105 POSTER

Radioguided localisation and open surgical biopsy of non-palpable suspicious breast lesions

A.C.S. Barros[1], M. Cardoso[1], P.Y. Sheng[2], P.A. Costa[3], E. Muranaka[1]. [1]*Hospital Sírio Libanês, Gynecology, São Paulo, Brazil;* [2]*Hospital Sírio Libanês, Radiology, São Paulo, Brazil;* [3]*Hospital Sírio Libanês, Nuclear Medicine, São Paulo, Brazil*

The choice of the technique for elucidating non-palpable suspicious breast lesions, detected by mammography, is still controversial. We are here presenting our experience with one of these techniques, the ROLL (radioguided occult lesion localisation) method. A total of 71 patients with abnormal mammography and non-palpable breast lesions (49 BI-RADS 4 and 22 BI-RADS 5) were studied. The day before surgery a 20-gauge needle was placed into the centre of the lesions under stereotaxic guidance by mammography followed by an injection of 0.2 ml of dextran labelled with technetium 99m. Open surgical biopsies were performed on the next day guided by gamma probe and the specimens were radiographed to confirm lesion excision. In all cases mammography of excised tissue showed the lesions presence within the specimens. Thus the lesions removal rate was 100%. In most of the cases, 65/71 (91.5%), lesions were removed in the first 3–4 cm of tissue excision, and in the remainning other 6 (8.5%) it was needed another resection to remove them. It was observed that ROLL technique generally allowed good lesion centring and small excising volume. Patient's acceptance was excellent and there was not any remarkable complication. Final histopathological results were: infiltrating carcinoma 27 (38.1%), ductal in situ carcinoma 14 (19.7%) and benign alterations 30 (42.2%). It was conduded that ROLL is a valid alternative for biopsy of suspicious non-palpable breast lesions with advantages over wire hook guided biopsy.

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Intraoperatory Radiolocalization (RLI) and Sentinel Lymph Node Biopsy (SLNB) in Ductal Carcinoma In-Situ (DCIS): our experience

A.V. Granai[1], O. Buonomo[1], C.A. Pistolese[2], E. Cossu[2], G. Palmieri[3], A. Felici[1], D. Forcella[1], D. Mineo[1], O. Schillaci[4], T.C. Mineo[1]. [1]*University of Tor Vergata, Surgery, Rome, Italy;* [2]*University of Tor Vergata, Radiology, Rome, Italy;* [3]*University of Tor Vergata, Pathology, Rome, Italy;* [4]*University of Tor Vergata, Nuclear Medicine, Rome, Italy*

Introduction: DCIS of the breast is an heterogeneous group of lesions with different malignant potentials, controversial classification criteria and treatment protocols: our study proposes to evaluate the Lymph Nodes status by SLNB in DCIS lesions classified according to Tavassoli's DIN criteria.

Materials and Methods: From January 2000, 75 pts with high radiological suspect for malignant lesions were enrolled: 45 microcalcifications (60%), 17 nodules (23%), 10 nodules + micro (13%), 3 parenchimal distortions (4%). All pts, within 24 hours before surgery, underwent an intra-perilesional injection of 0.1 ml of Nanocoll® radiolabelled with 800μCi of 99m-Tc to identify the lesion and the Sentinel Lymph Node (SLN). All patients performed lymphoscintigraphy (LSG). The surgical procedure included RLI and excision of the tumor, and its Frozen Section Evaluation (FS). When the frozen section analysis confirmed for a DIN 1c, DIN 2–3, SLNB was performed at the same surgical time.

Results: The preoperative LSG identified SLNs in 74 (98.7%) carcinoma pts (in 2 cases the SLN was exclusively located in the omolateral Internal Mammary Chain (IMC); in 3 cases both in IMC and omolateral axilla). The primary breast lesions were located and excised in all cases (identification rate 100%); 87 axillary SLNs and 8 IMC SLNs (mean 1.28/pt) were biopsed. Definitive histological evaluation revealed: 6 DIN1a, 10 DIN1b, 18 DIN1c, 10 DIN2, 20 DIN3 and 11 DCIS with microinvasion. Four SLNs with metastatic disease (2 micro and 2 macrometastases) came from 4 pts with T1mic (respectively 3 DIN3 and 1 DIN1c at FS). The complete axillary lymph node dissection performed didn't reveal addictional metastatic disease.

