

**Results:** PR 54%, NC 29% and PD 17%.  $\alpha$ - and  $\beta$ -tubulin and class IV  $\beta$ -tubulin isotype were strongly expressed in the majority of samples and therefore no correlation with docetaxel activity was possible. Only 4 pts had tau negative tumors and 2/4 had no objective response. An inverse correlation was found between class II expression and docetaxel activity. Outcome was similar in the two groups of Class III expression.

MTAP	N	PR	NCIPD
Tau			
-	4	2	2
+	32	19	13
NE	5	1	4
Class II			
<50%*	15	11	4
>50%*	18	7	11
NE	8	4	4
Class III			
<50%*	11	7	4
>50%*	20	11	9
NE	10	4	6

Legend: % positive cells, NE: non evaluable

**Conclusion:** The limited number of analyzed pts softens the strength of our conclusions, however, according to these preliminary data, the evaluation of tau protein and class II  $\beta$ -tubulin deserves further investigation as potential predictive markers for docetaxel activity.

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### Prognostic factors of breast cancer patients with 1 to 3 lymph node metastases after adjuvant chemotherapy

Y. Lin<sup>1</sup>, S. Chen<sup>2</sup>, H. Chang<sup>1</sup>, S. Hsueh<sup>3</sup>, T. Hwang<sup>2</sup>. <sup>1</sup>Chang Gung Memorial Hospital, Division of Hematology/Oncology, Taipei, Taiwan; <sup>2</sup>Chang Gung Memorial Hospital, Department of Surgery, Taipei, Taiwan; <sup>3</sup>Chang Gung Memorial Hospital, Department of Pathology, Taipei, Taiwan

**Purpose:** To analyze prognostic factors of patients with breast cancer who had 1 to 3 axillary lymph nodes metastases after adjuvant chemotherapy.

**Methods:** From 1990 to 1998, a total of 572 breast cancer patients with 1 to 3 axillary lymph nodes metastases were studied. Among them, 443 received adjuvant chemotherapy with CMF (cyclophosphamide, methotrexate, fluorouracil), 23 patients received CAF (A: adriamycin), 53 patients received CEF (E: epirubicin), and 53 patients refused any adjuvant therapy. The median follow-up period was 37.5 months. Prognostic factors including tumor size, status of steroid receptors, administration of tamoxifen, tumor ploidy, S-phase fraction, SBR grading, age (less than 40 vs older), and angiolymphatic permeation were analyzed by Cox regression methods for overall survival (OS) and disease free survival (DFS).

**Results:** The median age was 47 years. The estimated 5-year OS and DFS was 85.6% and 77.4%, respectively. The local recurrent rate was 6.3%, and distant metastases rate was 16.5% to date. Patients did not received adjuvant chemotherapy survived significantly worse than those who received adjuvant chemotherapy. Univariate analysis revealed tumor size (<3 vs >3 cm), estrogen receptor, progesterone receptor, and age (less than 40 vs older) were significant prognostic factors for OS. While multivariate analysis revealed tumor size, age and estrogen receptor were three independent prognostic factors of OS. Tumor size, age, estrogen receptor and more than one positive node are the independent factors of DFS. The 5-year survivals for age less than 40 years and older years were 82 and 89.7%, respectively. (p value: 0.0025) While 5-year survivals for positive estrogen and negative estrogen were 91.7 and 85.4% respectively. (p value: 0.0042) The 5-year survival for tumor <3 and >3 were 89.6 and 80.4%, respectively. (p value: 0.048)

**Conclusion:** The study showed that the predictive factor of worse OS in patients with 1 to 3 positive axillary nodes were age less than 40 years, tumor size larger than 3 cm and negative estrogen receptor.

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### Ductal carcinoma in situ, pure infiltrating and combined DCIS-infiltrating breast cancers: comparison in a series of 2071 patients

M. Pavarana<sup>1</sup>, R. Pedersini<sup>1</sup>, M. Frisinghelli<sup>1</sup>, R. Micciolo<sup>2</sup>, R. Nortili<sup>1</sup>, A. Santo<sup>1</sup>, M. Giovannini<sup>1</sup>, G. Cetto<sup>1</sup>, A. Molino<sup>1</sup>. <sup>1</sup>Medical Oncology, University of Verona, Verona, Italy; <sup>2</sup>Institute of Statistics, University of Trento, Trento, Italy

**Purpose:** There is much debate as to whether an infiltrating breast tumor (BC) is always the last step in the evolution of a tumor that starts 'in situ' and then acquires greater malignancy until it becomes infiltrating. We

therefore compared the characteristics of pure ductal carcinoma in situ (IS), pure infiltrating ductal (IN) and combined (DCIS and infiltrating- CO) breast tumors in a series of 2071 patients (PTS) with BC (176 IS, 1241 IN and 654 CO) who underwent surgery in Verona hospitals.

