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Dose-intensive adjuvant Chemotherapy with Epirubicin/Paclitaxel vs. Epirubicin/Cyclophosphamide in breast cancer patients with 4–9/over 9 (second group) positive nodes: Preliminary data of this phase II/III trial

D. Elling[1], J. Krocker[1], S. Kümmel[1], A. Kohls[2], J. Heinrich[3], P. Breitbach[4], J. Blohmer[5], W. Lichtenegger[5]. *[1]Oskar Ziethen Hospital Berlin, Gynecology/Obstetrics, Berlin; [2]Human Hospital Ludwigsfelde, Gynecology/Obstetrics, Ludwigsfelde; [3]Hospital Stralsund, Gynecology/Obstetrics, Stralsund; [4]Hospital Neunkirchen, Gynecology/Obstetrics, Neunkirchen; [5]Charitre, Gynecology/Obstetrics, Berlin, Germany*

Taxanes and anthracyclines represent the two most active groups of agents for the treatment of breast cancer. The purpose is to evaluate this combination in patients with more than 3 positive lymph nodes in an adjuvant, dose-intensive, sequentially therapy in comparison with the standard chemotherapy regimen epirubicin/cyclophosphamide.

Methods: Since 9/96 191 patients with 4–9/over 9 positive lymph nodes have been recruited from 23 participating centers in an ongoing trial. 99 patients were prospectively randomised for first-line chemotherapy to treatment group A (epirubicin 90 mg/m"-paclitaxel 175 mg/m"; 4 cycles biweekly, supported by G-CSF 5 μg/kg/bw day 5–13 and 3 sequential cycles CMF 600/40/600 mg/m" at 2-weeks interval) and 92 patients to treatment group B (epirubicin 90 mg/m"-cyclophosphamide 600 mg/m"; 4 cycles triweekly, and 3 sequential cycles CMF 600/40/600 mg/m" at 3-weeks interval).

Results: Preliminary safety and toxicity data are evaluable for 929 cycles. Data about response rate and Disease-Free-Interval and and Overall Survival will be delivered later. For the hematological toxicity the main grade 3 and 4 (WHO) adverse events for A vs. B were: leucopenia 18.2% vs 11.1%, febrile neutropenia 1.2% vs 0.5% -anemia (<5.9 mmol/L) 0.7% vs 0.5%-thrombopenia 0.1% vs 0%. Non-hematological toxicity occurred more frequently in group A (WHO grade 2, 3, 4):-neuropathy 4.3% vs 0%,-nausea/emesis 31.2% vs 24.2%,-fatique 10,1.6% vs 3.4% and stomatitis 3.1% vs 0.5%.

Conclusion: The schedule of the dose-intensive application form with G-CSF-support (Epirubicin/paclitaxel) was well tolerated. After completion of this trial (12/1999), its role in relation to the standard chemotherapy with epirubicin/cyclophoshamide, accordingly to an higher efficacy and a significantly shorter treatment duration, will be possible. The study was grant supported by Bristol-Myers Squibb Oncology, Pharmacia Upjohn and Amgen Gmbh.

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Clinicopathological evaluation of MR imaging of nonpalpable breast cancer with bloody nipple discharge

K. Tanaka, K. Kanasugi, S. Noda, H. Shigeta, S. Nakano, H. Komoriyama, I. Tanaka, H. Ikezawa, M. Hagiwara, T. Shinagawa. *Department of Surgery, St. Marianna University School of Medicine, Yokohama City Seibu Hospital, Yokohama, Japan*

Purpose: MR mammography is a sensitive diagnostic method for the detection of breast cancer. We evaluated the utility of contrasted material enhanced and fat suppressed MR images (FFE and SPIR method) of the nonpalpable breast cancer cases with bloody nipple discharge comparing with surgical indication and pathological results.

Materials and Methods: From 1995 to 1999, 195 women underwent MR imaging in our hospital. There were 10 nonpalpable breast cancer cases with bloody nipple discharge. These cases were reviewed regarding to conventional diagnostic images, ductscopic findings, surgical approach and pathological results.

Results: MR mammography revealed high signal intensity in the early phase of a dynamic scan, which means malignant changes in all the cases. Cytological examination showed Class V in 3, Class III in 3 and Class II in 4 cases. MR images coincided with malignant area in 8 cases pathologically. Extensive intraductal component was identified in 9 cases on pathological examination.

