhuijs[1].
[1] *Netherlands Cancer Institute/Antoni van Leeuwenhoek, Radiology, Amsterdam, The Netherlands*

Purpose: To validate a Computer Aided Diagnosis (CAD) system for the assessment of MRI-detected breast lesions in clinical setting.

Methods: Since October 5th, 2000 a proprietary workstation for computerized analysis of breast lesions is in use in our hospital. All MRI scans of the breast (FLASH 3-D, both breasts) are sent to this CAD system using DICOM (500 patients so far). Currently, the radiologists employ the workstation as an additional aid for interactive detection of breast lesions. The system is also used by a research physician to semi-automatically segment and characterize lesions. The system calculates the volume of the lesion and the probability of malignancy based on washout, smoothness of uptake, mean and variation of margin sharpness. In addition, previously characterized lesions that have similar features and known pathology are displayed for comparison purposes. The probability of malignancy obtained by the CAD system is compared with the results of the radiologist and pathology (biopsy or follow-up of at least 1 year), and is currently used for research purposes only.

Results: One hundred fifty-four lesions (in 129 patients) were segmented and characterized. Eighty lesions were used to train the CAD system (40 benign and 40 malignant). The remaining lesions (34 benign, 40 malignant) were analyzed to validate the performance of the system prospectively. The benign lesions mainly consisted of Incidental Enhancing Foci (41%) and fibroadenomas (50%). The malignant lesions consisted mainly of IDC (63%), ILC (8%) and DCIS (13%). The success rate of segmentation was 97%. The performance of the CAD system for the prospective cases was good (AZ=0.86) but less high than the predicted performance (AZ=0.95). The difference in performance was caused by a difference in washout behavior of the benign lesions in the prospective set compared with the training set. Re-training the CAD system to include the temporal and morphological characteristics of the prospective cases recovers the performance of the system (cross validation: AZ=0.93).

Conclusion: Initial experiences with the CAD system show promising results to complement interpretation of the radiologists by objective evaluation of contrast-enhanced MRI of breast lesions.

Friday, 22 March 2002

POSTERS

Detection, diagnosis and screening

368 POSTER

Survival benefit of breast cancer screening persists after adjustment for confounding clinicopathological and socioeconomic factors

P. Klemi[1], I. Parvinen[2], L. Kauhava[3], P. Immonen-Raiha[4], O. Rasanen[5], H. Helenius[4]. [1] *Turku University Hospital, Pathology, Turku, Finland;* [2] *Finnish National Fund for Research and Development, Helsinki, Finland;* [3] *City of Turku, Turku, Finland;* [4] *University of Turku, Turku, Finland;* [5] *Cancer Society of Southwestern Finland, Turku, Finland*

The aim of the study was to analyse the value of breast cancer screening in the prevention of breast cancer mortality by taking into account important clinicopathological and socio-economic variables. A population-based mammography breast cancer-screening program of 36 000 women aged 40 -74 years was started in 1987 in the city of Turku, Finland. From 1987 to 1997 a total of 176 898 two view mammographic examinations were done and 531 invasive breast cancers were subsequently found (screen cancers). The screen cancers were more often smaller ($p<0.0001$), local ($p<0.0001$), and histologically better differentiated (grade I vs. II-III, $p<0.0001$) than the interval (n=149) and clinical (n=189) cancers. In Kaplan-Meier survival analysis women aged 40-49, 50 - 59, 60 - 69 and 70 - 74 whose breast cancer was found by screening had better survival than women whose cancer was found by other methods ($p=0.0766$, $p=0.0153$, $p<0.0001$ and $p=0.0085$ respectively). Cox's multivariate analysis adjusted for age was used to study the confounding effect of tumor size, histological grade, axillary nodal status, income, level of education and employment status on the differences in survival between the three cancer detection groups. When the clinicopathological and socio-economic variables were taken into account, the difference in survival remained significant between the three cancer detection groups ($p=0.0166$). The socio-economic status does not seem to have any substantial confounding effect. Survival was worst among women in the interval group (interval vs. screen cancer HR 2.30; CI 95% 1.29 to 4.10 and clinical vs. screen cancer HR 1.61; CI 95% 0.95 to 2.74). Breast cancer found by screening was associated with a smaller risk for dying of breast cancer.

369 POSTER

Survival of women with screen detected breast cancer

E. Wheeler[1]. [1] *West Midlands Cancer Intelligence Unit, Breast Screening Quality Assurance Reference Centre, Birmingham, UK*

Annually, for the past three years the British Association of Surgical Oncology (BASO) Breast Group has co-ordinated a survival study as part of a collaboration with the NHS Breast Screening Programme (NHSBSP). This retrospective study looks at the survival of all women diagnosed with screen detected invasive breast cancer within a designated time frame. Data were collected from screening units and cancer registries, collated locally at regional Quality Assurance Reference Centres (QARC's) and collated nationally at the West Midlands QARC.

4554 women were included in the 1999/2000 audit, all of whom had histologically confirmed invasive screen detected breast cancers diagnosed between 1st April 1994 and 31st March 1995. The end of the study period was set as 31st March 2000 to allow survival to be calculated for 5 years post diagnosis. 5 year relative survival calculated using the Hakulinen method was 93.6%. Cause-specific survival using the Kaplan-Meier method was undertaken. Of the 4554 women included in the study, 463 deaths occurred during the study period, 338 of which were attributed to breast cancer. The overall 5 year survival was 93.1%. This is similar to the 5 year survival rates of 92.5% and 93.9% recorded for screen detected breast cancers diagnosed between 1992/93 and 1993/94 respectively.

5 year survival varies with tumour grade, size and nodal status. Age does not appear to have any significant influence on survival. For women with tumours measuring between 1 and 9 mm 5 year survival was 97.5% while that for women with tumours measuring between 20 and 49 mm was only 87%. Tumour size is thus a good prognostic indicator. Grade also proved to be an important factor influencing survival. There was a 98% 5 year survival rate for women with grade I cancers. This decreased to 93.1% for grade II tumours and decreased further still to 83.2% for grade III tumours. The survival rates for women with node negative tumours (96.4%) was significantly better than for those with node positive tumours (82.9%).

The 2000/2001 survival audit will examine cancers diagnosed by the NHSBSP between 1st April 1992 and 31st March 1996. This audit, the results of which will be published April 2002, will determine survival rates for both invasive and non-invasive cancers. With an estimated 18,000 women included this audit promises to be the most comprehensive study focusing on the survival of women with screen detected breast cancer to date.

370 POSTER

The role of 3D-MRI in diagnosing ductal spreading of breast cancer

K. Hisamatsu[1], W. Takiyama[1], Y. Satou[1], S. Saiki[1], Y. Kirihara[1], H. Mukaida[1], N. Hirabayashi[1], M. Ishine[2], Y. Hayashi[3]. [1] *Hiroshima city asa hospital, Surgery, Hiroshima, Japan;* [2] *Hiroshima city asa hospital, Radiology, Hiroshima, Japan;* [3] *Hiroshima city asa hospital, Pathology, Hiroshima, Japan*

Introduction: In breast cancer patients, accurate diagnosis of ductal spreading is of great importanace for deciding sugical procedure. The role of imaging diagnosis using 3D-MRI in deciding of ductal spreading was assessed.

Material and Methods: Preoperative 3D-MRI were underwent 75 cases of breast cancer patients. These patients could be divided into five groups according to 3D-MRI images: pattern 1) localized type, 2) spiculated type, 3) widely enhanced type A (enhanced are: less than Quadrant) and 4) widely enhanced type B (enhanced are: more than Quadrant) and 5) multifocal type. Diagnosis of ductal spreading were confirmed histologically and relation between 3D-MRI patterns and ductal spreading were assesed retrospectively.

Results: Histological confirmed ductal spreading were seen 17% (1/6 cases), 38% (12/32 cases), 69% (9/13 cases), 80% (8/10 cases) and 43%

(6/14: multifocal) of patients with 3D-MRI pattern 1), 2), 3), 4), and 5), respectively.

Conclusion: These result suggests that MRI will be the useful breast imaging tool in diagnosing ductal spreading in breast cancer patients. Patients dipicting widely enhanced pattern by MRI should be recommended Quadrantectomy or mastectomy to perform breast conserving surgery with negative surgical margin.

371 POSTER

Interval cancer in the Norwegian breast cancer screening program: results from a rereading exercise

H. Wang[1], N. Bjurstam[2], H. Bjørndal[3], A. Braaten[4], L. Eriksen[5], P. Skaane[6], B. Vitak[7], S. Hofvind[1], S. Thoresen[1]. *[1] The Cancer Registry of Norway, Screening, Oslo, Norway; [2] Tromsø University Hospital, Mammography screening, Tromsø, Norway; [3] The Norwegian Radium Hospital, Mammography screening, Oslo, Norway; [4] Haukeland University Hospital, Mammography screening, Bergen, Norway; [5] Central Hospital, Rogaland County, Mammography screening; [6] Ullevål University Hospital, Oslo, Norway; [7] Lindkoping University Hospital, Lindkoping, Sweden Stavanger, Norway*

Introduction: The Norwegian Breast Cancer Screening Program is population based and offers women aged 50-69 years a two-view mammography examination every second year. The program started in 1996 as a pilot project consisting of two screening rounds, and data regarding the interval cancers are now analyzed. The purpose of this study was to investigate the proportion of interval cancers that could have been detected at screening.

Methods: A total of 247 interval cancers were diagnosed. A blinded review of screening mammograms was performed as a part of the program's quality assurance. The mammograms were made anonymous, and the subsequent interval mammograms were mixed with mammograms of screening detected cancers (118) and mammograms that were screening normal (373). In 15 cases both screening and diagnostic mammograms were not available, thus the final material consisted of 232 interval cancer cases. All mammograms were individually scrutinized by six radiologists, two of those did not work at the screening units involved in this study. The cases were placed into one of six categories: 1) normal/benign, 2) probably benign, 3) indeterminate 4) probably malign, 5) malign and 6) technical recall. Cases that were assigned a score of two or higher are considered as selected. Diagnostic mammograms were used to verify that the selected lesion corresponded the actual position of the interval cancer. The results presented are based on lesions selected correctly (technical recall included as correctly selected).