Conclusions: Our results indicate that the one-time realization of RLI and SLNB is a significant step forward in the search for a correct stadiative, therapeutic and surgical approach to intraductal neoplasia of the breast.

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PROFFERED PAPERS

Screening, detection and diagnosis

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Prevalent and incident rounds in a breast cancer screening program with mammography and MRI for high risk women

M. Kriege[1], C. Brekelmans[1], C. Boetes[2], E.J.T. Rutgers[3], R.A.E.M. Tollenaar[4], J. Oosterwijk[5], R. Manoliu[6], H. Peterse[7], H.J. de Koning[8], J.G.M. Klijn[1]. [1]*Erasmus MC–Daniel den Hoed Cancer Center, Family Cancer Clinic, Rotterdam, The Netherlands;* [2]*Univrsity Medical Center Nijmegen, Radiology, Nijmegen, The Netherlands;* [3]*Netherlands Cancer Institute, Surgery, Amsterdam, The Netherlands;* [4]*Leiden University Medical Center, Surgery, Leiden, The Netherlands;* [5]*University Hospital Groningen, Clinical Genetics, Groningen, The Netherlands;* [6]*VU University Medical Center, Radiology, Amsterdam, The Netherlands;* [7]*Netherlands Cancer Institute, Pathology, Amsterdam, The Netherlands;* [8]*Erasmus MC, Public Health, Rotterdam, The Netherlands*

Background: The MRISC study is a Dutch national multicentre prospective study for MRI screening in women with a familial or genetic predisposition for breast cancer. Participants were screened by a 6-monthly clinical breast examination (CBE) and yearly MRI and mammography with an independent evaluation. We found that screening facilitated breast cancer diagnosis in an earlier stage than in symptomatic age-matched controls. On average the relative sensitivity for mammography was in this study 43% and for MRI 74%, the false positive rate was 5% and 11% respectively. We concluded that MRI is a more sensitive screening method than mammography in this group, but less specific. But screening parameters can differ in different rounds of the program, especially in the first round compare to subsequent rounds. We investigated if positive tests and positive predictive values (PPV) are stable in the different rounds, the detection rate and tumor characteristics of prevalent and incident cancers and if screening parameters from first imaging tests differ from subsequent imaging tests.

Material and methods: From November 1999 to December 2002 we included 1874 women with a median follow-up of 2.1 years. In this group we found 39 breast cancers. Screening parameters were analyzed per screening round and first and subsequent mammography and MRI. We defined an imaging test with BI-RADS score 0, 3, 4 or 5 (probably benign or worse) as positive, because those were the cut-off points for additional examination.

Results: The positive test rate varied from 2.3% to 3.2% for CBE, 3.9% to 6.8% for mammography and 7.9% to 13.2% for MRI and PPV from 0 to 9.1% for CBE, 6.3% to 11.1% for mammography and 3.1% to 11.2% for MRI in the different screening rounds. The detection rate per 1000 tests in prevalent imaging rounds was 14.6 for mammography and 10.9 for MRI and for incident rounds 6.3 for mammography and 7.7 for MRI. From the prevalent cancers was 17% $\leq$ 1 cm and from the incident cancers 50% (p=0.21). The node negativity rate was 83% in the prevalent cancers and 74% in the incident cancers (p=0.63). The most women (83%) were screened before the study by CBE and mammography. There were 323 women who get a first mammography and 1729 who get a first MRI in this study. In first mammographies the false positive test rate is 6.7%, this is 1.4 times higher than in subsequent mammographies (false positive test rate 4.7%, p=0.13). In the first MRIs the false positive test rate is 13.1%, this is 1.5 times more than in subsequent rounds where this is 8.6% (p<0.001).

Conclusions: For all 3 screening modalities positive test rates and PPV are reasonably stable over time. The detection rate in the prevalent screening round is higher than in incident rounds. Prevalent cancers are larger than incident cancers. For both imaging modalities specificity increased in subsequent tests compared to first imaging tests.