Conclusion: MR mammography can be extremely useful in addition to conventional diagnostic modality in determining the surgical line.

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Role of increased arterial inflow in arm edema after modified radical mastectomy

E. Yildirim[1], P. Soydinç[2], N. Yildirim[2], U. Berberoğlu[1], E. Yüksel[2]. *[1]Department of Surgery, Ankara Oncology Hospital; [2]Department of Radiology, Ankara Numune Hospital, Ankara, Turkey*

Purpose: Chronic arm edema is a common finding after modified radical mastectomy and its pathophysiology is not clear. In a prospective randomized study the value of increased arterial inflow and venous abnormalities after mastectomy was evaluated.

Methods: Arterial and venous blood flow in axillary vessels of 39 patients with arm swelling and 16 patients without swelling were investigated by Doppler ultrasound.

Results: In patients with arm edema the arterial flow on surgical treated side was 689.73 $\pm$ 44.6 (mean $\pm$ sem) ml/min and 427.73 $\pm$ 30.8 ml/min on contralateral side ($p < 0.05$). In those without swelling the flow was 447.75 $\pm$ 37.8 ml/min on treated side and 354.95 $\pm$ 28.7 ml/min on contralateral side ($p > 0.05$). The difference between arterial flow measurements on treated sides of the patients with and without arm swelling was statistically significant. There was no significant difference between the measurements on contralateral sides of both groups. Venous abnormalities were not detected in both groups of patients.

Conclusion: Modified radical mastectomy causes increased inflow in ipsilateral arm and it may play an important role in the etiology of arm swelling in breast cancer patients.

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Measuring radiation fibrosis: The inter-observer reliability of two methods of determining the degree of radiation fibrosis

J. Marinus[1], C.G.J.H. Niël[2], R.A. de Bie[3], R.G.J. Wiggenraad[2], E.M. Schoppink[1], L.H. Beukema[1]. *[1]Medisch Centrum Haaglanden, Physical Therapy, Den Haag; [2]Medisch Centrum Haaglanden, Radiotherapy, Den Haag; [3]University Maastricht, Epidemiology, Maastricht, Netherlands*

Purpose: To compare the inter-observer reliability of the palpation method with the quantitative method of measuring tissue compliance with a "tissue compliance meter" (TCM) on women who had had breast conserving surgery and radiotherapy for breast cancer.

Method: 38 patients and 30 controls were measured with the palpation method by 2 radiotherapists and with the TCM by two physiotherapists. Measurements were taken on 4 locations of the breasts of all 68 women. Reliability coefficients were computed for both methods. A weighted kappa score was computed for the palpation method and this was compared with the intraclass correlation coefficient (ICC), which was computed for the TCM-method. The difference in compliance between both breasts in the patient group was compared with that of the control group.

Results: A weighted kappa of 0.65 was computed for the palpation method and an ICC of 0.91 was computed for the TCM-method. The difference in compliance between both breasts is significantly larger in the patient group then in the control group.

Conclusion: The inter-observer reliability of the TCM-method is superior to that of the palpation method, although both methods have a good reliability. Another advantage of the TCM-method is its greater sensitivity to change ('responsiveness'), since measurements are made on a continuous scale. At locations were the TCM is not applicable, palpation is a good alternative.

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Initial doxorubicinol 7-deoxyaglycone (Dol 7-d) levels and persisting cardiotoxicity after adjuvant doxorubicin in women with early breast cancer

L.M. Samuel[1], L. Fenn[2], R. Wright[2], J. Cummings[3], R. Leonard[1]. *[1]Western General Hospital, Clinical Oncology, Edinburgh; [2]Western General Hospital, Cardiology, Edinburgh; [3]Western General Hospital, ICRF Medical Oncology Unit, Edinburgh, United Kingdom*

Anthracycline containing adjuvant therapy improves outcome but long term cardiotoxicity remains a concern despite limiting the cumulative dose.

Anthracyclines are extensively metabolised. Quinone ring reduction leads to 7-deoxyaglycones with concommitant free radical superoxide formation. Differing Dol 7-d levels may reflect the variability seen in cardiotoxicity for the same cumulative dose.