Results: 50% of the lesions were not selected by any of the radiologists, 23% by one or two and 27% by three or more. 14% of the lesions were given a score higher than two by at least three radiologists.

Conclusions: There is no simple way of classifying an interval cancer as missed, and an experimental rereading exercise is undoubtedly very different from the daily screening work. However, based on these results from a mixed blinded review, it is reasonable to conclude that 27% of the lesions could have been detected at screening.

372 POSTER

Woman feels breast lump - clinican cannot. Can ultrasound scan arbitrate?

J.A. Cid, R.D. Macmillan, R.S. Rampaul, A.J. Evans, I.O. Ellis, H.C. Burrell, A.R.M. Wilson, J.F.R. Robertson, R.W. Blamey. *Nottingham City Hospital, Breast Unit, NG5, United Kingdom*

We investigated the role of Ultrasound Scan (USS) in the assessment of women complaining of a breast lump but with normal clinical examination.

434 women were prospectively recruited into this study between July 1999 and April 2001. All women were submitted for USS of the region of their breast they located with one finger. Where a solid mass was found on USS, a guided FNA/core biopsy was performed.

359 women (83%, mean age=36.6 yrs, range:14-69) had no abnormality on USS and were discharged. The remaining 75 women (17%, mean age=42.4yrs, range:18-66) with positive findings on USS were significantly older ($p<0.001$). Of these, 53 had cystic lesions (2/3 of women were >40 yrs), and 22 had solid lumps which were classified as benign (17), indeterminate (4), suspicious (1) or malignant (none). The final histological diagnosis was fibroadenoma (5), other benign (14) and malignant (3). The 3 cancers found were very small (≤7 mm), lymph node negative, and occurred in women >40 yrs. To date, only one woman has re-presented with breast cancer (4 mm, node negative, age 30) at a mean follow-up of 16 months (range 6-27).

For women complaining of a breast lump, impalpable to the examining clinician, this study shows that USS detects cysts and solid lesions in 17% of cases, of which 0.7% (3/434) were cancer. The cancers thus detected were of good prognosis. In such cases, clinical examination is accurate and paramount. USS should be the standard complementary investigation in older women.

373 POSTER

Accuracy of imprint cytology of core biopsy

S. Fernandes, D.R. Cheetham, G. Bradley, J. Aps, R. Reyes, M. Khan, T.K. Walters. *The Clinical Breast Unit Queen Mary's Hospital Sidcup, UK*

Introduction: Histological analysis of core biopsy takes a minimum of 24 hours, but imprint cytology of a core biopsy can be reported within an hour. This study validates the accuracy of imprint cytology from core biopsy of breast lesions in order to ascertain whether a reliable, rapid preliminary diagnosis can be made using this technique.

Methods: 235 consecutive core biopsies from breast lesions of 221 patients were performed. The cores were placed on 6 microscopy slides to obtain imprint cytology and the slides were stained with both Haematoxylin and Eosin and Giemsa. Cellularity was considered adequate for diagnosis if more than five groups of ductal cells were seen. Imprint cytology and routine histology of the cores were assessed independently by two pathologists.

Results:

	Imprints	Cores
Inadequate	8	12
Benign	97	95
Atypical	8	2
Suspicious	4	1
Malignant	117	124

Cellularity was adequate for diagnosis in 96% of imprints. Of 124 carcinomas diagnosed histologically, cytology was malignant or suspicious in 120.

No malignant imprint cytology was subsequently found to be from a histologically benign lesion and of 97 benign cytological results two of the subsequent cores were found to be malignant.

Conclusion: Imprint cytology of core biopsies correlates well with subsequent histological results and could be used to provide a rapid preliminary diagnosis. This rapidly available technique could reduce anxiety in patients with benign lesions and help treatment planning in patients with breast cancer.

374 POSTER

Does palpation alone constitute an adequate clinical breast examination?

W.H. Goodson[1], D.H. Moore[1,2]. *[1] California Pacific Medical Research Institute, Surgery, San Francisco; [2] University of California San Francisco, Epidemiology and Biostatistics, San Francisco*

Over one-third of breast cancers are first detected by palpation (often by the woman herself). However, clinical breast examination (CBE) is sometimes omitted in primary care practice, presumably in part because of the multiple steps recommended for routine CBE. Mahoney and Csima (Can Med Assoc J 1982; 127: 729) suggested that routine CBE be simplified to palpation of the supine patient, without visual inspection while sitting and/ or during arm maneuvers.

Methods: We reviewed the recorded CBE of 487 consecutive breast cancers of any stage to determine whether omission of visual inspection would miss cancers. Our CBE palpation method indexed ability to feel rib edges through breast tissue as an aide to identify subtle changes.

Results: 316 cancers had positive CBE (232 a mass; 75 subtle changes, i.e. asymmetry or vague density; 9 visible changes only). 392 had a positive mammogram. 8 cancers were missed both by palpation and by mammograms. 4 had negative mammograms and only visible changes on CBE (2 Paget's disease, one with a large axillary node, ONLY ONE with only skin retraction). Four cancers with both negative mammogram and negative CBE were found only in prophylactic mastectomy specimens.

Conclusions: Palpation of the supine patient as the only CBE (combined with mammography) will detect over 99% of breast cancers. Ultimately, however, it is an ethical question whether to simplify recommendations for CBE

- with the intent to increase overall frequency of CBE by primary care physicians - while knowing that rarely a cancer will be missed. (Only one of 483 detectable cancers would have been missed if CBE were simplified to only supine palpation.) Our results support modification of recommendations for routine CBE.

375 POSTER

Different types of solid, non-palpable breast lesions: stereotactic core needle biopsy using add-on stereotactic device

M. Berg[1], A. Koskela[2], M. Sudah[3], V. Kärjä[4], R. Vanninen[5]. [1] *Kuopio University Hospital and Kuopio University, Department of Clinical Radiology, Kuopio, Finland;* [2] *Kuopio University Hospital, Department of Clinical Radiology, Kuopio, Finland;* [3] *Kuopio University Hospital, Department of Radiology, Kuopio, Finland;* [4] *Kuopio University Hospital, Department of Clinical Pathology, Kuopio, Finland;* [5] *Kuopio University Hospital, Department of Clinical Radiology, Kuopio, Finland*

Purpose: To find out how many passes are required to detect malignancy in different types of solid, nonpalpable breast lesions using an add-on stereotactic equipment.

Methods and Materials: An add-on sterotactic core needle biopsy (SCNB) device with a 14-gauge needle was used to obtain multiple breast samples from 90 patients with 95 mammographically detected solid breast lesions (mean size 12,3 mm, range 4-50 mm). According to the interpretation of mammography images by two experienced radiologists the solid lesions were further divided into four groups; 1. Lesion with sharp borders (n=26) 2. Lesion with indistinct borders (n=46) 3. Stellate (n=22) and 4. Radial scar (n=1). All groups were analyzed separately for the accuracy of SCNB. The first sample was collected into container A, the 2nd and the 3rd into container B, and all additional samples into container C. The mean number of samples was 6 (range 4-11) per lesion. An experienced pathologist analyzed each container separately for the presence of malignancy.

Results: For final diagnosis, 40 lesions proved to be malignant and 5 benign in subsequent surgical excision. On mammographic one year follow-up 50 benign lesions without surgical excision showed no signs of malignancy. For all solid lesions, sensitivity of multiple samples was 100% (containers A-C). One of 26 solid lesions with sharp borders proved to be malignant, the corresponding value for lesions with indistinct borders was 18/46, and for stellate lesions 20/22. One lesion interpreted as radial scar also containing microcalsifications proved to be malignant in all samples (6) obtained in SCNB. The sensitivity of the first sample (container A) obtained from the lesions having indistinct borders was 83% (3 false negatives) while the sensitivity for the first sample from stellate lesions was 95% (one false negative), and sensitivity of 100% was achieved with the first sample from sharp-bordered lesions. One solid lesion with indistinct borders remained false negative case after two additional samples because of insufficient biopsy material, while among stellate lesions the sensitivity of three samples reached 100%. Two solid lesions interpreted as stellate on mammography proved to be radial scars without malignancy in surgical resection.

Conclusion: Regardless of the mammographic type of the lesion three passes are sufficient to detect malignancy in a nonpalpable solid breast lesion with SNCB using an add-on stereotactic device.

376 POSTER

A self completed questionnaire is better than routine follow up for eliciting symptoms of recurrent or metastatic disease in breast cancer patients

S. Bower, H. Gray, S. Boreham, L. Mcewan, M. Smith, C. Mortimer, T. Archer, J. Levay, D. O'Driscoll, A. Tate. *Ipswich Hospital Nhs Trust, Breast Unit, Ipswich, United Kingdom*

Introduction: Traditionally, all women with breast cancer are followed up routinely for many years regardless of individual likelihood of recurrence or development of metastases. An alternative method of providing surveillance for women with breast cancer has been developed in the form of a questionnaire.

Methods: A questionnaire was developed to detect symptoms of recurrent or metastatic disease. This was given to 100 patients attending follow up breast clinics who were at least two years from diagnosis of breast cancer. Patients were then seen routinely for direct questioning and clinical examination. Entries in patient notes were compared with the responses on the questionnaire.

Conclusion: The questionnaire tested was a more accurate method of eliciting symptoms of recurrent or metastatic disease in breast cancer patients than conventional clinical review. Combined with automated mammography recall this surveillance method is a safe and probably both a time and cost effective way of managing follow up in breast cancer patients.