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108 ORAL

The frequency of breast cancer screening: results of a randomised trial

R. Blamey[2], S. Duffy[2]. [1]*Nottingham City Hospital, Breast Institute, UK;* [2]*Breast Screening Frequency Trial Group*

This randomised trial in 110,000 women between 1989 and 1996 compared screening at the standard interval of 3 years (Controls – C) with screening annually (Trials – T), in women aged 50–64. A previous analysis used the Nottingham Prognostic Index (NPI) to predict outcomes of invasive carcinoma diagnosed; these predictions were based on observed survivals

in cancers prior to 1988. However survival within each NPI group has improved, due to better therapy. Recalculation is based on new figures and the prediction is compared with the observed outcome:

Invasive cancer	Diagnosed (n)		Predicted survival at 6 years (n)		Observed survival (median FU 6 years) (n)	
	C	T	C	T	C	T
GPG	92	113	89	110	91	111
MPG	87	96	71	79	69	85
PPG	22	20	11	10	14	11
Total	2010	229	171 (86%) NS	199 (87%)	174 (87%) Relative fatality 0.77 (0.45–1.35)	207 (90%)

There is good agreement between the predicted and observed 6 year survivals, neither show significant difference between C and T groups. Although in the Trial group there were more cases in the GPG and less in the PPG, this was not large enough to significantly improve survival and the absolute difference is 3% less deaths in the trial group at 6 years.

Conclusion: There is no significant advantage to annual screening over the standard 3 yearly NHS screening and shortening of the screening interval would certainly not be cost effective.

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Final results of Russia/WHO prospective randomized trial of breast self-examination (1985–2003)

V.F. Semiglazov[1], E.A. Mikhailov[2], A.G. Manikhas[3], V.M. Moiseynko[4], V.N. Sagaidak[5], S.A. Protsenko[6], V.G. Ivanov[7]. [1]*N.N. Petrov Research Institute of oncology, Breast cancer, St. Petersburg, Russian Federation;* [2]*Cancer Research Center RAMS, Breast Cancer, Moscow, Russian Federation*

This study was conducted to determine whether an intensive program of breast self-examination (BSE) instruction will reduce the number of women dying from breast cancer.

Methods: Between 1985 and 1989, 96,292 (from 198,126) women (ages 40–64 y) in 14 randomly selected polyclinics in St. Petersburg and in 50 industrial polyclinics in Moscow were taught BSE (randomisation by the WHO, Geneva, Switzerland). 101,834 women in 64 other randomly selected polyclinics were controls. Physicians provided weekly breast clinics in all 128 polyclinics. Women were able to seek consultation either by self-referral or on the advice of their physician. For both BSE and control groups, all identified abnormalities were biopsied and treated at the oncological institutes.

Results: BSE compliance was 76.4% at the end of the eighth year of the study. More women in the BSE group came to the breast clinic for suspected pathology (7061) than in the control group (3825; p0.05). More benign breast lesions were diagnosed in the BSE group (1032) than in control group (547; P<0.05). The number of cancers diagnosed was similar in the BSE and the control groups (733 and 702 respectively, P=0.09). Kaplan-Meier 15-year survival from the time of diagnosis of breast cancer was 53.8% for the BSE group and 51.1% for control (P>0.5). There were 338 (0.35%) breast cancer death in the BSE group and 343 (0.33%) in the control group (N.S.).

Conclusion: Intensive teaching in BSE did not reduce mortality from breast cancer.

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Additional breast lesions in patients with breast cancer at MR imaging: impact on clinical management

E.E. Deurloo[1], J.L. Peterse[2], E.J.T. Rutgers[3], A.P.E. Besnard[1], K.C.A. Gilhuijs[1]. [1]*The Netherlands Cancer Institute/Antoni van Leeuwenhoek hospital, Radiology, Amsterdam, The Netherlands;* [2]*The Netherlands Cancer Institute/Antoni van Leeuwenhoek hospital, Pathology, Amsterdam, The Netherlands;* [3]*The Netherlands Cancer Institute/Antoni van Leeuwenhoek hospital, Surgery, Amsterdam, The Netherlands*

Purpose: 1. To inventory the additional workup for lesions detected at MR imaging in patients eligible for breast-conserving therapy (BCT) on the basis of conventional imaging and palpation, and to inventory the impact of this workup on clinical management. 2. To evaluate the performance of clinical reading to exclude malignancy with high confidence without additional workup.

Material and Methods: 116 patients with 118 proven breast cancers underwent MRI of both breasts prior to BCT. Additional lesions were enhancing lesions other than the proven cancer. The frequency of occurrence of additional lesions, the additional workup that was required, and the number of patients in which treatment was changed due to more extensive disease detected by MRI were established. The performance of clinical reading, and the performance of the combination of clinical reading and computerized analysis were obtained in the task of excluding malignancy at high confidence.