**Methods:** We recorded the age of every PTS at diagnosis, menopausal status, modality of diagnosis (symptomatic or clinically silent BC), familial history (no, first, or second degree), diameter (mm), axillary nodal status (0, 1-3, >3 positive nodes), G (1, 2, 3), ER and PgR (<10%, 11-100% of positive/total cells), Ki-67 (<10%, 11-25%, >25% of positive/total cells), and c-erb B2 expression (- or +). The association between the variables was studied using the chi-square-test.

**Results:** The frequency of IS decreased and that of IN and CO tumors increased with increasing age (p<0.01); as expected, we had 60% of the IS, 27% of the IN and 38% of the CO patients who were asymptomatic (p<0.01). We also found 45%, 32% and 22% of IS, 16.5%, 45.5% and 38% of IN, and 24%, 45% and 30% of CO tumors with diameters of respectively <10 mm, 10-20 mm and >20 mm (p<0.01); but no differences were found in the distribution of ER (p=0.418) and PgR (p=0.264); 6.5% of the IS, 20.1% of the IN and 18.2% of the CO tumours had high Ki-67 values (p<0.01); G3 was found in 54% of the IS, 30% of the IN, and 31% of the CO tumors (p<0.01).

We also repeated all of the correlations after a diameter-adjusted analysis: statistically significant results were obtained considering Ki-67, G and ER in IN and CO but not in IS.

c-erb B2 was interestingly distributed, being positive in 69% of IS, 40% of IN and 50% of CO (p<0.01); the associations were: IS vs IN vs CO, p=0.000079; IS vs IN, p=0.000117; IS vs CO, p=0.013579; IN vs CO, p=0.010498

**Conclusion:** In our study DCIS is more often diagnosed in younger and asymptomatic PTS, is smaller, and has lower Ki-67 values: it may therefore appear as a tumor in an initial phase that can evolve to IN with greater malignancy. We also found that many DCIS have a higher G and higher percentage of c-erb B2 positivity than CO and IN, which suggests that not all infiltrating cancers (i.e. low-grade and/or c-erb B2 negative tumors) derive from an in situ counterpart.

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### Prognosis after breast conservative treatment in a T1 tumour group patients

I. Monteiro Grillo<sup>1</sup>, M. Jorge<sup>1</sup>, N. Pimentel<sup>1</sup>, M. Ortiz<sup>1</sup>, M.C. Pinto<sup>2</sup>, A. Gouveia<sup>3</sup>. <sup>1</sup>Hospital Santa Maria, Radiation Therapy, Lisboa, Portugal; <sup>2</sup>Hospital Santa Maria, Gynaecology, Lisboa, Portugal; <sup>3</sup>Hospital Santa Maria, Statistics, Lisboa, Portugal

**Purpose:** To evaluate risk factors related to local recurrence after breast conservative treatment and the association with subsequent distant metastases.

**Patients and Methods:** Between 1983 and 1999, 452 patients (pts) with T1, N0-1 breast cancer, underwent conservative surgery and adjuvant radiotherapy. Pts were irradiated to the ipsilateral breast to a dose of 46 Gy and a boost was delivered to a total dose of 14-20Gy. Pts with positive nodes were submitted to adjuvant systemic therapy, and postmenopausal pts received hormone therapy. There were 17 patients with  $\leq$  5mm tumors (Group 1); 112 pts with >5-  $\approx$  10 mm tumors (Group 2); 323 pts with >10-  $\approx$  20mm tumors (Group 3). Local recurrence (LR) risk factors were studied: age, histological multifocality, surgical margins, histologic grade, nodal status, tumor size. The end points considered were LR and distant metastases (DM).

**Results:** With a median follow-up time of 53 months (range:12-214), 15 patients developed a LR, as first event, and the median interval to-LR was 38 months (range: 8-133). Five of these pts developed a subsequent DM with a median interval between both events of 14 months (range: 4-30). Twenty five patients developed DM, as first event, and the median interval to DM was 32 months (range 7-124). Median time to-LR was shorter in pts who developed DM, 15 months (range 11-43). The 10 years probability of survival for the whole group of pts was 80.2% (95%CI: 72.3-86.1%). The 10 years probability of LR and DM for Group 1 was 0% and 10% (1.5-52.7%) respectively; for Group 2 was 3.2% (1.0-9.6%) and 6.6% (3.0-4.4%), and for Group 3 was 6.5% (3.3-12.3%) and 10% (6.6-15.0%). The 5 and 10 years probability of survival after isolated LR was 72.0% (41.1-88.6%) and 54% (17-80%), and the relative risk of DM after LR was 4.7 (95% CI: 1.8-12.1), p=0.002.

**Conclusion:** LR after breast conservative treatment (BCT) is associated with DM and poor prognosis. Pts with early LR after BCT, are at high risk.