377 POSTER

Advantages in breast lesion diagnosis using 3 D sonography

Walter Cimpoca. *Landesklinik fur Spezielle Gynaecologie, Salzburg, Austria*

High resolution sonography of the female breast has become a valuable tool in breast diagnosis. The 3 - dimentional sonografic imaging offers valuable criteria for the differentiation of palpable and nonpalpable breast lesions. Furthermore the 3D sonografic imaging enables the accurate needle location in ultrasound guided core needle biopsy for the histological evaluation of suspicious breast lesions.

In order to evaluate possible advantages with the use of 3D-US technique, we analysed 300 patients referred to our special breast care unit undergoing clinical, sonographical and invasive diagnosis for breast lesions. High resolution 2D sonography had a sensitivity to detect malignancy of 96% and a specifity of 70% overall. In the nonpalpable group of breast lesions 3D sonography increased specificity from 65 to 72%, while sensitivity was 92% in both cases.

In invasive diagnosis, we experienced a total of nine false negative and one false positive CNB in 300 cases.

Core needle biopsy had a sensitivity of 96% and a specificity of 99% with a median of 1.66 biopsies per lesion.

Three dimensional sonography is a valuable tool in breast diagnosis offering additional information for dignity assessment and increasing diagnostic accuracy especially in small, non - palpable breast lesions. Core needle biopsy is a reliable method to obtain a histologic specimen in doubtful cases helping to avoid unnessecery operative evaluation. 3D targeting allows better documentation of correct needle position in CNB helping to reduce puncture frequency without compromising a precise diagnosis.

378 POSTER

Low spatial resolution in FFDM is no disadvantage to assessment of microcalcifications

L. Bartella, N. Perry, K.L.C. Young. [1] *Princess Grace Hospital, National Breast Screening Programme, London, UK*

Background: Full Field Digital Mammography(FFDM) seems set to replace conventional film - screen technique. Concern has been raised over FFDM diminshed spatial resolution (5-6 lp/mm). If valid, this could compromise detection of calcification and diagnosis of DCIS. However, in our centre we were not able to perceive any difference between microfocus magnification and on-screen magnification when assessing microcalcification.

Aim: To evaluate replacement of analog microfocus technique by on-screen digitial magnification for microcalcification, and to analyse the relative importance of spatial resolution versus contrast detail test scores.

Methods: We performed phantom image quality testing on our digital unit (GE 2000D), using the TORMAX and TORMAM phantoms. We subsequently compared these results with average scores for over 90 film-screen mammography systems.

Results: Although our digital unit had a lower spatial resolution (6-7 lp/mm) than the film-screen systems (up to 15 lp/mm), both TORMAX and TORMAM scores were superior for digital soft-copy reporting compared to hard-copy reporting, film-screen technique and analog microfocus magnification.

Conclusion: Despite lower spatial resolution, the superior contrast and image manipulation abilities of FFDM obviate the need for conventional microfocus magnification in the radiographic work up of microcalcifications. Sufficent information is provided on FFDM upon which to base a decision to proceed to diagnostic interventional procedures such as core biopsy or mammotome excision.

379 POSTER

Can a pre-operative core biopsy differentiate reliably between invasive and pre-invasive breast malignancy?

D. Ghusn, M.L. Humphreys, I. Daltrey, J.B. Brisrol, H.Y. Chan. *Cheltenham General Hospital, General Surgery, Cheltenham, United Kingdom*

Introduction: Traditionally, a patient who presented with a palpable breast lump was assessed by Triple Assessment. FNA was the pathological com-

ponent. With the increase in the incidence of mammographically detected, impalpable breast lesions, this has not always been useful or feasible.

In recent years, there has been a move in some breast units towards the use of core biopsy (CB) alone or as a adjunct to FNA. Theoretically, this may allow the distinction between insitu and invasive carcinoma preoperatively, because of the preservation of intact histological structure.

This study assesses whether pre-operative CB showing DCIS alone has sufficient pathological basis to influence management of patients with either a palpable lump or a mammographic appearance suggestive of malignancy.

Method: This was a retrospective review of data collected prospectively on a computerised pathology database from 1993-2001. All patients who had a pre-operative CB showing DCIS alone were included. The histology from the surgical specimen was reviewed to assess whether it was invasive or in-situ disease.

Results: There were 122 patients in total. They were all female. 67(54.9%) had palpable lumps and 55(45.1%) had impalpable lesions. Of the palpable lumps, 3(28.7%) were shown to have purely insitu disease and 30(24.6%) had invasive malignancy.

Of the impalpable lesions, 32(26.2%) had insitu disese alone and 22(18%) had invasive malignancy. There were 3(2.5%) false positives in total.

The likelihood of a palpable lesion being pure DCIS was 52%. Similarly the chance of an impalpable lesion being pure DCIS was 58.2% (CHI squared 0.699; p=0.40)

Conclusion: Pre-operative CB was an accurate indicator of breast malignancy. However it was not a reliable discriminator between insitu and invasive disease.

Interestingly, there appeared to be no difference in the likelihood of invasion in the final histology between palpable and impalpable lesions. Our incidence of invasive carcinoma on stereotactically biopsied, impalpable lesions was higher than that reported in the literature.

380 POSTER

Mammographically suspected radial scar: preoperative diagnosis, histology and surgical planning

A. Masterson[1], H. Fenlon[2], M. Kennedy[3], M. Kerin[4], F. Flanagan[5]. *[1] The Mater Misericordae Hospital, Radiology, Dublin 7, Ireland; [2] The Mater Misericordae Hospital and National Breast, Eccles, Radiology; [3] The Mater Misericordae Hospital and National Breast, Eccles, Pathology; [4] The Mater Misericordae Hospital and National Breast, Eccles, Surgery; [5] Mater Misericordae Hospital and National Breast Scr, Eccles Unit, Radiology*

Purpose: Radial scars are benign high-risk breast lesions characterised radiographically by spicules that surround a lucent centre. Mammographic detection necessitates excision biopsy. This study is to determine our ability to detect malignancy pre operatively in mammogrphically suspected radial scars.

Materials and Methods: A review of women attending for mammography to the symptomatic and screening programme in the Eccles Unit was performed. An evaluation of mammographically suspected radial scars were correlated with ultrasound and pre and postoperative histology.

The accuracy of the preoperative diagnosis for malignancy following trucut biopsy under US or streotactic guidance is reported. The histology of both the preoperative biopsy samples and the operative excision samples were examined.

Results: Of 25,000 mammograms 69 cases of suspected radial scar were evaluated. We found that out of the 69 cases 51 had a pre-operative core biopsy, 41 had a benign diagnosis on final excision biopsy, 28 had a malignant diagnosis on excision biopsy. A preoperative diagnosis of benign disease was made in 5 cases that subsequently had a malignant diagnosis on excision biopsy. In three cases a diagnosis of DCIS was made on excision, while in two a diagnosis of infiltrating ductal carcinoma was made. Thus out of 28 malignant cases confirmed on excision biopsy an accurate preoperative diagnosis was made in 23 patients. No false positive diagnosis was made.

Of the lesions found to be malignant on excision biopsy there were 5 tubular carcinomas, 8 DCIS, 11 ductal and 4 lobular carcinomas.

Conclusion: An accurate preoperative diagnosis is very helpful for the surgeon when planning breast surgery in these cases. In a benign lesion local excision is usually adequate. However in the case of a malignant lesion more radical surgery with axillary sampling is required.

381 POSTER

Effects of a microbubble contrast agent on breast tumours

E. Ogo[1], T. Fujii[2,3], T. Koga[2], H. Yanaga[2], S. Nakagawa[2,3], H. Deguchi[2], M. Uchda[1], N. Hayabuchi[1]. *[1] Kurume University, Radiology, Kurume, Japan; [2] Kurume University, Surgery, Kurume, Japan; [3] Kurume University, Research Center for Innovative Cancer Therapy, Kurume, Japan*

Purpose: To evaluate objectively effects of a microbubble contrast agent on the power doppler ultrasound(US) examination of breast tumors.

Materials and Methos: 49 patients aged 28-88 years underwent power doppler US before and after intravenous injection of a microbubble contrast agent. The sonomorphogic aspests of vascularization were analysed.

Results: 30 (78%) of 38 primary carcinoma and 4 (36%) of 11 benign tumor were enhanced in power doppler US. In comparing unenhanced power doppler US, the latter seemed to be slightly superior. Typical signs of malignancy were irregular vessel calibers, serpiginous courses, penetration of the tumor's margin, and irregular reticular vascularization. By improved analysis of the vascularization pattern, enhanced power doppler US was found to provide more relaible differential diagnosis information than unenhanced power doppler US in tumors and tumor like leisions of the breast.

Conclusion: After microbubble contrast agent injection, malignant and benign lesions behave differently in degree, onset, and duration of power doppler US enhancement.

382 POSTER

Add-on stereotactic 14-G core needle breast biopsy: how many passes are enough to detect malignancy?

A. Koskela, M. Sudah, M. Berg, V. Kärjä, P. Mustonen, R. Vanninen. *Kuopio University Hospital, Department of Clinical Radiology, Kuopio, Finland*

Purpose: To find out how many passes, using an add-on stereotactic equipment, are necessary to detect malignancy in a nonpalpable breast lesion.

Methods and Materials: An add-on stereotactic core needle biopsy (SCNB) device, with a 14-gauge needle, was used to obtain multiple breast samples from 194 consecutive patients (mean age 57 yrs, range 32-88 yrs) with 202 mammographically detected breast lesions (95 solid and 107 with microcalcifications (MC), mean size 11.7 mm). The first sample was collected into container A, the 2nd and the 3rd into container B, and all additional samples into container C. The mean number of samples was 7 (range 4-15) per lesion. An experienced pathologist analyzed each container separately for the presence of malignancy. All non-excised lesions were followed up with 1 and 2 year (40% of the patients thus far) mammography.