Results: MRI showed a larger extent of the index lesion in 10% of the patients (n=12). Furthermore, 50 additional lesions in 40 patients (35%) were detected. Twenty lesions were proven to be malignant, 30 were benign (7 pathology-proven, and 23 by follow up). Additional conventional workup (MRI-directed ultrasound-guided fine-needle aspiration or core biopsy) before surgery was performed in 78% of the additional lesions (39/50). In almost half of the cases (49%), the lesion was visible at workup and diagnosed by pathology. Treatment was changed to a more extensive approach in 22% (n=25). The specificity of clinical reading of additional lesions was 30% at 100% sensitivity (mean follow up 21 months). The combination of clinical reading with computerized analysis yielded higher specificity (96.6%) without loss of sensitivity.

Conclusion: In approximately half of the additional lesions conventional work up is useful to obtain the diagnosis. Clinical reading yields a low performance in identifying benign additional lesions. A significantly better performance is achieved by combining clinical reading with computerized analysis.

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Stereotactic directional vacuum-assisted breast biopsy in 480 patients with microcalcifications: radiological and pathological correlation

U. Kettritz[1], T. Decker[2], G. Morack[3]. [1]*HELIOS Klinikum Berlin, Berlin-Buch Breast Unit, Radiology, Berlin, Germany*

Background: Radiological criteria exist to assess microcalcifications (MCs) on mammograms. On the basis of the level of suspicion, lesions can be categorized according to the Breast Imaging Reporting and Data System (BI-RADS). We compared radiological analysis and histopathological findings of microcalcifications on mammography.

Material and methods: 480 consecutive MCs were analyzed and biopsied. Neither a palpable tumor nor a visible mass in mammograms or ultrasound was associated with the area of MC. Before biopsy, MCs were classified on mammograms by two experienced radiologists as probably benign (BI-RADS III), indeterminate (BI-RADS IVa), suspicious (BI-RADS IVb) or malignant (BI-RADS V) using the following criteria: MC morphology as punctate, pleomorphic, and branching, respectively; microcalcification distribution as diffuse, clustered, linear, or segmental, respectively. In addition, progression was assessed with earlier mammograms. Stereotactic biopsies were performed on a prone dedicated table with an 11-gauge vacuum assisted Mammotome®-biopsy device. Histopathological and radiological diagnoses were compared.

Results: Histopathology of MC bearing tissue revealed 321 (67%) benign lesions [adenosis and other fibrocystic changes 207, fibroadenoma 67, fat necrosis and scar 22, and other benign lesions 25). 159 (33%) were malignant lesions (ductal carcinoma in situ (DCIS) 110, DCIS and invasive cancer 23, "minimal intraductal neoplasia" (differential diagnosis atypical ductal hyperplasia versus non-high grade DCIS) 24, and CLIS 2]. Of the 480 lesions, 77 were classified radiologically as probably benign (BI-RADS III), 198 as indeterminate (BI-RADS IVa), 76 as suspicious (BI-RADS IVb), and 2 as malignant (BI-RADS V). Benign lesions were classified accurately as BI-RADS III lesions in 19%, and as suspicious lesions in 34%. Malignant lesions were classified as suspicious or malignant lesions in 61%.

Conclusions: There is considerable overlap in the mammographic appearances of benign and malignant MC lesions. Stereotactic vacuum assisted biopsies proved to be a safe and accurate method to assess MCs. We suggest that MCs should be biopsied preoperatively.

112 POSTER HIGHLIGHT

The effect of screening on mortality

R. Blamey, M. Mitchell, A. Evans. *Nottingham City Hospital, Breast Institute, UK*

Invasive cancers: Prognosis has greatly improved in recent year. The effect of screening has been difficult to calculate because of coincidental therapeutic improvements. Use of the Nottingham Prognostic Index (NPI) allows such analysis: earlier detection increases percentages in the better groups, whereas therapies improve prognosis within prognostic groups. The overall effect in the screening age group (50–64) on the whole tumour set (screen detected and symptomatic) at NCH is calculated.

DCIS: 25% of screen detected cases are DCIS (an excess of 20%), 70% of these are high grade. Taking the best estimates of the rate of development of invasive tumours from DCIS and their grades, the number of invasive tumours averted by treating the excess DCIS is calculated. The