Results: For final diagnosis, 85 lesions proved to be malignant and 9 benign in subsequent surgical excision, whereas 108 benign lesions were stable on mammographic follow-up. The result of the first sample was false negative significantly more often in MC lesions (n=14, including atypical ductal hyperplasia in two cases) than in solid lesions (n=4, p=0.03). Combined results of 3 samples (containers A and B) yielded a sensitivity of 97% (98% for solid and 96% for MC lesions). The overall results from multiple samples reached a sensitivity of 98%, thus, additional samples from container C did not significantly improve the sensitivity (test of proportions, p=0.68)

Conclusions: Three passes with an add-on 14 gauge SCNB device are sufficient to detect malignancy in a mammographically suspicious breast lesion. In a lesion with MC, a single specimen may lead to a false negative diagnosis. The diagnostic accuracy of the results obtained with an add-on stereotactic equipment are comparable with the prior published data achieved with a dedicated prone biopsy table.

383 POSTER

Association between HER2 status and histological diagnosis of breast cancer: analysis of the multinational HER2000 study

M. Altmannsberger[1], A.P. Dei Tos[2], J. Olofsson[3], R.Y. Osamura[4], A. Ryska[5]. *On behalf of the HER2000 Study Group; [1] Avdelningen för patologi & cytologi, Institut für Pathologie, Frankfurt am Main, Germany; [2] Department of Pathology, Regional Hospital, Treviso, Italy; [3] Avdelningen för patologi & cytologi, Universitetssjukhuset, Linköping, Sweden; [4] Department of Pathology, Tokai University School of Medicine, Kanagawa, Japan; [5] Fingerland's, Department of Pathology, Hradec Kralove, Czech Republic*

Background: It is now accepted that routine HER2 testing is essential for optimal breast cancer management because HER2-positive breast cancer

is known to be more aggressive, causing decreased survival, and is eligible for treatment using the novel therapy Herceptin. However, no study has examined HER2 status on a global scale. We have used IHC to obtain data on HER2 status in 15 countries in 5 regions (Europe, Latin America, Australia, Japan, South Africa) worldwide and examine the association between HER2 status and the histological diagnosis of breast cancer.

Methods: Formaldehyde-fixed, paraffin-embedded sections (3-5μm) of samples from primary breast tumours or metastases were retrospectively or prospectively tested for HER2 status using the validated HercepTest IHC kit. All samples were scored 0, 1+, 2+ or 3+ according to standard criteria outlined in the package insert for HercepTest. The histological type of the breast tumours tested was also determined.

Results: A total of 9,307 specimens were tested, 97% of which were from primary tumours and 93% of which were fixed in neutral-buffered formalin (NBF). For the purpose of this analysis, only tumours fixed in NBF and those with a histological diagnosis of invasive ductal (n=7,106) or lobular (n=1,014) carcinoma, carcinoma in situ (n=158) or certain special types (n=169) were included. Of the total of 8,447 samples available for analysis, HER2 status was scored as 0 in 46% of specimens; 1+ in 25%; 2+ in 14%; and 3+ in 15%. Variation in level of HER2 positivity between regions and centres was noted, except in Japan. Overall, the incidence of HER2 3+ samples was greatest in carcinoma in situ (24%), followed by invasive ductal carcinoma (17%), invasive lobular carcinoma (6%) and special types (3%). This pattern was observed in 3 of the 5 regions; samples were predominantly of one histological type (invasive ductal carcinoma) in the 2 regions in which the pattern was different (Japan and South Africa).

Conclusion: The overall incidence of HER2 positivity, defined as a score of 3+ using the HercepTest (15%), is as expected based on the published literature. However, incidence appears to depend on the histological diagnosis of the breast tumours examined.

384 POSTER

Techniques to aid in sampling difficult breast lesions using the upright stereotactic mammography unit

A. Masterson[1], J. Noonan[2], J. McAleese[3], F. Flanagan[4]. *[1] The Mater Misericordae Hospital, Radiology, Dublin 7, Ireland; [2] The Mater Misericordae Hospital, Symptomatic Breast Unit, Radiology; [3] The National Breast Screening Programme, Eccles Unit, Radiology; [4] The Mater Misericordae Hospital and The National Br, Ecc, Radiology*

Stereotactic-guided biopsy is frequently used to sample mammographically detected breast lesions, such as micro calcifications or lesions not visible at ultrasound.

Many units function very effectively with upright units and a reclinable chair, and do not require a dedicated prone table. While the upright unit is very effective overall, there are a number of clinical scenarios where lesions are difficult to biopsy, due to the location of the lesion, size of breast and size of patient. It can be difficult to position the patient in a way that enables the lesion to be sampled and so that the patient is comfortable to minimize motion.

Over the past 2 years of our screening programme we have developed some techniques that aid in the comfortable positioning of the patient to adequately sample these breast lesions, from any approach.

We have compiled a pictorial review to demonstrate these positions using the General Electric and Siemens Mammomat Opdima upright stereo units and the Hausted chair.

385 POSTER

Screening with breast sonography in women with dense breasts

P. Crystal[1,2], S. Strano[2], S. Shcharinsky[2], M. Verthaim[2], M. Koretz[2]. *[1] Soroka University Medical Center, Radiology, Beer-Sheva, Israel; [2] Soroka University Medical Center, Comprehensive Breast Center, Beer-Sheva, Israel*

Purpose: To evaluate diagnostic yield of breast ultrasonography (US) in the detection of breast cancer in women with dense breasts and normal mammographic and physical examination findings.

Material and Methods: One thousand one hundred asymptomatic women with dense breasts and normal mammography underwent physician performed screening breast US. US-guided core biopsy was undertaken for solid lesions found on sonography. The results were compared for usual risk and increased breast cancer risk women.

Results: In the group of 1100 women, 4 surgically proved cancers in 4 women (prevalence 0,36%) were detected with US alone. Mean surgical size of these cancers was 8 mm, and it smaller than mean size of mammographically detected cancers in screening population. Subgroup of increased risk women included 342 women and 3 occult cancers were detected by US (prevalence 0,88%). In the subgroup of usual risk women 1 cancer was found on US (prevalence 0,13%).

Conclusion: Screening US in dense breast women can depict otherwise occult malignancies that smaller than mammographically identified nonpalpable cancers. Adjunct of US to mammography in cohort of women with increased risk of breast cancer and dense breasts may be beneficial. Additional studies to examine issues of acceptability, reproducibility, and cost effectiveness are pertinent.

386 POSTER

First experience with the implementation of a quality system for the assessment and primary treatment of women referred in a population-based breast cancer screening programme in the region of a Comprehensive Cancer Centre in The Netherlands

P.A.M. Bun ev. Sevenstern[1], N.S. Klazinga[2]. *On behalf of the Committee for Quality Improvement; [1] Breast Cancer Screening Centre West, Leiden University Medical Center, Department of Radiology; [2] Academic Medical Center, Institute of Social Medicine, Amsterdam, Netherlands; [3] Comprehensive Cancer Centre West, Leiden, Netherlands*

Introduction: In the Netherlands special breast cancer screening services were set up to perform the breast cancer screening on a regional level. They are linked to the comprehensive cancer centres in cooperation with the municipal health services. When a suspicious lesion is found in the screening, the woman is referred to a hospital for further assessment. Further assessment is therefore not part of the screening process itself in contradiction to other countries.

To support the specialists in the region of the Comprehensive Cancer Centre West in the multidisciplinary task of diagnosis and treatment of the women referred to them through the screening programme a quality improvement system is developed and implemented.

Methods: A multidisciplinary committee was formed, in which all disciplines involved in diagnosis and primary treatment were represented: radiology, surgery, pathology and radiotherapy. The committee drafted a testable guideline, based on national and regional guidelines and practice experience. In the guideline review criteria are formulated varying in number per discipline. In the evaluation of the 11 hospitals the committee acts as audit team. Clinical data of around 30 women referred to each hospital are systematically collected and used for feedback to the specialists.

The evaluation focuses on organisational and medical procedures with regard to quality of care.

Results: Taken into account the total scores per discipline per hospital, none scored the best or worst in all four disciplines. Focussing on the individual review criteria per discipline, hospitals show more practice variation. Examples are: surgeon sees patient within one week (surgery), tip markerwire within 10 mm of the lesion (radiology), correlation between the abnormality seen on mammography and histology (pathology), interval between first operation and start radiotherapy less than six weeks (radiotherapy).Parallel to the evaluation visits to the hospitals, the committee worked on readjustment of the guidelines, including new review criteria per discipline.

Conclusions: A quality system for systematic evaluation of the existing care process can be developed. The variations of results in the first round motivate recommendations for improvement of the existing care process. During the evaluation process improvement is already observed. We aim at confirmation for sustained improvements in the next round.

387 POSTER

Does dynamic contrast enhanced magnetic resonance imaging have a role in the investigation of indeterminate microcalcification in the breast?

P. Kneeshaw[2], M. Lowry[1], L. Turnbull[1], P. Drew[2]. *[1] Centre For Magnetic Resonance Investigations, Hull Royal Infirmary, Hull, United Kingdom; [2] Academic Surgical Unit, Castle Hill Hospital, Hull, United Kingdom*

Introduction: Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) is an effective diagnostic modality for symptomatic breast disease. However, its role in evaluating clinically occult disease associated with mammographically indeterminate microcalcification remains unclear. The aim of the study was to evaluate the efficacy of DCE-MRI in the investigation of indeterminate microcalcification in the breast.

Methods: Women with areas of indeterminate microcalcification demonstrated on X-ray mammography had DCE-MRI examination of the breast. The data was evaluated morphologically and by post-processing evaluating signal intensity parameters and 2-compartment pharmacokinetic modelling to calculate the amplitude of contrast uptake and exchange rate in the whole region of interest and within the most enhancing 9-pixel square.

Results: 42 women were recruited. Histological diagnosis (n=37) revealed: invasive disease (n=2), DCIS (n=10), invasive + DCIS (n=12) and benign (n=13). The remaining patients (n=5) had benign FNAC followed by clinical and mammographic follow-up of at least 15 months (Range15-43 months). Comparing malignant and benign lesions, the mean values in arbitrary units for the maximum intensity time ratio, exchange rate and amplitude of contrast uptake were 42.70 (range 1.66-312.65) vs 9.79 (range 1.55-19.66) p=0.002; 5.47 (range 0.25-49.26) vs 1.18 (range 0.27-2.31) p=0.003; 8.61 (range 0.20-58.24) vs 1.19 (range 0.00-4.70) p=0.007.

Discussion: DCE-MRI is able to distinguish benign from malignant clinically occult lesions associated with indeterminate microcalcification and is therefore a potentially useful investigation in this group of patients.

388 POSTER

Typically benign and typically malignant microcalcification with discordant histology: pathological-radiological review

A. Masterson[1], M. McNicholas[2], H. Fenlon[2], M. Kennedy[3], M. Kerin[4], F. Flanagan[2]. *[1] The Mater Misericordae Hospital, Radiology, Dublin 7, Ireland; [2] The Mater Misericordae Hospital and Breast Check, Eccles Unit, Radiology; [3] The Mater Misericordae Hospital and Breast Check, Eccles Unit, Pathology; [4] The Mater Misericordae Hospital and Breast Check, Eccles Unitd, Surgery*

According to the Birads Classification less than 5% of category 5 microcalcifications are benign. However, excision biopsy is still essential to exclude potential discordance at core biopsy. We present a pictorial display of the radiographic - pathological correlation of typically malignant and typically benign calcification, which on excision biopsy were found to have discordant histology.

Over the past 18 months of our screening programme we report cases of mammographically typical malignant microcalcification, which turned out to be benign on excision biopsy.

During this time we also report cases with typical radiographic features of benign type calcification, often described as plasma cell mastitis. These patients underwent excision biopsy of the calcification as it was felt that there had been an interval change in the appearance of the calcification. Histological examination of the specimen revealed foci of DCIS. We had a further 2 cases with coarse calcification with some features that were felt not to be completely benign. On excision biopsy these were found to be malignant.

We illustrate features of the calcification some of which may aid in determining possible underlying malignancy in these and similar cases.

389 POSTER

Characteristics of false positive lesions appeared in dynamic contrast-enhanced t1-weighted MR imaging of the breast

Y. Sawai[1], J. Arisawa[1], H. Inaji[2], H. Koyama[2], T. Kasugai[3], S. Ishiguro[3]. *[1] Osaka Medical Center for Cancer and Cardiovascular, Diagnostic Radiology, Osaka, Japan; [2] Osaka Medical Center for Cancer and Cardiovascular, Surgery, Osaka, Japan; [3] Osaka Medical Center for Cancer and Cardiovascular, Pathology, Osaka, Japan*

Introduction: Contrast-enhanced T1-weighted MR imaging is useful modality to depict the presence and the extent of breast cancers, but it is well known that instead of high sensitivity, specificity of this imaging modality is significantly low. We retrospectively reviewed the false- positively contrast-enhanced lesions in MR images of the breast.

Material and Methods: We found MR images of 15 false positive cases. In all cases, three-dimensional fat suppressed dynamic MR imaging was performed with a bolus injection of Gd-DTPA at a dose of 0.1mmol/kg. 11 of 15 lesions underwent surgery or biopsy after the imaging examination. The correlation between the determination of tumor extension by MR imaging and that of histologic assessment diagnosed by surgical biopsy was assessed.

Results: The size of the lesions is ranged 3 -15mm (median 8mm) In 3 cases, lesions were solitary, well-circumscribed and strongly enhanced with smooth margin in the early phase of dynamic MR after administration of Gd-DTPA. The size of all these cases are more than 8mm. All of 3 cases were proved histologically intraductal papilloma. In 12 cases, lesions were weakly or moderately contrast-enhanced, less than 10mm in size, and 9 of 12 cases had multiple lesions scattered disorderly. Eight of 12 cases were undergone surgery or biopsy. Histologically, various condition of mastopathy was found in 5 cases, only normal breast tissue was found in 3 cases. Four cases of false-positive suspicious lesions are followed without surgery or biopsy and stay unchanged.

Conclusion: Strongly contrast-enhanced well-circumscribed lesion with smooth margin, or weakly contrast-enhanced lesion scattered disorderly are characteristic on dynamic MR imaging of false positives, however, these features may often overlap with the features of true positive lesions. MR-guided breast biopsy system should be required in future as ideal resolution to avoid oversurgery caused by false positively depicted lesions in MR imaging.

390 POSTER

Ultrasound-guided core needle biopsy for the non-palpable breast lesions

B.W. Park[1], E.K. Kim[2], K.S. Lee[3]. *[1] Yonsei University, Surgery, Seoul, Korea; [2] Yonsei University, Diagnostic Radiology, Seoul, Korea; [3] Yonsei University, Surgery, Seoul, Korea*

Objectives: This study was designed to evaluate the usefulness of ultrasound (US)-guided core needle biopsy for non-palpable breast lesions and to compare the result by 14 gauge needle with that by 16 gauge.

Design and Methods: Core specimens from 512 non-palpable lesions in 471 patients, 198(38.7%) by 16 gauge core-needle and 314(61.3%) by 14 guauge, were obtained from April 1996 to March 2001. Pathologic results of core biopsy and of surgery were compared and were statistically analyzed according to 14 and 16 gauge needle biopsy.

Results: The mean age of patients was 44 (range: 20-72). The sizes of lesions were measured from 0.3cm to 3cm, averaging 0.9cm. Of the 512 breast lesions sampled, 71 (13.9%) were invasive carcinoma(IDC), 7(1.4%) were ductal carcinoma in situ (DCIS), 4(0.8%) were atypical ductal hyperplasia(ADH) and 428(83.6%) were benign. Of 71 invasive carcinoma diagnosed by core biopsy, 53 were surgically excised and all were proved to be invasive carcinoma. Of 7 DCIS, 4 turned out DCIS and 3 turned out invasive carcinoma by surgery. Of 4 ADH, two were IDC and the other two were diagnosed with ADH and benign each by surgery. Fifty-five of 428 benign lesions were surgically excised. Of 55, 5 were invasive carcinoma and 1 was DCIS. There were at least 6 false-negative core biopsy results (1.2%), 1 in 14 gauge needle group, and 5 in 16 gauge needle group. Biopsy with 16 gauge needle showed significantly higher false negative results than that with 14 gauge (Fisher exact test, $p<0.05$). There was no significant difference in complications between groups.

Conclusions: US-guided core needle biopsy for the non-palpable lesion is very useful to reduce unnecessary surgery and 14 gauge needle would be better than 16 gauge needle in terms of accuracy.

391 POSTER

Comparison of diagnostic roles of ultrasound, Tc-99m MIBI scintimammography and contrast enhanced MRI in detection of breast cancer

Y.J. Jung, J.S. Lee, H.S. Kwak, Y.T. Bae, M.S. Sim. *Pusan national university College of Medicine, General surgery, Pusan, Korea*

Objective: Ultrasound, Tc-99m MIBI Scintimammography(SMM), and contrast enhanced MRI(CEMRI) were validated as useful diagnostic tools for the primary breast cancer. Although ultrasound is cheap and convenient, it has the problem of low specificity. So there are increasing demand for SMM or CEMRI as an alternative. We compared diagnostic usefulness of ultrasound with SMM, and SMM with CEMRI in diagnosis of breast cancer.

Materials and Methods: (1) The one study includes 158 patients who were performed ultrasound and SMM for palpable breast masses from Jan. 1998 to Dec.1999. (2) The other study included 43 breast lesions of 40 suspected breast cancer patients. All patients were performed SMM & CEMRI. The pathologic results were obtained by operation or FNAB in these two studies.

Results: (1) Malignancy were 110 and benign breast disease were 48. Ultrasound revealed 84 True Positive(TP), 30 True Negative(TN), 7 False Positive(FP), 8 False Negative(FN), and 29 indeterminates. SMM revealed 95 TP, 29 TN, 19 FP, 15 FN. The sensitivity, specificity, positive predictive value, and negative predictive value of SMM were 86%, 60%, 83%, and 66% respectively. Among 7 FP by ultrasound findings, 3 were TN by SMM. Among 8 FN by ultrasound findings, 6 were TP by SMM. Among 29 indeterminates by ultrasound, SMM revealed 13 TP and 9 TN. (2) Malignancy

were 39 and benign breast disease were 4. SMM showed 37 TP, 3 TN, 1 FP, 2 FN. The sensitivity was 94.8%. CEMRI revealed 31 TP, 1 TN, 2 FP, 4 FN and 5 indeterminate cases. The sensitivity was 88.5%. In the assessment of axillary lymph node metastasis, SMM showed 9 TP, 10TN, 0FP, 3 FN. The sensitivity and specificity were 75% and 100%. CEMRI revealed 6 TP, 9TN, 1FP, 6 FN. The sensitivity and specificity sere 50% and 90%. Among 5 indeterminate cases with MRI findings, SMM correctly diagnosed malignant breast diseases in 3 lesions. However, SMM showed 1 FP and 1 FN. SMM could correctly diagnosed malignant breast diseases more 5 lesions than CEMRI.

Conclusion: In these studies, SMM was more sensitive and more specific method than Ultrasound or CEMRI in detection of primary breast cacner and axillary LN metastasis. SMM could correctly diagnosed malignant breast diseases in cases with indeterminate MRI or indeterminate ultrasound findings. Therefore, SMM may have complementary role in diagnosing the breast cancer.

392 POSTER

Breast cancer clinical features in our elderly patients: causes of delayed diagnosis

M. Gomez, M. Vernet-Tomas, C. Marine, M. Castillo, P. Fuste, R. Carreras.
Hospital Del Mar, Obstetrics And Gynaecology, Barcelona, Spain

Objective: The aim of our study was to review clinical features of breast cancer in our elderly patients (75 years old or more) compared to younger patients (less than 75 years old), as we are concerned that clinical stage is usually advanced at the time of diagnosis.

Setting: 40 elderly patients and 77 younger patients attending our Hospital from October 1999 to October 2001 were included. Sympthoms and time of evolution, breast cancer familiar and personal history, menarche, nulliparity, menopause and TNM were reviewed.

Results: The mean age in the elderly group was 81.74 (75-91) and in the younger group 57.59 (34-74). Interestingly the mean time of symptoms' evolution in the elderly group was 113.54 days (7-2190) but 51.28 days (1-2160) in the younger group. In the elderly group 13% patients were T1 (44% in the younger group), 79% were N0 (83% in the younger group) and 10% were M1 (4% in the younger group).

Conclusion: Elderly patients present with advanced clinical stages. As not included in mamographic screening in our area (included 50-70 years old), efforts should be made by general practitioners, gynaecologists and other health providers to avoid delayed diagnosis. We think that even information about self-exploration would be useful in this aged group.

393 POSTER

Imaging characteristics of suspected radial scar: aids in determining malignancy

A. Masterson[1], M. McNicholas[2], M. Kennedy[3], M. Kerin[4], F. Flanagan[5].
[1] The Mater Misericordae Hospital, Radiology, Dublin 7, Ireland; [2] The Mater Misericordae Hospital and The National Br, Ecc, Radiology; [3] The Mater Misericordae Hospital and The National Br, Ecc, Pathology; [4] The Mater Misericordae Hospital and The National Br, Ecc, Surgery; [5] The Mater Misericordae Hospital and The National Br, Ecc, Radiology

Purpose: Radial scars are high risk benign breast lesions characterised radiographically by spicules that surround a lucent centre. An evaluation of all mammographically suspected radial scars in our unit was performed retrospectively, to determine imaging factors that might indicate malignancy, pre-operativly.

Materials and Methods: Retrospective review of women attending for mammography to the symptomatic and screening programme in the Eccles Unit was performed. Of 25,000 mammograms 69 cases of suspected radial scar were evaluated, and correlation between ultrasound, mammograms and histology findings.

All patients underwent further imaging; additional mammographic views and US, most had image-guided biopsy and all had therapeutic surgery performed. Mammograms were assessed for nature of spicules, size of area of architectural distortion, calcifications and presence of asymmetric density. Ultrasound was assessed for visibility, size of lesion, presence of mass, streaking and shadowing. Note was made of women on Hormone Replacement Therapy, age of patient, previous surgery and family history.

Results: Radial Scars that turned out to be malignant tended to be more visible on US and demonstrated significant shadowing, compared with benign lesions. They also tended to have an associated density. Both macro and micro calcifications tended to be common in both groups. There was no significant difference between the 2 groups when family history, previous surgery, age or HRT were examined.

Conclusion: (i) US can be very helpful in helping to determine ultimate malignancy in suspected radial scars. (ii) Pre-operative diagnosis is still worth performing, so that a simple one step procedure can ensue. (iii) Because of the wide overlap in features we recommend that all radial scars still require excision biopsy.

394 POSTER

Digital mammography and mammotome biopsy in the evaluation of breast microcalcifications without accompanying mass

R. Chrzan[1], T.J. Popiela[2], B. Podsiadlo-Kleinrok[1], J. Tabor[2], W. Nowak[2].
[1] Collegium Medicum Jagiellonian University, Radiology, Kraków, Poland; [2] Collegium Medicum Jagiellonian University, 1-st Department of General and Gastrointestinal Sur, Kraków, Poland

Purpose: The aim of the study is to determine the efficiency of digital mammography, compared to conventional mammography, in the evaluation of breast microcalcifications without accompanying mass, with pathological verification using mammotome biopsy.

Materials and Methods: Conventional mammography with magnified views and digital mammography of clusters of breast microcalcifications without accompanying mass were performed in 84 women (age range 40-72 years). BIRADS category ratings were assigned independently to conventional and digital images. In 30 women with BIRADS category 2 (benign) in conventional and digital imaging only routine screening was ordered. In 54 women with categories 3-5 (probably benign, suspicious, malignant) in conventional or digital imaging, subsequent mammotome biopsy was used for pathological verification. Statistical analysis was finally performed, with calculation of positive predictive values for benign and malignant lesions in BIRADS 3-5 categories, independently for conventional and digital imaging.

Results: Digital mammography, compared to conventional mammography, allowed better prediction of atypical and malignant lesions. It better described the number, shape and extent of microcalcifications.

Conclusion: Digital mammography with possible subsequent mammotome biopsy should be the method of choice in the evaluation of microcalcifications without accompanying mass.

395 POSTER

Mammotome biopsy guided by digital mammography and ultrasonography in the detection of pre-clinical breast cancer - own experience

J. Tabor[1], T.J. Popiela[1], W. Nowak[1], B. Podsiadlo-Kleinrok[2], R. Chrzan[2].
[1] Collegium Medicum Jagiellonian University, 1-st Department of General and GI Surgery, Kraków, Poland; [2] Collegium Medicum Jagiellonian University, Radiology Department, Kraków, Poland

Aim: The aim of the study was to evaluate the usefulness of Mammotome Biopsy guided by digital mammography (SMB) and ultrasonography (MB H-H) in the detection of pre-clinical breast cancer.

Material and Methods: Between March - October, 2001, visualising examinations were performed in 319 women, aged 32-72 years, with confirmed pre-clinical lesions (cat. III, IV BIRADS), which were qualified to further diagnostic examinations. All patients underwent SMB using 11-GA needle. SMB was performed in 107 women (group I) with pathological microcalcifications, distorsions of architecture and nodular lesions visible only in mammography. MB H-H was performed in the remaining 210 patients (group II) with nodular lesions and distorsions of architecture detected by USG. In 2 women subjected to SMB examination could not be performed due to technical problems.

Results: Pre-invasive and invasive breast cancer was detected in 12% of group I patients (DCIS in 10%, and invasive in 2%). In group II breast cancer was confirmed in 13% of patients (invasive in 9%, and DCIS in 4%). Atypical ductal hyperplasia was found in 12% of group I, and 4.6% of group II. In the remaining cases benign breast lesions were detected. One patient (0.9%) after SMB developed haematoma requiring surgical intervention and in the remaining group 25% patients subjected to SMB and 38% undergoing MB H-H developed haematomas, less in size then 20mm, spontaneously reabsorbed up to 3 months.

Conclusions: BM is the alternative to open surgical biopsy, especially in detection of non-palpable preclinical lesions. It is minimally invasive method associated with low risk of complications. It can be performed on ambulatory basis, and ensures good cosmetic effect.

396 POSTER

Learning curve for add-on stereotactic breast biopsy

A. Koskela[1], M. Berg[1], M. Sudah[1], V. Kärjä[2], A. Malinen[1], R. Vanninen[1]. [1] *Kuopio University Hospital, Kuopio University, Department of Clinical Radiology;* [2] *Kuopio University Hospital, Department of Clinical Pathology, Kuopio, Finland*

Purpose: To evaluate the learning curve for breast biopsy using an add-on stereotactic core needle biopsy device.

Materials and Methods: Altogether 213 consecutive patients (mean age 56 yrs, range 22-88 yrs) with 221 mammographically detected nonpalpable breast lesions (110 solid and 111 with microcalcifications (MC), mean size 11.8 mm) participated this prospective study. An add-on stereotactic core needle biopsy (SCNB) device and a 14-gauge needle were used for biopsy. Each biopsy was performed by one of five radiologists, who were experienced in breast imaging but none of whom had prior clinical experience with SCNB. The results of the first five biopsies (group 1) of each radiologist were compared with their subsequent cases (group 2). In addition, the biopsy material obtained by three of the radiologists, was collected as follows: the first sample into container A, the 2nd and the 3rd into container B and all additional samples into container C. The mean number of samples was 7 (range 2-20) per lesion. An experienced pathologist analysed each container separately for the presence of malignancy. All non-excised lesions were followed up with mammography.

Results: For final diagnosis 89 lesions proved to be malignant and 9 benign in subsequent surgical excision. In 123 lesions no signs of malignancy was detected in follow-up mammography. For all five radiologists, no significant difference was noted between the results of their first five biopsies (n=25, sensitivity 100%) compared to the subsequent cases (n= 196, sensitivity 99%). In the additional study, in which the samples were divided into three containers (A-C), the sensitivity of three samples (containers A and B) reached 100% in both groups(the first five as well as the subsequent biopsies).

Conclusion: Breast biopsy from a nonpalpable breast lesion with an add-on SCNB device is an easily adopted procedure. Without prior operator experience sensitivity as high as 100% with only three passes is achieved for detecting malignancy. A larger number of passes is not necessary for unexperienced radiologists.

397 POSTER

Initial results of concordance between the biofield diagnostic system test (BDS) and Ki-67 labeling index to discriminate highly proliferating palpable breast lesions

W. Gatzemeier, C. Tinterri, L. Regolo, R. Gennari, S. Scevola, B. Ballardini, V. Zanini, A. Costa. *The Maugeri Foundation, Division of Surgery and Senology, Pavia, Italy*

Introduction: The Ki-67 antigen expression was measured in 296 patients from 28 to 70 years of age with breast cancer in whom the Biofield Diagnostic System (BDS) was also applied preoperatively. The BDS is a non-invasive device that aims at providing an objective diagnosis from measurement of proliferation rates by comparing electropotentials in a quadrant of the breast containing suspicious lesions with the net electrical activity with that of uninvolved segments with sensors placed on the surface. The patients were a subset of a multinational study involving 1501 patients with BDS scores (Lancet 1998; 352:359). The retrospective analysis of this subgroup provided a correlation between BDS and Ki- 67 of 86% in discriminating highly proliferate lesions.

Patients and Methods: In order to further confirm these findings we initiated a prospective study to investigate 100 consecutive breast cancer patients in our institution to correlate preoperative BDS results with those of the definitive pathological diagnosis including the Ki-67 expression, receptor status and other prognostic indicators.

Results: The preliminary analysis of the data of the initial patients were encouraging. The BDS provides an immediate, objective, cost-effective result and can be repeated as often as necessary. The test is simple to perform and is acceptable to patients.

Conclusion: With the complete evaluation of all data it will be possible to distinguish whether BDS is useful to determine tumour proliferation rates preoperatively. This information might be important for the decision making process.

398 POSTER

Displacement of breast tissue and needle deviations during stereotactic procedures

E.E. Deurloo[1], K.G.A. Gilhuijs[1], L.J. Schultze Kool[1], S.H. Muller[1]. [1] *Netherlands Cancer Institute/Antoni van Leeuwenhoek, Radiology, Amsterdam, The Netherlands*

Rationale and Objectives: Both displacement of breast tissue as well as displacement of the needle influence the diagnostic accuracy of stereotactic breast biopsy procedures. The aim of this study was to quantify the displacement of breast tissue and the inaccuracy of needle positioning for biopsy (14-gauge) and localization (19.5-gauge) needles and to assess their clinical relevance.

Methods: The images of 84 patients who underwent a stereotactic procedure (biopsy or localization procedure) between May 1st 1998 and April 20th 2000 were used. For the calculation of displacement of breast tissue, differences between the coordinates of identifiable microcalcifications in the images before (baseline) and after needle positioning were analyzed (n=52). The influences of total distance from microcalcification to target, needle type, and the type of the lesion on the displacement of tissue were analyzed.

For accuracy of needle positioning, differences between the coordinates of the needle tip and the target were analyzed in breast tissue (n=97) and in air (n=246).

Results: The average distance between the planned target position and the actual target position (i.e., tissue displacement) was 2.1 mm for biopsy needles (95% prediction interval [PI] 0.6-7.8) and 1.0 mm (95% PI 0.3-3.9) for localization needles. Mean inaccuracy of needle positioning in breast tissue was 1.1 mm (95% PI 0.4-3.0) and 1.8 mm (95% PI 0.7-4.6) for biopsy and localization needles, respectively. The inaccuracy of needle positioning in air (i.e., the instrument error) was 0.44 mm (95% PI 0.2-0.7)

Conclusions: Tissue and needle displacements cause a total positioning error of 2.4 mm in stereotactic core biopsy, which will limit the attainable diagnostic accuracy.

399 POSTER

The probability and nature of breast tumours with an indeterminant R3 lesion on mammography

H.N. Khan[1], B.H. Hayee[1], A. Antonio[1], N. Griffiths[1]. [1] *William Harvey Hospital, Breast Unit, Dept of surgery*

Introduction: Diagnosis of breast cancer is based on triple assessment at initial presentation i.e. clinical, cytological or histological and radiological findings. Mammography is mainstay radiological investigation. Lesions on mammography are classified R1-5 based on probability of carcinoma, with R1 definite benign and R5 definite malignant. We aimed to assess the probability and nature of cancer in the radiological indeterminant group R3.

Patients and Methods: A retrospective study was carried out. Case-notes of all women with R3 lesions on mammography between January 1984 to January 2000 in a distict hospital were reviewed. Classification was by a single radiologist. Positive cases were defined as histological evidence of breast cancer after therapeutic or diagnostic excision. Histological type and evidence of distant spread at presentation was also sought from the case-notes.

Results: 875 lesions in 792 women were classified as R3 during the study period. Median age of population was 60 years. 123 lesions were malignant in 108 women. Median age of positive cases was 60 years (range 28 - 90). 14% of R3 lesions were therefore positive for cancer. All positive lesions were ductal carcinoma. None of the patients had evidence of distant spread at presentation.

Conclusions: 14% of indeterminant R3 lesions on mammography are malignant with histology of ductal carcinoma. R3 positive lesions indicate early disease.

400 POSTER

Non-palpable breast cancer: the impact of increased mammographic screening and use of percutaneous image guided core biopsy on surgical treatment

M. Carmon[1,2], S. Strano[3], E. Feigin[1,2], L. Rivkin[1,2], M. Goldberg[1,2], D. Fisher[4], A. Fisher[5], O. Lernau[1,2]. *[1] Shaare Zedek Medical Center, Surgery A, Jerusalem, Israel; [2] Ben Gurion University, Faculty of Health Sience, Beer Sheva, Israel; [3] Rachel Nash Comprehensive Breast Clinic, Jerusalem, Israel; [4] Shaare Zedek Medical Center, Radiology, Jerusalem, Israel; [5] Meuhedet Health Fund, Radiology, Jerusalem, Israel*

Background: Major efforts are being directed at the early diagnosis of breast cancer. The percentage of nonpalpable tumors is steadily increasing as a result of increased screening by mamography. In most patients with non-palpable lesions, Percutaneous image guided biopsies have replaced wire localization and open surgical excisional biopsy for obtaining tissue diagnosis. In the last several years, the Israel Ministry of Health initiated a mammographic screening program. Percutaneous image guided biopsies have also become widely available.

Objective: To asses the impact of increased mammography screening and image guided core biopsy on surgical decision making and treatment of breast cancer in the breast service of Shaare Zedek Medical Center, Jerusalem.

Materials and Methods: The charts of 483 patients operated on in our department for primary breast carcinoma during the years 1997-2001 were reviewed. Data related to mode of diagnosis, tumor stage, resection margins and number and types of surgeries were recorded and analyzed. The term non-palpable tumors relates to tumors not palpable before and after imaging, therefor necessitating wire localization for surgical excision.

Results: Analysis of the activity in our breast service in the years 1997 to 2001 disclosed the following findings:

1) The percentage of patients diagnosed with non-palpable tumors rose from 16.2% in 1997 to 47.4% in 2001, with an average size of 2.6 Cm for palpable and 1.7 Cm for non-palpable tumors.

2) For non-palpable tumors, I) The rate of pre-operative diagnosis rose from 6.2% in 1997 to 96.4% in 2001, II) The rate of involved or very close margins was reduced by 75% in the patient group diagnosed pre-operatively compared to those without preoperative diagnosis, and III) The percentage of patients who had two operations fell from 56.2 in 1997 to 11.1 in 2001.

Conclusions: The mamographic screening program in Jerusalem during the years 1997-2001 was effective in increasing the relative percentage of nonpalpable breast cancers with reduced tumor size at diagnosis. The improved availability of preoperative tissue diagnosis in these patients reduced the number of surgical procedures needed.

401 POSTER

The effect of suction volume on the diagnostic accuracy of breast fine-needle aspiration cytology

C.L. James, C.G. Burt, N. Ibrahim, A.K. Sahu, S.J. Cawthorn. *Frenchay Hospital, General Surgery - Breast Care Centre, Bristol, UK*

Introduction: The value of fine needle aspiration cytology (FNAC) as an integral part of the triple assessment of palpable breast lumps is well established. A standard technique involves passing a 23 gauge needle through a palpable lump 6 to 10 times while aspirating with a 20 ml syringe. Some patients find FNAC painful and distressing, and it is our impression that discomfort increases with the amount of suction applied to the syringe. We report a pilot study to identify the suction volume required to produce diagnostic FNAC samples.

Method: In this prospective study 44 surgically excised breast tumours (2 benign, 42 malignant) were sampled 3 times each using 2 ml, 5 ml and 10 ml of suction pressure in a random order. Aspirates were collected with a 23 gauge needle attached to a 20 ml syringe in a holder using 6 passes through the specimen. All slides were examined by a consultant pathologist and categorised as either sufficient for diagnosis or non-diagnostic.

Results:

	2 ml suction n = 44 (%)	5 ml suction n = 44 (%)	10 ml suction n = 44 (%)
Diagnostic slides	38 (86.4)	40 (90.9)	42 (95.5)
Non-diagnostic slides	6 (13.6)	4 (9.1)	2 (4.5)

The results were analysed using Friedmans' non-parametric two-way analysis of variance, which found no significant difference in the number of slides satisfactory for diagnosis between the three suction volumes ($p = 0.18$, adjusted for ties).

Conclusion: The results suggest that 2 ml of aspiration pressure is sufficient to produce an equivalent number of diagnostic slides compared to the more commonly used 10 ml suction pressure. All diagnosis rates were within the range quoted in the literature, as would be anticipated for FNAC samples from excised specimens. A prospective randomised controlled trail is planned to investigate the adequacy of different aspiration volumes and associated patient discomfort on breast lumps in *situ*.

402 POSTER

Accuracy of core needle biopsy diagnoses following the introduction of the method

É. Ambrózay[1], G. Cserni[2], G. Forrai[3]. *[1] Bács-Kiskun County Teaching Hospital, Kecskemét, H; [2] Bács-Kiskun County Teaching Hospital, Kecskemét, Hungary; [3] Faculty of Health Sciences, Semmelweis University, Budapest*

Core needle biopsy (B) allows tissue diagnosis of breast lesions; its introduction in the diagnostic arsenal requires analysis of its performance.

We report our initial 106 ultrasound guided (n=94) or stereotactic (n=12) Bs of 105 patients (median age: 57). Physical examination (P), mammography (R), ultrasound (U), cytology (C) and B were reported on a five score system (1: inadequate [pathology], normal [imaging]; 2: benign; 3: atypical; 4: suspicious for malignancy; 5: malignant).

Of the 106 lesions 78 were operated on: 10 were benign (1 B1, 8 B2, 1 B3 - a complex sclerosing lesion /CSL), and 68 were malignant (64 B5, 2 B4, 1 B3 (P1R3U1) and 1 B2 (P4R4U4C4); the two latter representing a false-negative rate of <3%. Of cases scoring <5 on any of P, R or U, 50 were operated on: 8 were benign (8 B2), and 42 were malignant (38 B5, 2 B4, 1 B3 and 1 B2). Of the 33 cases scoring 5 on P, R or U, 31 were malignant on B, and 2 CSL were reported B1 and B3, respectively. 38 cases were assessed by C and B simultaneously. The inadequacy rate of C and B were 16% and 3%, respectively. Of the B5 cases there were 4 C1, 6 C2, 1 C3, 6 C4 and 2 C5; the only B4 scored C2, and 4 of the B2 cases were scored C4 (3 benign lesions and 1 invasive ductal carcinoma).

Core needle biopsy was a strong diagnostic adjunct in our hands, it helped to clarify most suspicious and atypical lesions, allowing definitive treatment on the basis of preoperative diagnosis, and it performed better than fine needle aspiration cytology (false-negative rates of 3% and 18%, respectively; no suspicious lesions versus 3 suspicious lesions finally diagnosed as benign), although cytology complemented core biopsy in one case.

403 POSTER

False-negative mammogram: what lessons can we learn?

P. Crystal[1,2], S. Strano[2,3], S. Shcharynski[2], B. Kirshtein[4], M. Koretz[2,4]. *[1] Soroka University Medical Center, Radiology, Beer-Sheva, Israel; [2] Soroka University Medical Center, Comprehensive Breast Center, Beer-Sheva, Israel; [3] Rachel Nash Comprehensive breast center, Jerusalem, Israel; [4] Soroka University Medical Center, Surgery, Beer-Sheva, Israel*

The aim of this study was to review the cases of false-negative screening mammography and analyze the factors that may lead to failure in breast cancer diagnosis.

We reviewed mammograms of breast cancer cases that were diagnosed in our hospital from 1998 to 2001. False-negative mammogram was defined as histological diagnosis of a carcinoma within one year of a negative mammographic report, or cases in which the cancer could be seen on a previous mammogram in retrospect for more than 1 year.

We divided causes of false-negative screening reports to four main causes: inherent limitations of screen-film mammography, inadequate radiographic technique, subtle or unusual lesion characteristics, and interpretation error.

The restricted display contrast of screen-film mammography is well-known factor that results in decreased visualization of breast tumors and microcalcifications in women with dense fibroglandular tissue. We present herein two cases in which breast US permit diagnosis of nonpalpable cancers in women with dense tissue.

Inadequate radiographic technique may be caused improper positioning, insufficient compression or wrong exposure. We present examples of inadequate technique, which should be eliminated by strict quality control program.

Lesion characteristics that may lead to false-negative mammogram include small size, a site where visualization is difficult, probably benign appearance and no apparent growth.

Interpretation error in both, mammography and breast sonography may lead to delayed diagnosis of breast cancer.

Recognition of these various factors should help decrease the rate of false-negative mammograms.

404 POSTER

Hormonal receptor status and HER2 expression in correlation between age, pathological type, mammographical and ultrasound view of breast cancer treated in oncology clinic of military medical academy, Warsaw, Poland.

M. Gornas[1], E. Pienkowska[1], W. Kozlowski[2], P. Wisniewski[2], J. Sieluzycka[3], P. Gornas[4], C. Szczylik[1]. *[1] Military Medical Academy, Oncology Clinic, Breast Pathology Unit; [2] Military Medical Academy, Pathology Department, Warsaw, Poland; [3] Military Medical Academy, Radiology Department, Warsaw, Poland; [4] Kredyt Bank SA, Out - Patient Clinic, Warsaw, Poland*

Introduction: The aim of the study was to determinate the correlation between biological characteristic of breast cancer, age of patients, mammographical findings and/or ultrasound view of lesions. The question is, if radiogram or ultrasound view of the lesion could help the treatment planning in different groups of patients.

Material and Methods: We have analysed case reports of 116 breast cancer patients treated in Breast Pathology Unit (BPU) of Oncology Clinic since The 1st of January 2000 till the 30th of October 2001. All of patients have become radical modified mastectomy. In most of cases hormonal receptor status and HER-2 expression in breast cancer tissue were determined using immunohistochemical assay. Retrospectively mammographical and ultrasound pictures have been analysed.

Results: 116 breast cancer patients, age 35-81 (average 57) have started treatment in BPU since the 1st of January 2000 till now. In 16 of cases HER-2 expression couldn't be determined (mostly because of technical problems). HER-2 overexpression was found in 32 cases. In 15 of these cases no hormonal receptors were found, in 17 of them ER or/and PR were positive. ER anr/orPR positive cancers were found most frequently (23/32) in the group of 51-60 years old women, then (10/20) over age of 70. In our material HER-2 overexpression most frequently (3/4) was detected in breast cancer patients 30-40 of age, less frequently (3/20) in the group over 70 years old. Most of HER-2 positive cases (14/32) were determined as infiltrating ductal carcinoma, 10/32 mixed (DCIS and invasive component), 2/32 lobular, 1/32 mucinosus, 1/32 apocrinal, 4/32 DCIS. HER-2 positive cases have been found in "dense breast", but the mammographical and ultrasound views were differentiated in most of cases.

Conclusion: The age of patients could be one of circumstances correlating with biological characteristic of breast cancer. Neither mammography, nor ultrasound examination is sufficient for anticipation of treatment planning in breast cancer.

Friday, 22 March 2002 16:30–18:00

PROFFERED PAPERS

Clinical implications of the sentinel node

405 ORAL

Quality control in the EORTC-AMAROS (after mapping of the axilla: radiotherapy or surgery) trial nr 10981

P.S. Verduijn[1], R.L.J.H. Bourez[1], E.J.T. Rutgers[1], V. Distante[2], C.J.H. van de Velde[3]. *[1] The Netherlands Cancer Institute, Surgery, Amsterdam, The Netherlands; [2] Florence, Surgery, Florence, Italy; [3] Leiden University Medical Centre, Surgery, Leiden, The Netherlands*

Introduction: The EORTC-AMAROS trial is a phase III randomised non-inferiority trial comparing a complete ALND versus RT to the axilla in SNB positive patients, where-as SNB patients will be followed for the end-points of the study as well. The involved patients will have an operable invasive breast cancer of over 5 mm and less than 3 cm, without clinically suspected regional lymph nodes. Quality control constitutes an important part of the trial design.

Methods: Before a participating centre is allowed to enter patients, at least 30 SN procedures have to be performed, with a minimum of 27 patients with accurate SN identification. After 30 cases, the centre will be visited and all cases will be reviewed. If quality criteria are not fulfilled, the learning phase will be extended by steps of 10 patients until the last 30 patients have met the criteria. The quality of RT will be controlled by evaluation of a dummy run and an annual evaluation of the filed radiation data of 10 randomly chosen patients done by the RT co-ordinator (or an independent representative).

Amendments: Two amendments were made. One amendment concerned the learning phase of the SN procedure. It states that if a surgeon has performed 30 SNB procedures without ALND under the guidance of a surgeon who has performed at least 30 SNB procedures followed by ALND in accordance to the criteria mentioned in the protocol, this surgeon is also allowed to enter patients in the trial. The other amendment concerned adjuvant systemic treatment. Stating that different schemes (of adjuvant treatment) on the basis of the number of positive nodes are allowed, but not recommended.

Results: Until 1-11-01, 13 sites have been site-visited. Three site visits are planned of which 1 is a second control visit taking place 1 year after the initial visit. During this second visit the records of the included patients will be compared with the matching CRF's. Encountered problems before approval were: -Difficulties in producing an adequate radiotherapy dummy-run (n=4), -Inadequate surgical SN procedure (n=1), -Inadequate probe (n=1), -Inadequate lymfoscintigraphy technique (n=1). So far 6 centres are including patients, the other 7 are being assessed or solving problems to meet all criteria. The total amount of patients included at 1-11-01 equals 111. Result and solutions to prevent problems on the on-site visits will be presented.

406 ORAL

Sentinel node biopsy performed under local anesthesia in early-stage breast carcinoma; the experience of the European Institute of Oncology

G. Gatti[1], A. Frasson[1], C. Magalotti[1], P. Naninato[1], S. Michelini[2], S. Zurrida[1], P. Veronesi[1], V. Galimberti[1], P. Arnone[1], A. Luini[1]. *[1] European Institute of Oncology, Senology Division, Milan, Italy; [2] European Institute of Oncology, General Director, Milan, Italy*

The practice of sentinel node biopsy has dramatically changed the surgical approach to early-stage breast cancer. The impact of this technique on patients' quality of life and on treatment costs, without compromising oncological information, allowed the application of the biopsy to a large population of patients. At the European Institute of Oncology in Milan we recently applied sentinel node biopsy under local anesthesia to a selected group of patients, to verify the feasibility of this procedure and its impact on our therapeutic pathway in case of early-stage breast carcinoma.

From September 2000 till November 2001, 102 patients affected by infiltrating T1/T2-N0 breast tumor received sentinel node biopsy under local anesthesia at the European Institute of Oncology in Milan, Italy. These patients had a citologically/histologically proven infiltrating, unifocal breast carcinoma with a maximum diameter of 2,5 cm. There was no clinical and ultrasonographic evidence of axillary node involvement by the disease. Patients were injected with a mixture of colloidal human albumin particles marked with 99m-Technetium the day before surgery or the same day at a distance of few hours in the Nuclear Medicine Division. Sentinel node was identified using a gamma probe and removed during a surgical session performed under local anesthesia; it was then examined both with extensive histology and immunohistochemistry.

No patients suffered of immediate or late surgical complication. No cases of postoperative axillary haematoma or infection were observed in the days and weeks after sentinel node biopsy. All patients were able to undergo conservative surgery for the breast carcinoma 7-8 days later, with no delay due to problems deriving from the node biopsy. Also the cost analysis we performed showed a good impact of sentinel node biopsy performed under local anesthesia on total treatment costs both for the Institute and the patients.

Our experience indicates that sentinel node biopsy performed under local anesthesia can be a good alternative to standard intra-operative evaluation of the sentinel node in patients with an unifocal, early stage breast carcinoma citologically or histologically proven at the moment of the hospitalization.